

IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Jointly sponsored by

EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO



General Safety Requirements Part 3 No. GSR Part 3



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IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

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

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

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

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

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

RELATED PUBLICATIONS

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

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

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

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

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

**RADIATION PROTECTION AND
SAFETY OF RADIATION SOURCES:
INTERNATIONAL BASIC
SAFETY STANDARDS**



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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".

RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES: INTERNATIONAL BASIC SAFETY STANDARDS

GENERAL SAFETY REQUIREMENTS

JOINTLY SPONSORED BY:

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FOOD AND AGRICULTURE ORGANIZATION OF
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INTERNATIONAL ATOMIC ENERGY AGENCY,
INTERNATIONAL LABOUR ORGANIZATION,
OECD NUCLEAR ENERGY AGENCY,
PAN AMERICAN HEALTH ORGANIZATION,
UNITED NATIONS ENVIRONMENT PROGRAMME,
WORLD HEALTH ORGANIZATION

This publication includes a CD-ROM containing the IAEA Safety Glossary:
2007 Edition (2007) and the Fundamental Safety Principles (2006),
each in Arabic, Chinese, English, French, Russian and Spanish versions.

The CD-ROM is also available for purchase separately.

See: <http://www-pub.iaea.org/MTCD/publications/publications.asp>

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.

PREFACE BY THE SPONSORING ORGANIZATIONS

ESTABLISHMENT OF THE INTERNATIONAL BASIC SAFETY STANDARDS BY THE IAEA BOARD OF GOVERNORS AND THEIR APPROVAL BY THE SPONSORING ORGANIZATIONS

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards are jointly sponsored by the European Commission (EC), the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO) (the Sponsoring Organizations).

The Board of Governors of the IAEA established the draft text in English of the revised International Basic Safety Standards (hereinafter referred to as ‘these Standards’) as a standard of the IAEA at its meeting on 12 September 2011.

The Steering Committee for Nuclear Energy, the governing body of the OECD/NEA, approved these Standards and agreed to jointly sponsor them at its meeting held on 27–28 October 2011.

The Director General of the FAO confirmed its endorsement and co-sponsorship of these Standards on 29 October 2011.

The Executive Director of UNEP confirmed its support for and co-sponsorship of these Standards by letter addressed to the Director General of the IAEA dated 12 March 2012.

The ILO’s Governing Body approved publication of these Standards at its 313th Session on 21 March 2012.

The WHO’s Executive Board noted these Standards on 28 May 2012 at its 131st meeting, and this completed the necessary action by WHO as a co-sponsor.

The EC notified endorsement of these Basic Safety Standards on behalf of the European Atomic Energy Community (Euratom) by letter addressed to the Director General of the IAEA dated 14 August 2012.

For PAHO, the 28th Pan American Sanitary Conference endorsed these Standards on 20 September 2012, and requested PAHO to cooperate with its member states on their implementation. This completed the authorization process for joint sponsorship by the Sponsoring Organizations.

The IAEA, on behalf of the Sponsoring Organizations, is hereby issuing these Standards as General Safety Requirements No. GSR Part 3 in the IAEA Safety Standards Series. These Standards are to be issued as a final publication in Arabic, Chinese, English, French, Russian and Spanish. General Safety Requirements No. GSR Part 3 supersedes General Safety Requirements No. GSR Part 3 (Interim edition) issued in 2011, which itself superseded the

International Basic Safety Standards that were issued as IAEA Safety Series No. 115 in February 1996 (hereinafter referred to as the ‘BSS of 1996’) under the joint sponsorship of the FAO, IAEA, ILO, OECD/NEA, PAHO and the WHO.

BASIS FOR THESE STANDARDS

In the system of international intergovernmental organizations, the first endeavour by the IAEA to establish international standards for radiation protection and safety was made in the 1950s. The Board of Governors of the IAEA first approved health and safety measures in March 1960¹, when it was stated that “The Agency’s basic safety standards...will be based, to the extent possible, on the recommendations of the International Commission on Radiological Protection (ICRP)”.

The Board of Governors of the IAEA first approved Basic Safety Standards in June 1962; they were published by the IAEA as IAEA Safety Series No. 9². A revised edition was issued in 1967³. A third revision was published by the IAEA as the 1982 Edition of IAEA Safety Series No. 9⁴; this edition was jointly sponsored by the IAEA, ILO, OECD/NEA and the WHO. The next edition was International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, published by the IAEA as IAEA Safety Series No. 115 in February 1996⁵, and jointly sponsored by the FAO, IAEA, ILO, OECD/NEA, PAHO and the WHO.

¹ INTERNATIONAL ATOMIC ENERGY AGENCY, The Agency’s Health and Safety Measures, INFCIRC/18, IAEA, Vienna (1960); The Agency’s Safety Standards and Measures, INFCIRC/18/Rev.1, IAEA, Vienna (1976).

² INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection, IAEA Safety Series No. 9, IAEA, Vienna (1962).

³ INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection (1967 Edition), IAEA Safety Series No. 9, IAEA, Vienna (1967).

⁴ INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection (1982 Edition), IAEA Safety Series No. 9, IAEA, Vienna (1982).

⁵ FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, IAEA, Vienna (1996).

These Standards apply the IAEA Safety Fundamentals: Fundamental Safety Principles (SF-1)⁶, which includes a statement of the fundamental safety objective and a unified set of principles representing a common safety philosophy across all areas of application of the IAEA safety standards. The fundamental safety objective of protecting people — individually and collectively — and the environment from harmful effects of ionizing radiation has to be achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks.

SF-1 constitutes the basis on which, under the IAEA's safety standards programme, these Standards establish requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. It also provides the rationale for the IAEA's wider safety related programme. SF-1 was jointly sponsored by Euratom, the FAO, ILO, International Maritime Organization (IMO), OECD/NEA, PAHO, UNEP and the WHO.

These Standards are published in the IAEA Safety Standards Series, which includes other related international standards, such as the Regulations for the Safe Transport of Radioactive Material (the IAEA Transport Regulations (No. SSR-6)); Governmental, Legal and Regulatory Framework for Safety (General Safety Requirements No. GSR Part 1); Preparedness and Response for a Nuclear or Radiological Emergency (No. GS-R-2); The Management System for Facilities and Activities (No. GS-R-3); Safety Assessment for Facilities and Activities (General Safety Requirements No. GSR Part 4); Predisposal Management of Radioactive Waste (General Safety Requirements No. GSR Part 5); and Decommissioning of Facilities (General Safety Requirements No. GSR Part 6).

