

SAFETY STANDARDS

safety series

**International
Basic Safety Standards
for Protection against
Ionizing Radiation
and for the Safety of
Radiation Sources**

JOINTLY SPONSORED BY FAO, IAEA, ILO, OECD/NEA, PAHO, WHO



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CORRIGENDA
to
International Basic Safety Standards for Protection against Ionizing Radiation
and for the Safety of Radiation Sources
Safety Series No. 115

p. 48

In para. II.14(b) replace “focal spot position” with “focal spot size”.

p. 88

In footnote a to Table I-I add the following two parent nuclides and progeny (first and sixth):

Sr-80	Rb-80
Ag-108m	Ag-108

p. 91

In para. II-2 replace “para. 205” with “para. 2.5”.

p. 92

In footnote 40 replace “para. 418” with “para. I-18”.

p. 277

In footnote d to Table II-IX replace “time” with “half-time”.

p. 285

In Table IV-II replace “Gy·a⁻¹” with “Sv·a⁻¹”.

p. 289

In para. V-11 replace “V-11–V-16” with “V.11–V.16”.

p. 299

In the definition of **Committed effective dose** after “integration time τ ” insert “and w_T is the tissue weighting factor for tissue T”.

p. 304

In the definition of **Health professional** replace “paediatry” with “podiatry”.

p. 307

In the definition of **Multiple scan average dose** replace the limits of integration with “+nI/2” and “-nI/2”.

p. 319

In the Index spaces not preceded by commas should be inclusive intervals; e.g., “2.10 2.14” should be “2.10–2.14”.

p. 319

In the entry for **authorized person** delete “2.7”.

p. 321

Replace the entry for **embryo** with “**embryo/foetus** I.17, I.27, II.16, II.18, Table IV-I”.

p. 322

Replace “foetus (see embryo)” with “foetus (see embryo/foetus)”.

p. 324

Replace “programme (see protection and safety programme)” with “programme (see protection and safety)”.

**INTERNATIONAL
BASIC SAFETY STANDARDS
FOR PROTECTION AGAINST
IONIZING RADIATION
AND FOR THE SAFETY OF
RADIATION SOURCES**

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Jointly sponsored by:

Food and Agriculture Organization of the United Nations
International Atomic Energy Agency
International Labour Organisation
Nuclear Energy Agency of the
Organisation for Economic Co-operation and Development
Pan American Health Organization
World Health Organization

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 1996

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FOREWORD

These International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources mark the culmination of efforts that have continued over the past several decades towards the harmonization of radiation protection and safety standards internationally. The Standards are jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO) (the Sponsoring Organizations).

The unprecedented international effort to draft and review the Standards involved hundreds of experts from the Member States of the Sponsoring Organizations and from specialized organizations. The meeting of the Technical Committee that endorsed the Standards in December 1993 was attended by 127 experts from 52 countries and 11 organizations. A further Technical Committee verified the technical editing and the translations between English and Arabic, Chinese, French, Russian and Spanish.

The IAEA's Board of Governors approved the Standards at its 847th Meeting on 12 September 1994. For PAHO, the XXIV Pan American Sanitary Conference endorsed the Standards on 28 September 1994 following a recommendation from the 113th Meeting of the PAHO Executive Committee on 28 June 1994. The Director General of the FAO confirmed the FAO's technical endorsement of the Standards on 14 November 1994. WHO completed its adoption process for the Standards on 27 January 1995 when the Director-General's report on the subject was noted by the Executive Board at its 95th session. The ILO's Governing Body approved publication of the Standards at its meeting on 17 November 1994. The OECD/NEA Steering Committee approved the Standards at its meeting on 2 May 1995. This completed the authorization process for joint publication by all the Sponsoring Organizations.

The IAEA is herewith issuing the Standards in their final edition, which supersedes the Interim Edition (Safety Series No. 115-I) issued in December 1994. The Standards are issued in the IAEA Safety Series as a final publication in Arabic, Chinese, English, French, Russian and Spanish.

EDITORIAL NOTE

The Principal Requirements of these Standards, which are presented in the main body of the text, generally use the form 'shall' in making statements about requirements, duties and obligations. The Detailed Requirements, which are presented in the Appendices, also use 'shall' in statements consequential to the Principal Requirements, with the implication that these requirements apply unless other more desirable options for protection and safety have been established. As exceptions to this general rule, the requirements on or related to the justification of practices and of interventions, statements referring to the declaration of pregnancy by female workers and a number of statements on medical exposures use the form 'should' to mean a desired option, and a general condition, for protection and safety.

Many Principal Requirements of the Standards are not addressed to any specific party, the implication being that they should be fulfilled by the appropriate party(ies). Conversely, the Detailed Requirements in the Appendices generally specify the appropriate party(ies) responsible for fulfilling the requirement.

The values of committed effective dose per unit intake and the gut transfer factors given in Schedule II are based on the latest information provided by the ICRP and are consistent with the relevant ICRP publications. These values underwent quality assurance checking, as a result of which revisions were made. Please note that the values presented here consequently differ from those published in the Interim Edition of the Standards (Safety Series No. 115-I).

The use of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

PREFACE

BACKGROUND

Although all the Sponsoring Organizations are involved in the international harmonization of radiation protection and safety, the IAEA is specifically authorized under the terms of its Statute to establish standards of safety for the protection of health and the minimization of danger to life, in consultation with the United Nations and the specialized agencies concerned. Not surprisingly, therefore, in the family of international governmental organizations, the first endeavour to establish standards for radiation protection and safety was made at the IAEA. The Board of Governors of the IAEA first approved radiation protection 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 first approved basic safety standards in June 1962; they were published by the IAEA as Safety Series No. 9². A revised version was published in 1967³. A third revision was published by the IAEA as the 1982 Edition of Safety Series No. 9⁴; this Edition was jointly sponsored by the IAEA, the ILO, the OECD/NEA and the WHO.

In 1990, an important step towards international harmonization of radiation protection and safety took place: an Inter-Agency Committee on Radiation Safety (IACRS) was constituted as a forum for consultation on and collaboration in radiation safety matters between international organizations⁵. The IACRS initially comprised the Commission of the European Communities (CEC), the Council for Mutual Economic Assistance (CMEA) (now defunct), the FAO, the IAEA, the ILO, the OECD/NEA, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the WHO. The PAHO joined subsequently. The ICRP, the International Commission on Radiation Units and Measurements (ICRU), the International Electrotechnical Commission (IEC), the International Radiation Protection Association (IRPA) and the International Organization for Standardization (ISO)

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, Safety series No. 9, IAEA, Vienna (1962).

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

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

⁵ See IAEA Annual Report for 1990, IAEA/GC(XXXV)/953, p. 86.

have observer status on the IACRS. The objective of the IACRS is to promote consistency and co-ordination of policies with respect to the following areas of common interest: applying principles, criteria and standards of radiation protection and safety and translating them into regulatory terms; co-ordinating research and development; advancing education and training; promoting widespread information exchange; facilitating the transfer of technology and know-how; and providing services in radiation protection and safety.

Within this framework, the Sponsoring Organizations established a Joint Secretariat for the preparation of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, the 'Standards', contained in this publication. The Joint Secretariat was co-ordinated by the IAEA. The Standards supersede the previous basic international standards and reflect knowledge gained subsequently and developments in radiation protection and safety and related fields.

The Standards are based primarily on the recommendations of the ICRP. The ICRP is a non-governmental scientific organization founded in 1928 to establish basic principles and recommendations for radiation protection; the most recent recommendations of the ICRP were issued in 1991⁶.

Moreover, in relation to safety, the Standards take account of the principles recommended by the International Nuclear Safety Advisory Group (INSAG) which, under the auspices of the IAEA, has been elaborating nuclear safety concepts since 1985, such as its Basic Safety Principles for Nuclear Power Plants⁷; many of these principles are relevant to radiation sources and installations other than nuclear installations. The quantities and units used in the Standards are primarily those recommended by the ICRU, a sister organization of the ICRP.

The Standards are published in the IAEA Safety Series. This series of publications encompasses Safety Fundamentals, Safety Standards, Safety Guides and Safety Practices relating to nuclear safety and radiation protection, including radioactive waste management⁸. The IAEA Safety Series includes other related international standards, such as the Nuclear Safety Standards (NUSS) for nuclear power plants, the Regulations for the Safe Transport of Radioactive Material, and the forthcoming Radioactive Waste Management Standards (RADWASS). The other organizations of

⁶ INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, Publication No. 60, Pergamon Press, Oxford and New York (1991).

⁷ INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Basic Safety Principles for Nuclear Power Plants, Safety Series No. 75-INSAG-3, IAEA, Vienna (1988).