The other Sponsoring Organizations have also produced standards, codes and guides in their respective spheres of activity. Notably, the ILO has established a Convention concerning the Protection of Workers against Ionising Radiations, 1960 (No. 115) and a Recommendation concerning the Protection of Workers against Ionising Radiations, 1960 (No. 114). The ILO has also issued a code of practice for the radiation protection of workers as well as other relevant publications. The PAHO and the WHO have issued a number of publications relating to the protection and safety of workers and of patients

⁶ EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

in medical applications of radiation. The FAO and the WHO have established, through the Joint FAO/WHO Codex Alimentarius Commission, guideline levels for radioactive substances in foodstuffs moving in international trade. The WHO produces guidelines for drinking water quality that include criteria to assess the safety of drinking water with respect to its radionuclide content.

The OECD/NEA has issued publications on specific topics relating to radiation protection and safety. Euratom, since 20 February 1959, has adopted Basic Safety Standards for protection of the health of the general public and workers against the dangers of ionizing radiation laid down in Council Directives (Euratom), and regularly updated these in close cooperation with the development of international standards. The Euratom Standards are binding on EU member states, and the unique responsibility of Euratom in establishing such standards implies that its sponsorship of international standards encourages their harmonized implementation worldwide without prejudice to Euratom procedures and legislation.

These Standards are to be applied by the Sponsoring Organizations to their own operations, and are recommended for use by States and national authorities and by other international organizations in relation to their own activities. The application of these standards by EU member states is ensured by the implementation of binding Euratom legislation.

International conventions and the IAEA safety standards, appropriately supplemented by industry standards and detailed national requirements, establish a consistent and comprehensive basis for the proper protection of people and the environment from harmful effects of ionizing radiation.

REVISION PROCESS FOR THE INTERNATIONAL BASIC SAFETY STANDARDS

These Standards reflect continuing efforts over several decades towards the harmonization of safety standards internationally. The international effort to review and revise the BSS of 1996 involved hundreds of experts from the member states of the Sponsoring Organizations and from specialized organizations.

At its meeting in November 2004, the IAEA's Commission on Safety Standards requested the IAEA Secretariat to prepare an outline for a possible review and revision of the BSS of 1996 for presentation at its meeting in June 2005.

In September 2005, the General Conference of the IAEA, by way of resolution GC(49)/RES/9A, requested the IAEA Secretariat to undertake a review

of the BSS of 1996. The Inter-Agency Committee for Radiation Safety (IACRS)⁷ agreed, at its meeting in October 2005, to the establishment of a joint secretariat (hereinafter referred to as the ‘BSS Secretariat’). In December 2005, the IAEA formally invited representatives of the United Nations and other intergovernmental organizations to jointly coordinate the review and revision of the BSS of 1996 through the establishment of the BSS Secretariat. The BSS Secretariat was coordinated by the IAEA and comprised representatives of the EC, FAO, IAEA, ICRP, ILO, OECD/NEA, PAHO, UNEP and the WHO.

In September 2006, the Director General of the IAEA reported to the IAEA General Conference that the review of the BSS of 1996 had concluded that, while there was no major issue necessitating urgent revision, there was a case to be made for a revision in order to take account of numerous improvements that had been suggested. The IAEA General Conference, by way of resolution GC(50)/RES/10, noted the review of the BSS of 1996 that had been carried out in response to para. 10 of resolution GC(49)/RES/9, and noted that a revision was to be coordinated by the BSS Secretariat. Resolution GC(50)/RES/10 also urged that the BSS Secretariat carefully consider and justify potential changes, taking into account their implications for national regulations.

In the fourth quarter of 2006, an outline for the revision of the BSS of 1996 was approved by the four IAEA Safety Standards Committees and was endorsed by the IAEA Commission on Safety Standards. The IAEA Safety Standards Committees advised the Secretariat that the comprehensive and complete character of the BSS of 1996 should be retained in the new edition, which should continue to underpin the regulatory infrastructure to control sources and practices in radiation safety in all areas, including medicine, general industry, the nuclear industry, radioactive waste management and the transport of radioactive material. They further advised that the new edition should cover the categories of occupational exposure, medical exposure and public exposure, and should cover both normal circumstances of exposure and emergency situations.

The revision of the BSS of 1996 commenced in early 2007 with a series of drafting meetings on thematic areas, hosted by the IAEA, ILO, WHO, OECD/NEA and the PAHO. The draft developed at these meetings provided the basis for discussions at a technical meeting held in July 2007, with the

⁷ The IACRS provides a forum for the exchange of information between the agencies/organizations on their respective activities related to radiation safety. The IACRS is composed of members from the EC, FAO, IAEA, ILO, OECD/NEA, PAHO, United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the WHO. The following non-governmental organizations currently have observer status: International Commission on Radiation Units and Measurements (ICRU), ICRP, International Electrotechnical Commission, International Radiation Protection Association and International Organization for Standardization (ISO).

participation of representatives of the Sponsoring Organizations. The technical meeting concluded that the new edition of the BSS should follow, to the extent possible, the new recommendations of the ICRP, including in particular the designation of situations of exposure in accordance with ICRP Publication 103⁸, i.e. ‘planned exposure situations’, ‘emergency exposure situations’ and ‘existing exposure situations’.

Further, the technical meeting recommended that the structure of the new edition should be based on the designations of ‘planned exposure situations’, ‘emergency exposure situations’ and ‘existing exposure situations’, with corresponding main sections following a similar layout: occupational exposure, public exposure and (for ‘planned exposure situations’ only) medical exposure. The technical meeting further recommended that there would also need to be a main section dealing with generic requirements that are applicable in all exposure situations.

The technical meeting also recommended that the new edition should cover protection of the environment, to be consistent with the Fundamental Safety Principles.

The text of this new edition takes into account the findings of UNSCEAR and also recommendations of the ICRP. The technical meeting noted that since both UNSCEAR and the ICRP had noted that there had been no significant change in the radiobiology underlying radiation protection in terms of nominal risk coefficients of dose, the values for dose limits and related quantities in the new edition would not be changed.

The four IAEA Safety Standards Committees endorsed the decisions made at the technical meeting regarding the proposed structure of the new edition at their meetings in late 2007.

In September 2007, the IAEA General Conference, by way of resolution GC(51)/RES/11, noted the forthcoming publication of the 2007 Recommendations of the ICRP, and again urged the Secretariat to consider carefully and to justify any potential changes to the BSS of 1996, while ensuring consistency with ICRP recommendations and taking into account the implications for national regulations and the importance of maintaining stability in international standards.

Further drafting and review meetings with the Sponsoring Organizations were held from late 2007 to 2009. The IAEA Safety Standards Committees and groups of experts from some of the Sponsoring Organizations provided comments on draft texts of the new edition in 2008 and 2009. A further technical meeting with the participation of the Sponsoring Organizations was held in

⁸ INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Elsevier (2007).

December 2009 to discuss a statement on radon that was issued by the ICRP in November 2009, and to assess its implications for the new edition. The technical meeting made recommendations on the text for the new edition on exposure due to radon in dwellings and occupational exposure due to radon.