⁸ The objectives and principles underlying the Standards are summarized in INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and the Safety of Radiation Sources: Safety Fundamentals, Safety Series No. 120, IAEA, Vienna (1996).

the Joint Secretariat have also produced codes and guides in their respective spheres of activity. Notably, the ILO has 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 documents relating to the safety of workers and patients in medical applications of radiation; the FAO and the WHO have established, through the Codex Alimentarius Commission, guideline levels for radioactive substances in foodstuffs moving in international trade; and the OECD/NEA has published documents on specific topics relating to radiation protection and safety.

OBJECTIVE

The purpose of the Standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation (hereinafter termed radiation) and for the safety of radiation sources that may deliver such exposure.

The Standards have been developed from widely accepted radiation protection and safety principles, such as those published in the Annals of the ICRP and the IAEA Safety Series. They are intended to ensure the safety of all types of radiation sources and, in doing so, to complement standards already developed for large and complex radiation sources, such as nuclear reactors and radioactive waste management facilities. For these sources, more specific standards, such as those issued by the IAEA, are typically needed to achieve acceptable levels of safety. As these more specific standards are generally consistent with the Standards, in complying with them, such more complex installations will also generally comply with the Standards.

The Standards are limited to specifying basic requirements of radiation protection and safety, with some guidance on how to apply them. General guidance on applying some of the requirements is available in the publications of the Sponsoring Organizations and additional guidance will be developed as needed in the light of experience gained in the application of the Standards.

SCOPE

The Standards comprise basic requirements to be fulfilled in all activities involving radiation exposure. The requirements have the force that is derived from the statutory provisions of the Sponsoring Organizations. They do not entail any obligation for States to bring their legislation into conformity with them, nor are they intended to replace the provisions of national laws or regulations, or the standards in force. They are aimed rather to serve as a practical guide for public authorities and services, employers and workers, specialized radiation protection bodies, enterprises and safety and health committees.

The Standards lay down basic principles and indicate the different aspects that should be covered by an effective radiation protection programme. They are not intended to be applied as they stand in all countries and regions, but should be interpreted to take account of local situations, technical resources, the scale of installations and other factors which will determine the potential for application.

The Standards cover a broad range of practices and sources that give rise to or could give rise to exposure to radiation, and many of the requirements have therefore been drafted in general terms. It follows that any given requirement may have to be fulfilled differently for different types of practice and source, according to the nature of the operations and the potential for exposures. Not all the requirements will apply to every practice or to every source, and it is up to the appropriate Regulatory Authority to specify which of the requirements are applicable in each case.

The scope of the Standards is limited to the protection of human beings only; it is considered that standards of protection that are adequate for this purpose will also ensure that no other species is threatened as a population, even if individuals of the species may be harmed. Moreover, the Standards apply only to ionizing radiation, namely gamma and X rays and alpha, beta and other particles that can induce ionization. They do not apply to non-ionizing radiation such as microwave, ultra-violet, visible light and infrared radiation. They do not apply either to the control of non-radiological aspects of health and safety. The Standards recognize that radiation is only one of many sources of risk in life, and that the risks associated with radiation should not only be weighed against its benefits but also viewed in perspective with other risks.

STRUCTURE

The Standards comprise a Preamble, the Principal Requirements, Appendices and Schedules. The Preamble states the aims and the bases of the Standards, explains the underlying principles and philosophy, and describes appropriate governmental arrangements for applying the Standards. The Principal Requirements specify what is imperative in order to fulfil the aims of the Standards. Consequential Detailed Requirements, subsidiary to the Principal Requirements, are specified in the Appendices. Quantitative standards and guidance are provided in the Schedules. A Glossary, the list of experts who contributed to the drafting and review process, and the list of the representatives of countries and organizations on the Technical Committees which endorsed the Standards in December 1993 and which verified the translations and technical editing of the Standards in August/September 1994 are also included. The Sponsoring Organizations are also briefly described.

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PREAMBLE: PRINCIPLES AND FUNDAMENTAL OBJECTIVES

It has been recognized since early studies on X rays and radioactive minerals that exposure to high levels of radiation can cause clinical damage to the tissues of the human body. In addition, long term epidemiological studies of populations exposed to radiation, especially the survivors of the atomic bombing of Hiroshima and Nagasaki in Japan in 1945, have demonstrated that exposure to radiation also has a potential for the delayed induction of malignancies. It is therefore essential that activities involving radiation exposure, such as the production and use of radiation sources and radioactive materials, and the operation of nuclear installations, including the management of radioactive waste, be subject to certain standards of safety in order to protect those individuals exposed to radiation.

Radiation and radioactive substances are natural and permanent features of the environment, and thus the risks associated with radiation exposure can only be restricted, not eliminated entirely. Additionally, the use of human made radiation is widespread. Sources of radiation are essential to modern health care: disposable medical supplies sterilized by intense radiation have been central to combating disease; radiology is a vital diagnostic tool; and radiotherapy is commonly part of the treatment of malignancies. The use of nuclear energy and applications of its by-products, i.e. radiation and radioactive substances, continue to increase around the world. Nuclear techniques are in growing use in industry, agriculture, medicine and many fields of research, benefiting hundreds of millions of people and giving employment to millions of people in the related occupations. Irradiation is used around the world to preserve foodstuffs and reduce wastage, and sterilization techniques have been used to eradicate disease carrying insects and pests. Industrial radiography is in routine use, for example to examine welds and detect cracks and help prevent the failure of engineered structures.

The acceptance by society of risks associated with radiation is conditional on the benefits to be gained from the use made of radiation. Nonetheless, the risks must be restricted and protected against by the application of radiation safety standards. The Standards provide a desirable international consensus for this purpose.

The Standards draw upon information derived from extensive research and development work by scientific and engineering organizations, at national and international levels, on the health effects of radiation and on techniques for the safe design and operation of radiation sources; and draw upon experience in many countries in the use of radiation and nuclear techniques. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), a body set up by the United Nations in 1955, compiles, assesses and disseminates information on the health effects of radiation and on levels of radiation exposure due to different sources; this information was taken into account in developing the Standards. Purely

scientific considerations, however, are only part of the basis for decisions on protection and safety, and the Standards implicitly encourage decision makers to make value judgements about the relative importance of risks of different kinds and about the balancing of risks and benefits.

RADIATION EFFECTS

Exposure to radiation at high doses can cause effects such as nausea, reddening of the skin or, in severe cases, more acute syndromes that are clinically expressed in exposed individuals within a short period of time after the exposure. Such effects are termed 'deterministic effects' because they are certain to occur if the dose exceeds a threshold level. Radiation exposure can also induce somatic effects such as malignancies which are expressed after a latency period and may be epidemiologically detectable in a population; this induction is assumed to take place over the entire range of doses without a threshold level. Also, hereditary effects due to radiation exposure have been statistically detected in other mammalian populations and are presumed to occur in human populations also. These epidemiologically detectable effects — malignancies and hereditary effects — are termed 'stochastic effects' because of their random nature.

Deterministic effects are the result of various processes, mainly cell death and delayed cell division, caused by exposure to high levels of radiation. If extensive enough, these can impair the function of the exposed tissue. The severity of a particular deterministic effect in an exposed individual increases with the dose above the threshold for the occurrence of the effect.

Stochastic effects may ensue if an irradiated cell is modified rather than killed. Modified cells may, after a prolonged process, develop into a cancer. The body's repair and defence mechanisms make this a very improbable outcome at small doses; nevertheless, there is no evidence of a threshold dose below which cancer cannot result. The probability of occurrence of cancer is higher for higher doses, but the severity of any cancer that may result from irradiation is independent of the dose. If the cell damaged by radiation exposure is a germ cell, whose function is to transmit genetic information to progeny, it is conceivable that hereditary effects of various types may develop in the descendants of the exposed individual. The likelihood of stochastic effects is presumed to be proportional to the dose received, without a dose threshold.

In addition to the aforementioned health effects, other health effects may occur in infants due to exposure of the embryo or foetus to radiation. These effects include a greater likelihood of leukaemia and, for exposure above various threshold dose values during certain periods of pregnancy, severe mental retardation and congenital malformations.

Since a small likelihood of occurrence of stochastic effects at even the lowest doses is assumed, the Standards cover the entire range of doses with the aim of constraining any radiation detriment that may arise. The many aspects of the concept of radiation detriment make it undesirable to select any single quantity to represent it. The Standards are therefore based on a concept of detriment as recommended by the ICRP, which for stochastic effects includes the following quantities: the probability of fatal cancer attributable to radiation exposure; the weighted probability of incurring a non-fatal cancer; the weighted probability of severe hereditary effects; and the length of lifetime lost if the harm occurs.