The draft text of the new edition was submitted for comment to IAEA Member States on 28 January 2010. Each of the Sponsoring Organizations also submitted the draft text to its headquarters or to its member states for comment by their respective processes and procedures. More than 1500 comments were received from 41 IAEA Member States and from Sponsoring Organizations by the closing date of 31 May 2010, and these comments were considered in preparing a revised draft text.

The Nuclear Safety Standards Committee and the Transport Safety Standards Committee approved the draft text of the new edition at their meetings in November 2010. The Radiation Safety Standards Committee and the Waste Safety Standards Committee approved the draft text at their meetings in December 2010. The Committees noted that the ICRP was to release a statement relating to the dose limit for the lens of the eye, which should be taken into account prior to endorsement by the Commission on Safety Standards of the draft text of the new edition.

The ICRP, in April 2011, issued a statement on tissue reactions in which it recommended for occupational exposure a dose limit for equivalent dose to the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with the dose in no single year exceeding 50 mSv. Previously, this dose limit had been 150 mSv per year. The Commission on Safety Standards did endorse the draft text of the new edition at its meeting in May 2011, but requested that Member States be consulted on the proposed new dose limit for the lens of the eye. Member States were invited to provide comment on the proposed new dose limit for the lens of the eye by 7 July 2011. Following a recommendation from the outgoing and incoming Chairs of the Radiation Safety Standards Committee, the Chair of the Commission on Safety Standards approved the new dose limit for the lens of the eye on 12 July 2011.

APPLICATION OF THE INTERNATIONAL BASIC SAFETY STANDARDS

In responding to the Secretariat's submission to the IAEA Board of Governors, GOV/2011/42, the Board, at its meeting on 12 September 2011, established the draft text in English of the new edition "as an Agency safety standard — in accordance with Article III.A.6 of the Statute"⁹ and "authorized the Director General to promulgate these Safety Requirements...and to issue

⁹ Statute of the International Atomic Energy Agency, IAEA, Vienna (1990).

them as a Safety Requirements publication in the Safety Standards Series”. The Board also encouraged Member States “to implement arrangements for meeting these Safety Requirements”. At its 55th regular session, the IAEA General Conference, in resolution GC(55)/RES/9, encouraged Member States “to use safety standards issued by the IAEA in their national regulatory programmes, and noted the need to consider the periodic alignment of national regulations and guidance to internationally established standards and guidance”.

These Standards embody the international benchmark for radiation safety requirements, with major implications for policy making and decision making. Their adoption and application will facilitate the application of international safety standards and will make for greater consistency between the arrangements for protection and safety of different States. It is, therefore, desirable that all Member States adopt and apply these requirements. These safety requirements will be binding on the IAEA in relation to its own operations and they will be binding on States in relation to operations assisted by the IAEA.

These Standards are also to be applied by the Sponsoring Organizations to their own operations. They are recommended for use by States and national authorities and by other international organizations in relation to their own activities. The application of these Standards by EU member states is ensured by the implementation of binding Euratom legislation. Other States that are member states of the other Sponsoring Organizations may adopt the requirements, at their own discretion, or in accordance with their membership obligations, for application to their own activities.

It is recognized that it will take some time to make changes to existing systems of radiation protection in order to fulfil the requirements fully. The IAEA Secretariat envisaged that, for the IAEA’s own operations and for those operations assisted by the IAEA, arrangements needed to be in place to fulfil the requirements within a period of one year from the date of their adoption.

These Standards are intended for application and use by governmental authorities, including regulatory bodies responsible for authorizing facilities and activities; by organizations operating nuclear facilities, some mining and raw material processing facilities such as uranium mines, radioactive waste management facilities, and any other facilities producing or using radiation sources for industrial, research or medical purposes; by organizations transporting radioactive material; by organizations decommissioning facilities; and by staff and technical and scientific support organizations supporting such organizations and authorities.

Member States also subscribe to international conventions relating to nuclear and radiation related activities conducted within their jurisdiction. The Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the

Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the ILO Convention concerning the Protection of Workers against Ionising Radiations, 1960 (No. 115) all place specific obligations on the Contracting Parties. These Basic Safety Standards and other IAEA safety standards constitute a useful tool for Contracting Parties to assess their performance under these international conventions. International conventions and IAEA safety standards, appropriately supplemented by industry standards and detailed national requirements, establish a consistent and comprehensive basis for the proper protection of people and the environment from harmful effects of ionizing radiation.

These Standards and other IAEA safety standards also support the application of the Code of Conduct on the Safety and Security of Radioactive Sources, the Code of Conduct on the Safety of Research Reactors, and the International Health Regulations, an international instrument that is legally binding on WHO member states.

LEGAL NATURE OF IAEA SAFETY STANDARDS

The statutory basis for the IAEA safety standards is to be found in Article III.A.6 of the Statute. By virtue of that provision the Agency is authorized:

“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 (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State’s activities in the field of atomic energy.”

Pursuant to that authorization, the first step in establishing IAEA safety standards was taken when the IAEA Board of Governors, on 31 March 1960, approved the Health and Safety Document: “The Agency’s Safety Standards and Measures” (INFCIRC/18). Thereafter, various safety standards (e.g. the BSS and the IAEA Transport Regulations) were established in accordance with Article III.A.6 and “The Agency’s Safety Standards and Measures”

(INFCIRC/18), which was revised in 1975 and approved by the IAEA Board in February 1976 (reproduced in INFCIRC/18/Rev.1).

Paragraph 1 of INFCIRC/18/Rev.1 contains the following relevant definitions:

“1.1 “Safety standards” means standards, regulations, rules or codes of practice established to protect man and the environment against ionizing radiation and to minimize danger to life and property.

“1.2 “The Agency’s safety standards” means safety standards established by the Agency under the authority of the Board of Governors. Such standards comprise:

- (a) The Agency’s basic safety standards for radiation protection, which prescribe maximum permissible doses and dose limits;
- (b) The Agency’s specialized regulations, which are safety prescriptions relating to particular fields of operation; and
- (c) The Agency’s codes of practice, which establish for particular activities the minimum requirements which, in the light of experience and the current state of technology, must be fulfilled to ensure adequate safety. Codes of practice are, as appropriate, supplemented by safety guides recommending a procedure or procedures that might be followed in implementing them.

“1.3 “Safety measure” means any action, condition or procedure to ensure the observance of safety standards.”