PRACTICES AND INTERVENTIONS

Human activities that add radiation exposure to that which people normally incur due to background radiation, or that increase the likelihood of their incurring exposure, are termed 'practices' in the Standards. The human activities that seek to reduce the existing radiation exposure, or the existing likelihood of incurring exposure which is not part of a controlled practice, are termed 'interventions'.

The Standards apply to both the commencement and the continuation of practices that involve or could involve radiation exposure, and also to existing de facto situations in which exposure or its likelihood can be reduced or prevented by means of some intervention. For a practice, provisions for radiation protection and safety can be made before its commencement, and the associated radiation exposures and their likelihood can be restricted from the outset. In the case of intervention, the circumstances giving rise to exposure or the likelihood of exposure already exist, and their reduction can only be achieved by means of remedial or protective actions.

The practices for which the Standards are intended include the following: activities involving the production of radiation sources; the use of radiation and radioactive substances in medicine, research, industry, agriculture and teaching; the generation of nuclear power, including the entire cycle of related activities from the mining and processing of radioactive ores to the operation of nuclear reactors and fuel cycle facilities and the management of radioactive wastes; and activities, such as the underground mining of coal and of phosphatic and other minerals, that may enhance exposure to naturally occurring radioactive substances. Situations that may require intervention include: chronic exposure to naturally occurring sources of radiation such as radon in dwellings, and to radioactive residues from past activities and events; and emergency exposure situations such as might result from accidents or from deficiencies in existing practices.

TYPES OF RADIATION EXPOSURE

It is virtually certain that some radiation exposures will result from the normal performance of practices and that their magnitudes will be predictable, albeit with some degree of uncertainty: such expected exposures are referred to in the Standards as 'normal exposures'. Also, exposure scenarios can be envisaged for which there is a potential for exposure, but no certainty that an exposure will in fact occur; such unexpected but feasible exposures are termed 'potential exposures'. Potential exposures can become actual exposures if the unexpected situation does occur; for example as a consequence of equipment failure, design or operating errors, or unforeseen changes in environmental conditions, e.g. at a disposal site for radioactive waste. If the occurrence of such events can be foreseen, the probability of their occurrence and the resulting radiation exposure can be estimated.

The means specified in the Standards for controlling normal exposures is the restriction of the doses delivered. The primary means for controlling potential exposures is by good design of installations, equipment and operating procedures; this is intended to restrict the probability of occurrence of events that could lead to unplanned exposures and to restrict the magnitudes of the exposures that could result if such events were to occur.

The relevant radiation exposures covered by the Standards encompass the exposures, both normal and potential, of workers pursuing their occupations, of patients in diagnosis or treatment, and of members of the public who may be affected by a practice or by an intervention. For intervention situations the exposure can be chronic or, in some cases of emergencies, temporary. Thus exposures are divided into: 'occupational exposures' which are incurred at work and principally as a result of work; 'medical exposures' which are principally exposures of patients in diagnosis or treatment; and 'public exposures' which comprise all other exposures.

The Standards are intended to cover all people who may be exposed to radiation, including those in future generations who could be affected by present practices or interventions.

BASIC PRINCIPLES

The principles of radiation protection and safety on which the Standards are based are those developed by the ICRP and by INSAG. The detailed formulation of these principles can be found in the publications of these bodies and they cannot easily be paraphrased without losing their essence. However, a brief — although simplified — summary of the principles is as follows: a practice that entails or that could entail exposure to radiation should only be adopted if it yields sufficient benefit to the exposed individuals or to society to outweigh the radiation detriment it causes

or could cause (i.e. the practice must be justified)¹; individual doses due to the combination of exposures from all relevant practices should not exceed specified dose limits; radiation sources and installations should be provided with the best available protection and safety measures under the prevailing circumstances, so that the magnitudes and likelihood of exposures and the numbers of individuals exposed be as low as reasonably achievable, economic and social factors being taken into account, and the doses they deliver and the risk they entail be constrained (i.e. protection and safety should be optimized); radiation exposure due to sources of radiation that are not part of a practice should be reduced by intervention when this is justified, and the intervention measures should be optimized; the legal person authorized to engage in a practice involving a source of radiation should bear the primary responsibility for protection and safety; a safety culture should be inculcated that governs the attitudes and behaviour in relation to protection and safety of all individuals and organizations dealing with sources of radiation; in-depth defensive measures should be incorporated into the design and operating procedures for radiation sources to compensate for potential failures in protection or safety measures; and protection and safety should be ensured by sound management and good engineering, quality assurance, training and qualification of personnel, comprehensive safety assessments and attention to lessons learned from experience and research.

QUANTITIES AND UNITS

Although most of the requirements of the Standards are qualitative, the Standards also establish quantitative limits, and guidance levels. For these purposes, the main physical quantities used in the Standards are the rate of nuclear transformation of radionuclides (the activity) and the energy absorbed by a unit mass of a substance from the radiation to which it is exposed (the absorbed dose). The unit of activity is the reciprocal second, representing the number of nuclear transformations (or disintegrations) per second, which is termed the becquerel (Bq). The unit of absorbed dose is the joule per kilogram, termed the gray (Gy).

The absorbed dose is the basic physical dosimetric quantity of the Standards. However, it is not entirely satisfactory for radiation protection purposes because effectiveness in damaging human tissue differs for different types of ionizing radiation. Consequently, the absorbed dose averaged over a tissue or organ is multiplied by a radiation weighting factor to take account of the effectiveness of the given type of radiation in inducing health effects; the resulting quantity is termed the equivalent

¹ Usually, compliance with the principle of justification is adequately demonstrated in respect of a type of activity by the existence or the laying down of regulations specifically concerning the type of activity.

dose. The quantity equivalent dose is used when individual organs or tissues are irradiated, but the likelihood of injurious stochastic effects due to a given equivalent dose differs for different organs and tissues. Consequently, the equivalent dose to each organ and tissue is multiplied by a tissue weighting factor to take account of the organ's radiosensitivity. The sum total of such weighted equivalent doses for all exposed tissues in an individual is termed the effective dose. The unit of equivalent dose and of effective dose is the same as that of absorbed dose, namely joule per kilogram, but the name sievert (Sv) is used in order to avoid confusion with the unit of absorbed dose (Gy).

When radionuclides are taken into the body, the resulting dose is received throughout the period of time during which they remain in the body. The committed dose is the total dose delivered during this period of time, and is calculated as a specified time integral of the rate of receipt of the dose. Any relevant dose restriction is applied to the committed dose from the intake.

The total impact of the radiation exposure due to a given practice or source depends on the number of individuals exposed and on the doses they receive. The collective dose, defined as the summation of the products of the mean dose in the various groups of exposed people and the number of individuals in each group, may therefore be used to characterize the radiation impact of a practice or source. The unit of collective dose is the man-sievert (man·Sv).

GOVERNMENTAL REGULATION

The Standards are intended to place requirements on those legal persons authorized to conduct practices that cause radiation exposure or to intervene in order to reduce existing exposures; these legal persons have the primary responsibility for applying the Standards. Governments, however, have responsibility for their enforcement, generally through a system that includes a Regulatory Authority, and for planning and taking actions in different circumstances. In addition, Governments generally provide for certain essential services for radiation protection and safety and for interventions that exceed or that complement the capabilities of the legal persons authorized to conduct practices.

The Standards are based therefore on the presumption that a national infrastructure is in place enabling the Government to discharge its responsibilities for radiation protection and safety.

NATIONAL INFRASTRUCTURES

Essential parts of a national infrastructure are: legislation and regulations; a Regulatory Authority empowered to authorize and inspect regulated activities and to enforce the legislation and regulations; sufficient resources; and adequate

numbers of trained personnel. The infrastructures must also provide ways and means of addressing societal concerns which extend beyond the legal responsibilities of the legal persons authorized to conduct practices involving sources of radiation. For example, national authorities ensure that appropriate arrangements are made for detecting any buildup of radioactive substances in the general environment, for disposing of radioactive wastes and for preparing for interventions, particularly during emergencies that could result in exposure of the general public. They also need to provide for the control of sources of radiation for which no other organization has responsibility, such as natural sources and radioactive residues from past practices.

National infrastructures must provide for adequate arrangements to be made by those responsible for the education and training of specialists in radiation protection and safety, as well as for the exchange of information among specialists. A related responsibility is to set up appropriate means of informing the public, its representatives and the information media about the health and safety aspects of activities involving exposure to radiation and about regulatory processes. This provides information to facilitate the political process of setting national priorities and allocating resources for protection and safety and also helps to make the regulatory process more readily understandable.