INTERPRETATION OF THE TEXT

A list of definitions that apply for the purposes of these Standards is included. The list of definitions includes: definitions of new terms that are not included in entries in the IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2007 Edition); revised definitions of terms that are defined in entries in the IAEA Safety Glossary (2007 Edition); and existing terms and their existing definitions from entries in the IAEA Safety Glossary (2007 Edition), included here for ease of reference. The entries for the new terms and for the revised definitions will be included in the next revision of the IAEA Safety Glossary and the revised definitions will, thus, supersede the pre-existing definitions for the purposes of the IAEA safety standards. Further relevant definitions not included here are provided in the IAEA Safety Glossary. See also: <http://www-ns.iaea.org/standards/safety-glossary.asp>

Also included is a CD-ROM containing the IAEA Safety Glossary (2007 Edition) and the Fundamental Safety Principles (2006), each in Arabic, Chinese, English, French, Russian and Spanish versions. The CD-ROM is also available for purchase separately. See: <http://www-pub.iaea.org/MTCD/publications/publications.asp>

The text of these Standards was developed in drafting and review meetings and technical meetings which were held in English only. The IAEA Secretariat made official translations into Arabic, Chinese, French, Russian and Spanish of the draft standard for the purpose of submission of the draft new edition to the IAEA Board of Governors for approval. The approved text was issued in November 2011 as a Safety Requirements publication in an Interim Edition in English only in the IAEA Safety Standards Series. This Interim Edition was submitted to the other Sponsoring Organizations for their approval. Versions of the IAEA Secretariat's official translations of the draft new edition of these Standards into Arabic, Chinese, French, Russian and Spanish for the IAEA Board of Governors were included in the Interim Edition on an accompanying CD-ROM.

The references included herein are to editions that were current as of the time of establishment of these Standards. Editions that supersede these references may be adopted under national legislation. In the event that the publications referenced here are superseded, please refer to the most recent editions. See also: <http://www-ns.iaea.org/standards/>

The IAEA Secretariat is to issue this safety standard as a jointly sponsored IAEA Safety Requirements publication in Arabic, Chinese, French, Russian and Spanish, as well as in English. Comments and queries on matters of technical content, terminology and language, and notification of any apparent errors, omissions or mistranslations, may be submitted by email to Rad.prot.unit@iaea.org and Safety.Standards@iaea.org, or via the IAEA safety standards web site, <http://www-ns.iaea.org/standards/>, for consideration by the IAEA Secretariat in a future review process.

The IAEA, on behalf of all the Sponsoring Organizations, wishes to express its sincere appreciation to all those who assisted in the process of reaching and formulating a consensus, and in the drafting, review and revision of these Standards.

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.

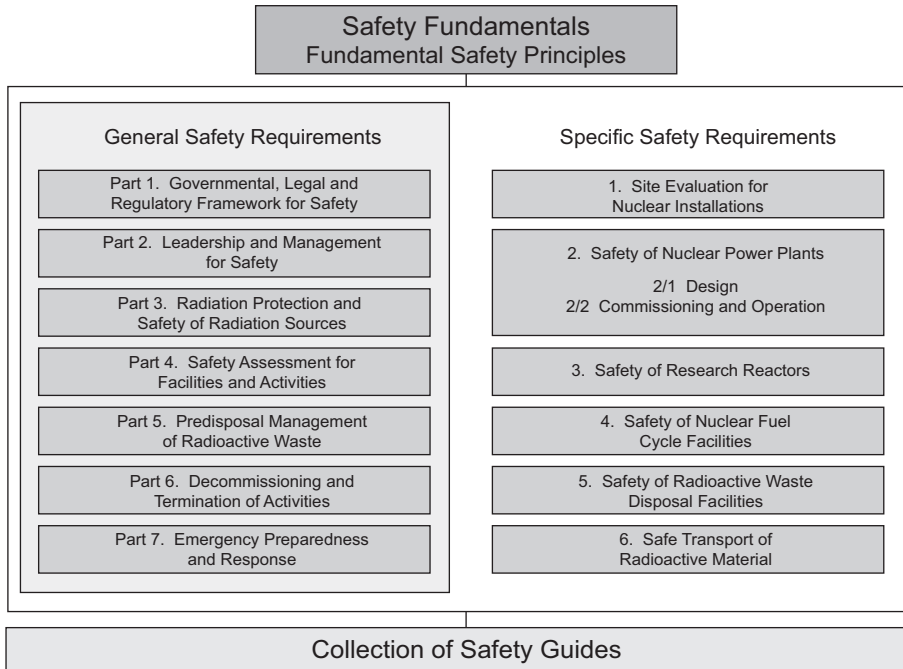


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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 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

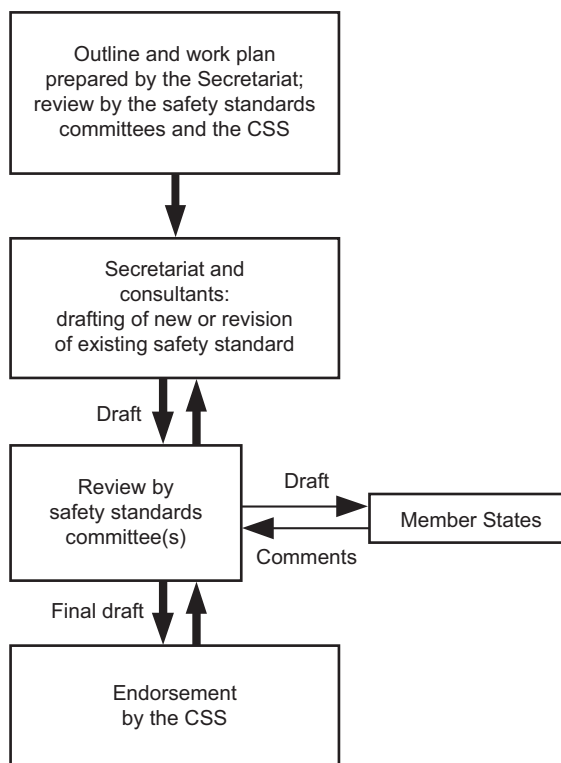


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. This General Safety Requirements publication, IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (hereinafter referred to as ‘these Standards’), is issued in the IAEA Safety Standards Series. It supersedes International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources issued in 1996 (the ‘BSS of 1996’)¹. Section 1 does not include requirements, but explains the context, concepts and principles for the requirements, which are established in Sections 2–5 and in the schedules.

1.2. Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation² and radioactive material may also be of artificial origin and they have many beneficial applications, including uses in medicine, industry, agriculture and research as well as for nuclear power generation. The radiation risks to people and the environment that may arise from the use of radiation and radioactive material must be assessed and must be controlled by means of the application of standards of safety³.

1.3. Exposure of human tissues or organs to radiation can induce the death of cells on a scale that can be extensive enough to impair the function of the exposed tissue or organ. Effects of this type, which are called ‘deterministic effects’, are clinically observable in an individual only if the radiation dose exceeds a certain threshold level. Above this threshold level of dose, a deterministic effect is more severe for a higher dose.

¹ FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, IAEA, Vienna (1996).

² The term ‘radiation’ in the context of these Standards means ionizing radiation.

³ Obligations expressed as ‘must’ statements in Section 1 are quoted from the Fundamental Safety Principles [1].

1.4. Exposure to radiation can also induce the non-lethal transformation of cells, which may still retain their capacity for cell division. The human body's immune system is very effective at detecting and destroying abnormal cells. However, there is a possibility that the non-lethal transformation of a cell could lead, after a latency period, to cancer in the individual exposed, if the cell is a somatic cell; or such a transformation of a cell could lead to hereditary effects, if the cell is a germ cell. Such effects are called 'stochastic' effects. For the purposes of these Standards, it is assumed that the probability of the eventual occurrence of a stochastic effect is proportional to the dose received, with no threshold. The 'detriment-adjusted nominal risk coefficient of dose', which includes the risks of all cancers and the risks of hereditary effects, is 5% per sievert [2]. This risk coefficient may need to be adjusted as new scientific knowledge becomes available.

1.5. The requirements established in these Standards are governed by the objectives, concepts and principles of the Fundamental Safety Principles [1]. These Standards draw upon information derived from the experience of States in applying the requirements of the BSS of 1996⁴, and from experience in many States in the use of radiation and nuclear techniques. These Standards draw upon extensive research and development work by national and international scientific and engineering organizations on the health effects of radiation exposure and on measures and techniques for the safe design and use of radiation sources. These Standards also take account of the findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [3] and the Recommendations of the International Commission on Radiological Protection (ICRP) [2]. As scientific considerations are only part of the basis for making decisions on protection and safety, these Standards also address the use of value judgements relating to the management of risks.

The system of protection and safety

1.6. As stated in the Fundamental Safety Principles [1], "The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation." This objective must be achieved without unduly limiting the

⁴ FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, IAEA, Vienna (1996).

operation of facilities or the conduct of activities that give rise to radiation risks⁵. Therefore, the system of protection and safety aims to assess, manage and control exposure to radiation so that radiation risks, including risks of health effects and risks to the environment, are reduced to the extent reasonably achievable.

1.7. These Standards are based on the following safety principles stated in the Fundamental Safety Principles [1]:

Principle 1: Responsibility for safety

The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.

Principle 2: Role of government

An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

Principle 3: Leadership and management for safety

Effective leadership and management for safety must be established and sustained in organizations concerned with, and facilities and activities that give rise to, radiation risks.

Principle 4: Justification of facilities and activities

Facilities and activities that give rise to radiation risks must yield an overall benefit.

⁵ The term ‘radiation risks’ is used in a general sense to refer to:

- Detrimental health effects of radiation exposure (including the likelihood of such effects occurring).
- Any other safety related risks (including those to the environment) that might arise as a direct consequence of:
 - Exposure to radiation;
 - The presence of radioactive material (including radioactive waste) or its release to the environment;
 - A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

Principle 5: Optimization of protection

Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

Principle 6: Limitation of risks to individuals

Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

Principle 7: Protection of present and future generations

People and the environment, present and future, must be protected against radiation risks.

Principle 8: Prevention of accidents

All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.

Principle 9: Emergency preparedness and response

Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

Principle 10: Protective actions to reduce existing or unregulated radiation risks

Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

The three general principles of radiation protection, which concern justification, optimization of protection and application of dose limits, are expressed in Safety Principles 4, 5, 6 and also 10 [1].

1.8. The prime responsibility for safety must rest with the person or organization responsible for facilities and activities⁶ that give rise to radiation risks [1]. Other parties also bear certain responsibilities. For instance, suppliers of radiation generators and radioactive sources have responsibilities in relation to their design and manufacture and operating instructions for their safe use. In the case of medical exposures, because of the medical setting in which such exposures occur, primary responsibility for protection and safety for patients lies with the health professional responsible for administration of the radiation dose, who is referred to in these Standards as the ‘radiological medical practitioner’. Other types of health professional may be involved in the preparation for, and the conduct of, radiological procedures, and each type has specific responsibilities, as established in these Standards.

1.9. A properly established governmental, legal and regulatory framework for safety provides for the regulation of facilities and activities that give rise to radiation risks. There is a hierarchy of responsibilities within this framework, from governments to regulatory bodies to the organizations responsible for, and the persons engaged in, activities involving radiation exposure. The government is responsible for the adoption within its national legal system of such legislation, regulations, and standards and measures as may be necessary to fulfil all its national and international obligations effectively, and for the establishment of an independent regulatory body. In some cases, more than one governmental organization may have the functions of a regulatory body for activities within their jurisdictions relating to the control of radiation and radioactive material.

1.10. Both the government and the regulatory body have important responsibilities in establishing the regulatory framework for protecting people and the environment from harmful effects of radiation, including establishing standards. These Standards require the government to ensure that there is coordination of government departments and agencies that have responsibilities

⁶ The term ‘facilities and activities’ is a general term encompassing any human activity that may cause people to be exposed to radiation risks arising from naturally occurring or artificial sources. The term ‘facilities’ includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive material is produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required. The term ‘activities’ includes: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.

for protection and safety, including the regulatory body, and of departments and agencies concerned with public health, the environment, labour, mining, science and technology, agriculture and education. Standards have to be developed by means of consultation with those who are or who could be required to apply them.

1.11. The government is also responsible for ensuring, as necessary, that provision is made for support services, such as education and training, and technical services. If these services are not available within the State, other mechanisms to provide them may have to be considered. The regulatory body is responsible for carrying out its required regulatory functions, such as the establishment of requirements and guidelines, the authorization and inspection of facilities and activities, and the enforcement of legislative and regulatory provisions.

1.12. Leadership in safety matters has to be demonstrated at the highest levels in an organization, and safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of management so that requirements for protection and safety are established and applied coherently with other requirements, including those for health, human performance, quality, protection of the environment and security, together with economic considerations. The application of the management system also has to ensure the promotion of safety culture, the regular assessment of safety performance and the application of lessons learned from experience. Safety culture includes individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels. The term ‘management system’ reflects and includes the concept of ‘quality control’ (controlling the quality of products) and its evolution through ‘quality assurance’ (the system for ensuring the quality of products) and ‘quality management system’ (the system for managing quality).

1.13. The operation of facilities or the conduct of activities that introduce a new source of radiation, that change exposures or that change the likelihood of exposures has to be justified in the sense that the detriments that may be caused are outweighed by the individual and societal benefits that are expected. The comparison of detriments and benefits often goes beyond the consideration of protection and safety, and involves the consideration of economic, societal and environmental factors also.

1.14. The application of the justification principle to medical exposures requires a special approach. As an overarching justification of medical exposures, it is accepted that the use of radiation in medicine does more good than harm. However, at the next level, there is a need for generic justification, to be carried

out by the health authority in conjunction with appropriate professional bodies, of a given radiological procedure. This applies to the justification of new technologies and techniques as they evolve. For the final level of justification, the application of the radiological procedure to a given individual has to be considered. The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account by means of referral guidelines developed by professional bodies and the health authority.

1.15. The optimization of protection and safety, when applied to the exposure of workers and members of the public, and carers and comforters of patients undergoing radiological procedures, is a process for ensuring that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection would be the best possible under the prevailing circumstances. Optimization is a prospective and iterative process that requires both qualitative and quantitative judgements to be made.

1.16. As is the case with justification, the application of the optimization principle to the medical exposure of patients, and to that of volunteers as part of a programme of biomedical research, requires a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that a cancer is not cured or the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome.

1.17. For planned exposure situations, exposures and risks are subject to control to ensure that the specified dose limits for occupational exposure and those for public exposure are not exceeded, and optimization is applied to attain the desired level of protection and safety.

1.18. All practical efforts must be made to prevent and mitigate nuclear or radiological accidents. The most harmful consequences arising from facilities and activities have come from the loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or other source of radiation. Consequently, to ensure that the likelihood of an accident having harmful consequences is extremely low, measures have to be taken:

- To prevent the occurrence of failures or abnormal conditions (including breaches of security) that could lead to such a loss of control;

- To prevent the escalation of any such failures or abnormal conditions that do occur;
- To prevent the loss of, or the loss of control over, a radioactive source or other source of radiation.

1.19. Arrangements must be made for emergency preparedness and response for nuclear or radiological incidents. The primary goals of preparedness and response for a nuclear or radiological emergency are:

- To ensure that arrangements are in place for an effective response at the scene and, as appropriate, at the local, regional, national and international levels, to a nuclear or radiation emergency;
- To ensure that, for reasonably foreseeable incidents, radiation risks would be minor;
- For any incidents that do occur, to take practical measures to mitigate any consequences for human life and health and the environment.

Types of exposure situation

1.20. For the purpose of establishing practical requirements for protection and safety, these Standards distinguish between three different types of exposure situation: planned exposure situations, emergency exposure situations and existing exposure situations [2]. Together, these three types of exposure situation cover all situations of exposure for which these Standards apply:

- (a) A *planned exposure situation* is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, the associated exposures and their likelihood of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of facilities, equipment and operating procedures, and by training. In planned exposure situations, exposure at some level can be expected to occur. If exposure is not expected to occur with certainty, but could result from an accident or from an event or a sequence of events that may occur but is not certain to occur, this is referred to as ‘potential exposure’.
- (b) An *emergency exposure situation* is a situation of exposure that arises as a result of an accident, a malicious act or any other unexpected event, and requires prompt action in order to avoid or to reduce adverse consequences. Preventive measures and mitigatory actions have to be considered before

an emergency exposure situation arises. However, once an emergency exposure situation actually arises, exposures can be reduced only by implementing protective actions.

- (c) An *existing exposure situation* is a situation of exposure that already exists when a decision on the need for control needs to be taken. Existing exposure situations include situations of exposure to natural background radiation. They also include situations of exposure due to residual radioactive material that derives from past practices that were not subject to regulatory control or that remains after an emergency exposure situation.

If an event or a sequence of events that has been considered in the assessment of potential exposure does actually occur, it may be treated either as a planned exposure situation or, if an emergency has been declared, as an emergency exposure situation.

1.21. The descriptions that are given in para. 1.20 of the three types of exposure situation are not always sufficient to determine unequivocally which type of exposure situation applies for particular circumstances. For instance, the transitions from an emergency exposure situation to an existing exposure situation may occur progressively over time; and some exposures due to natural sources may have some characteristics of both planned exposure situations and existing exposure situations. In these Standards, the most appropriate type of exposure situation for particular circumstances has been determined by taking practical considerations into account. For the purposes of these Standards, the exposure of aircrew to cosmic radiation is considered under existing exposure situations in Section 5. The exposure of space crew to cosmic radiation presents exceptional circumstances and these are considered separately in Section 5.

Dose constraints and reference levels

1.22. Dose constraints and reference levels are used for optimization of protection and safety, the intended outcome of which is that all exposures are controlled to levels that are as low as reasonably achievable, economic, societal and environmental factors being taken into account. Dose constraints are applied to occupational exposure and to public exposure in planned exposure situations. Dose constraints are set separately for each source under control and they serve as boundary conditions in defining the range of options for the purposes of optimization of protection and safety. Dose constraints are not dose limits: exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it could result in follow-up actions.

1.23. While the objectives of the use of dose constraints for controlling occupational exposure and public exposure are similar, the dose constraints are applied in different ways. For occupational exposure, the dose constraint is a tool to be established and used in the optimization of protection and safety by the person or organization responsible for a facility or an activity. For public exposure in planned exposure situations, the government or the regulatory body ensures the establishment or approval of dose constraints, taking into account the characteristics of the site and of the facility or activity, the scenarios for exposure and the views of interested parties. After exposures have occurred, the dose constraint may be used as a benchmark for assessing the suitability of the optimized strategy for protection and safety (referred to as the protection strategy) that has been implemented and for making adjustments as necessary. The setting of the dose constraint needs to be considered in conjunction with other health and safety provisions and the technology available.

1.24. Reference levels are used for optimization of protection and safety in emergency exposure situations and in existing exposure situations. They are established or approved by the government, the regulatory body or another relevant authority. For occupational exposure and public exposure in emergency exposure situations and in existing exposure situations, a reference level serves as a boundary condition in identifying the range of options for the purposes of optimization in implementing protective actions. The reference level represents the level of dose or the level of risk above which it is judged to be inappropriate to plan to allow exposures to occur, and below which the optimization of protection and safety is implemented. The value chosen for the reference level will depend on the prevailing circumstances for the exposures under consideration. The optimized protection strategies are intended to keep doses below the reference level. When an emergency exposure situation has arisen or an existing exposure situation has been identified, actual exposures could be above or below the reference level. The reference level would be used as a benchmark for judging whether further protective actions are necessary and, if so, in prioritizing their application. Optimization of protection and safety is to be applied in emergency exposure situations and in existing exposure situations, even if the doses initially received are below the reference level.

1.25. The ICRP recommends a range of doses spanning two orders of magnitude within which the value of a dose constraint or reference level would usually be chosen [2]. At the lower end of this range, the dose constraint or reference level represents an increase, of up to about 1 mSv, over the dose received in a year

from exposure due to naturally occurring radiation sources⁷. It would be used when individuals are exposed to radiation from a source that yields little or no benefit for them, but which may benefit society in general. This would be the case, for instance, in establishing dose constraints for public exposure in planned exposure situations.

1.26. Dose constraints or reference levels of 1–20 mSv would be used when the exposure situation — but not necessarily the exposure itself — usually benefits individuals. This would be the case, for instance, when establishing dose constraints for occupational exposure in planned exposure situations or reference levels for exposure of a member of the public in existing exposure situations.

1.27. Reference levels of 20–100 mSv would be used where individuals are exposed to radiation from sources that are not under control or where actions to reduce doses would be disproportionately disruptive. This would be the case, for instance, in establishing reference levels for the residual dose after a nuclear or radiological emergency. Any situation that resulted in a dose of greater than 100 mSv being incurred within a short period of time or in one year would be considered unacceptable, except under the circumstances relating to exposure of emergency workers that are addressed specifically in these Standards.

1.28. The selection of the value for the dose constraint or the reference level would be based on the characteristics of the exposure situation, including:

- The nature of the exposure and the practicability of reducing or preventing the exposure;
- The expected benefits of the exposure for individuals and society, or the benefits of avoiding preventive measures or protective actions that would be detrimental to living conditions, as well as other societal criteria relating to the management of the exposure situation;
- National or regional factors, together with a consideration of international guidance and good practice elsewhere.

1.29. The system of protection and safety required by these Standards includes criteria for protection against exposure due to radon that are based on the average

⁷ According to UNSCEAR [4], the worldwide average annual radiation dose from exposure due to naturally occurring radiation sources, including radon, is 2.4 mSv. In any large population, about 65% would be expected to have annual doses of between 1 and 3 mSv. About 25% of the population would be expected to have annual doses of less than 1 mSv, and about 10% would be expected to have annual doses greater than 3 mSv.

level of risk to a population with typical but various smoking habits. Owing to the synergistic effects of smoking and exposure due to radon, the absolute risk of lung cancer resulting from unit dose from exposure due to radon for people who are smokers is substantially greater than for those who have never smoked [3, 5, 6]. Information provided to people on the risks associated with exposure due to radon needs to highlight this increased risk for smokers.

1.30. Dose constraints are used in optimization of protection and safety for carers and comforters and for volunteers subject to exposure as part of a programme of biomedical research. Dose constraints are not applicable to the exposure of patients in radiological procedures for the purposes of medical diagnosis or treatment.

1.31. In X ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, a diagnostic reference level is used to indicate the need for an investigation. Periodic assessments are performed of typical doses or activity of the radiopharmaceuticals administered in a medical facility. If comparison with established diagnostic reference levels shows that the typical doses or activity of the radiopharmaceuticals administered are either too high or unusually low, a local review is to be initiated to ascertain whether protection and safety has been optimized and whether any corrective action is required.

Protection of the environment

1.32. In a global and long term perspective, protection of people and the environment against radiation risks associated with the operation of facilities and the conduct of activities — and in particular, protection against such risks that may transcend national borders and may persist for long periods of time — is important for achieving equitable and sustainable development.

1.33. The system of protection and safety required by these Standards generally provides for appropriate protection of the environment from harmful effects of radiation. Nevertheless, international trends in this field show an increasing awareness of the vulnerability of the environment. Trends also indicate the need to be able to demonstrate (rather than to assume) that the environment is being protected against effects of industrial pollutants, including radionuclides, in a wider range of environmental situations, irrespective of any human connection. This is usually accomplished by means of a prospective environmental assessment to identify impacts on the environment, to define the appropriate criteria for protection of the environment, to assess the impacts and to compare

the expected results of the available options for protection. Methods and criteria for such assessments are being developed and will continue to evolve.

1.34. Radiological impacts in a particular environment constitute only one type of impact and, in most cases, may not be the dominant impacts of a particular facility or activity. Furthermore, the assessment of impacts on the environment needs to be viewed in an integrated manner with other features of the system of protection and safety to establish the requirements applicable to a particular source. Since there are complex interrelations, the approach to the protection of people and the environment is not limited to the prevention of radiological effects on humans and on other species. When establishing regulations, an integrated perspective has to be adopted to ensure the sustainability, now and in the future, of agriculture, forestry, fisheries and tourism, and of the use of natural resources. Such an integrated perspective also has to take into account the need to prevent unauthorized acts with potential consequences for and via the environment, including, for example, the illicit dumping of radioactive material and the abandonment of radiation sources. Consideration also needs to be given to the potential for buildup and accumulation of long lived radionuclides released to the environment.

1.35. These Standards are designed to identify the protection of the environment as an issue necessitating assessment, while allowing for flexibility in incorporating into decision making processes the results of environmental assessments that are commensurate with the radiation risks.

Interfaces between safety and security

1.36. Safety measures and security measures have in common the aim of protecting human life and health and the environment. In addition, 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.

1.37. Security infrastructure and safety infrastructure need to be developed, as far as possible, in a well coordinated manner. All the organizations involved need to be made aware of the commonalities and the differences between safety and security so as to be able to factor both into development plans. The synergies between safety and security have to be developed so that safety and security complement and enhance one another.

OBJECTIVE

1.38. These Standards establish requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources.

SCOPE

1.39. These Standards apply for protection against ionizing radiation only, which includes gamma rays, X rays and particles such as beta particles, neutrons, protons, alpha particles and heavier ions. While these Standards do not specifically address the control of non-radiological aspects of health, safety and the environment, these aspects also need to be considered. Protection from harmful effects of non-ionizing radiation is outside the scope of these Standards.

1.40. These Standards are intended primarily for use by governments and regulatory bodies. Requirements also apply to principal parties and other parties as specified in Section 2, health authorities, professional bodies and service providers such as technical support organizations.

1.41. These Standards do not deal with security measures. The IAEA issues recommendations on nuclear security in the IAEA Nuclear Security Series.

1.42. These Standards apply to all situations involving radiation exposure that is amenable to control. Exposures deemed to be not amenable to control are excluded from the scope of these Standards.⁸

1.43. These Standards establish requirements to be fulfilled in all facilities and activities giving rise to radiation risks. For certain facilities and activities, such as nuclear installations, radioactive waste management facilities and the transport of radioactive material, other safety requirements, complementary to these Standards, also apply. The IAEA issues Safety Guides to assist in the application of these Standards.

1.44. These Standards apply to three categories of exposure: occupational exposure, public exposure and medical exposure.

⁸ It is generally accepted, for example, that it is not feasible to control ⁴⁰K in the body or cosmic radiation at the surface of the Earth.

1.45. These Standards apply to human activities involving radiation exposure that are:

- Carried out in a State which decides to adopt these Standards or which requests any of the Sponsoring Organizations to provide for the application of these Standards;
- Undertaken by States with the assistance of the Food and Agriculture Organization of the United Nations, the IAEA, the International Labour Organization, the Pan American Health Organization, the United Nations Environment Programme or the World Health Organization, in the light of relevant national rules and regulations;
- Carried out by the IAEA or involving the use of materials, services, equipment, facilities and non-published information made available by the IAEA or at its request or under its control or supervision; or
- Carried out under any bilateral or multilateral arrangement whereby the parties request the IAEA to provide for the application of these Standards.

1.46. Quantities and units used in these Standards are in accordance with the recommendations of the International Commission on Radiation Units and Measurements [7].

STRUCTURE

1.47. The requirements of these Standards are grouped into requirements applicable for all exposure situations and separate sets of requirements for planned exposure situations, emergency exposure situations and existing exposure situations. For each of the three types of exposure situation, the requirements are further grouped into requirements for occupational exposure, public exposure and (for planned exposure situations only) medical exposure.

1.48. The requirements established by these Standards, both numbered ‘overarching’ requirements in bold with titles and other requirements, are expressed as ‘shall’ statements. Each individual overarching requirement is followed by associated requirements.

1.49. Section 2 sets out the requirements that apply generally for all exposure situations and for all of the three categories of exposure (occupational exposure, public exposure and medical exposure). These requirements include the assignment of responsibilities to the government, the regulatory body, and principal parties and other parties with respect to the implementation of a

protection and safety programme and a management system, the promotion of safety culture and the consideration of human factors.

1.50. Section 3 sets out the requirements — in addition to those of Section 2 — for planned exposure situations. Section 3 includes requirements applicable to all three categories of exposure, requirements for the safety of sources, and separate sets of requirements in respect of occupational exposure, public exposure and medical exposure.

1.51. Section 4 sets out the requirements — in addition to those of Section 2 — for emergency exposure situations. Section 4 includes requirements in respect of public exposure and occupational exposure (i.e. exposure of emergency workers) in emergency exposure situations. It also includes requirements on the transitions from an emergency exposure situation to an existing exposure situation.

1.52. Section 5 sets out the requirements — in addition to those of Section 2 — for existing exposure situations. Section 5 includes requirements in respect of public exposure and occupational exposure in existing exposure situations. It includes requirements in respect of remediation of sites and habitation in areas with residual radioactive material, radon in homes and in workplaces, radionuclides in commodities, and exposure of aircrew and of space crew.

1.53. The organization of the requirements in these Standards for the relevant categories of exposure in each type of exposure situation is as shown in Table 1. General requirements for all exposure situations are given in Section 2, and requirements for different exposure situations are given in Sections 3–5. Thus, for any particular facility or activity, more than one section of these Standards will be relevant, as illustrated by the following examples:

- (a) The requirements for the regulatory body given in Section 2 are applicable for all exposure situations and all categories of exposure. They provide the regulatory framework within which persons or organizations responsible for facilities and activities have to comply with requirements placed on them. These requirements, thus, establish the general regulatory responsibilities of the regulatory body. Any further requirements on the regulatory body that apply for one type of exposure situation are given in Sections 3–5. These further requirements are in addition to the requirements given in Section 2.

TABLE 1. ORGANIZATION OF THE REQUIREMENTS OF THESE STANDARDS

	Occupational exposure	Public exposure	Medical exposure
Planned exposure situations	Section 2; Section 3: paras 3.5–3.67 and paras 3.68–3.116	Section 2; Section 3: paras 3.5–3.67 and paras 3.117–3.144	Section 2; Section 3: paras 3.5–3.67 and paras 3.145–3.185
Emergency exposure situations	Section 2; Section 4	Section 2; Section 4	Not applicable
Existing exposure situations	Section 2; Section 5	Section 2; Section 5	Not applicable

- (b) Persons or organizations responsible for a medical facility in which radiation generators or radioactive sources are used are subject to the requirements given in Section 2 for all exposure situations and all categories of exposure, and also to those requirements given in Section 3 that are common to all planned exposure situations (paras 3.5–3.67). In addition, such persons or organizations are subject to the separate requirements given in Section 3 for occupational exposure (such as exposure of medical staff operating medical devices that emit radiation) (paras 3.68–3.116), public exposure (such as exposure in rooms adjacent to rooms containing equipment that generates radiation) (paras 3.117–3.144) and medical exposure (such as exposure of patients) (paras 3.145–3.185).

1.54. Schedules I–IV provide numerical values in support of the requirements, covering exemption and clearance, categorization of sealed sources, dose limits for planned exposure situations and criteria for use in emergency preparedness and response.

1.55. Definitions of terms used are included in these Standards.

2. GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY

DEFINITIONS

2.1. Terms used have the meanings given under Definitions.

INTERPRETATION

2.2. Except as specifically authorized by the statutory governing body of a Sponsoring Organization, no interpretation of these Standards by any officer or employee of the Sponsoring Organization other than a written interpretation by the Director General of the Sponsoring Organization will be binding on the Sponsoring Organization.

RESOLUTION OF CONFLICTS

2.3. The requirements of these Standards are in addition to and not in place of other applicable requirements, such as those of relevant binding conventions and national laws and regulations.

2.4. In cases of conflict between the requirements of these Standards and other applicable requirements, the government or the regulatory body, as appropriate, shall determine which requirements are to be enforced.

2.5. Nothing in these Standards shall be construed as restricting any actions that may otherwise be necessary for protection and safety or as relieving the parties referred to in paras 2.40 and 2.41 from complying with applicable laws and regulations.

ENTRY INTO FORCE

2.6. These Standards shall enter into force one year after the date of their adoption or acknowledgement, as appropriate, by the Sponsoring Organization.

2.7. If a State decides to adopt these Standards, these Standards shall come into force at the time indicated in the formal adoption by that State.

APPLICATION OF THE PRINCIPLES OF RADIATION PROTECTION

Requirement 1: Application of the principles of radiation protection

Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied for all exposure situations.

2.8. For planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless it is justified.

2.9. For emergency exposure situations and existing exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protective actions or remedial actions are justified and are undertaken in such a way as to achieve the objectives set out in a protection strategy.

2.10. For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized⁹.

2.11. For planned exposure situations other than for medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded.

2.12. The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

⁹ 'Protection and safety is optimized' means that optimization of protection and safety has been applied and the result of that process has been implemented.

RESPONSIBILITIES OF THE GOVERNMENT¹⁰

Requirement 2: Establishment of a legal and regulatory framework

The government shall establish and maintain a legal and regulatory framework for protection and safety and shall establish an effectively independent regulatory body with specified responsibilities and functions.

2.13. The government shall establish and maintain an appropriate and effective legal and regulatory framework for protection and safety in all exposure situations.¹¹ This framework shall encompass both the assignment and the discharge of governmental responsibilities, and the regulatory control of facilities and activities that give rise to radiation risks. The framework shall allow for the fulfilment of international obligations.

2.14. The government shall ensure that adequate arrangements are in place for the protection of people and the environment, both now and in the future, against harmful effects of ionizing radiation, without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks. This shall include arrangements for the protection of people of present and future generations and populations remote from present facilities and activities.

2.15. The government shall establish legislation that, among other things:

- (a) Provides the statutory basis for requirements for protection and safety for all exposure situations;
- (b) Specifies that the prime responsibility for protection and safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks;
- (c) Specifies the scope of its applicability;
- (d) Establishes and provides for maintaining an independent regulatory body with clearly specified functions and responsibilities for the regulation of protection and safety;
- (e) Provides for coordination between authorities with responsibilities relevant to protection and safety for all exposure situations.

¹⁰ 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 here with the term ‘State’.

¹¹ Requirements on the governmental, legal and regulatory framework for safety of facilities and activities are established in Ref. [8].