National infrastructures must also provide facilities and services that are essential for radiation protection and safety, but are beyond the capabilities required of the legal persons who are authorized to conduct practices. Such facilities and services include those needed for intervention, personal dosimetry and environmental monitoring, and for calibration and intercomparison of radiation measuring equipment. Services could include the provision of central registries for occupational exposure records and the provision of information on equipment reliability. The provision of such services at the national level does not detract from the ultimate responsibility for radiation protection and safety borne by the legal persons authorized to conduct the practices.

THE REGULATORY AUTHORITY

Full and proper implementation of the Standards requires that a Regulatory Authority be established by the Government to regulate the introduction and conduct of any practice involving sources of radiation. Such a Regulatory Authority must be provided with sufficient powers and resources for effective regulation and should be independent of any Government departments and agencies that are responsible for the promotion and development of the practices being regulated. The Regulatory Authority must also be independent of registrants, licensees and the designers and constructors of the radiation sources used in practices. The effective separation of responsibilities between the functions of the Regulatory Authority and those of any

other party is to be made clear so that the regulators retain their independence of judgement and decision as safety authorities.

The Standards are worded on the assumption that a single Regulatory Authority is responsible for all aspects of radiation protection and safety in a country. In some countries, however, regulatory responsibility for different practices or different aspects of radiation protection and safety may be divided between different authorities. Consequently, the term Regulatory Authority is generally used in the Standards to mean the relevant Regulatory Authority for the particular source or aspect of radiation safety in question. Regardless of the division of regulatory responsibilities, the government must ensure that all aspects are covered; for example, it must ensure that a specific body is assigned responsibility for the regulatory surveillance of protection and safety measures for patients and of quality assurance measures for equipment and techniques for medical uses of radiation.

The type of regulatory system adopted in a country will depend on the size, complexity and safety implications of the regulated practices and sources, as well as on the regulatory traditions in the country. The mechanism for carrying out regulatory duties may vary, with some authorities being completely self-sufficient and others delegating some inspection, assessment or other duties to various governmental, public or private agencies. A Regulatory Authority may also be self-sufficient in specialist expertise or it may consult expert advisers and advisory committees.

The general functions of the Regulatory Authority include the following: the assessment of applications for permission to conduct practices that entail or could entail exposure to radiation; the authorization of such practices and of the sources associated with them, subject to certain specified conditions; the conduct of periodic inspections to verify compliance with the conditions; and the enforcement of any necessary actions to ensure compliance with the regulations and standards. For these purposes, mechanisms are needed for notification, registration and licensing of the sources within practices, with provision for the exclusion or exemption of sources or practices from regulatory requirements under certain conditions. Provision is also needed for the surveillance, monitoring, review, verification and inspection of sources and for ensuring that adequate plans exist for dealing with radiation accidents and carrying out emergency interventions. The effectiveness of radiation protection and safety measures for each authorized practice and the total potential impact of authorized practices need to be assessed.

The powers of the inspectors of the Regulatory Authority must be well defined and consistency of enforcement must be maintained, with provision for appeal by those responsible for sources. Directives to both inspectors and regulated legal persons must be clear. The Regulatory Authority may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents. An attitude of openness and co-operation must be fostered between regulated legal persons and inspectors, which includes facilitating access by inspectors to premises and to information.

An additional responsibility of the Regulatory Authority is to require all parties involved to develop a safety culture that includes: individual and collective commitment to safety on the part of workers, management and regulators; accountability of all individuals for protection and safety, including individuals at senior management level; and measures to encourage a questioning and learning attitude and to discourage complacency with respect to safety.

Due account needs to be taken by both the Regulatory Authority and the regulated legal persons of general experience and of new developments in radiation protection and the safety of sources.

PRINCIPAL REQUIREMENTS

1. GENERAL REQUIREMENTS

DEFINITIONS

1.1. Terms shall be interpreted as defined in the Glossary.

PURPOSE

1.2. These Standards specify the basic requirements for protection of people against exposure to ionizing radiation and for the safety of radiation sources, hereinafter termed protection and safety.

SCOPE

1.3. The Standards apply to practices, including any sources within the practices, and interventions which are:

- (a) carried out in a State that chooses to adopt the Standards or requests any of the Sponsoring Organizations to provide for the application of the Standards;
- (b) undertaken by States with the assistance of the FAO, the IAEA, the ILO, the PAHO, or the WHO, in the light of relevant national rules and regulations;
- (c) carried out by the IAEA or involve 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
- (d) carried out under any bilateral or multilateral arrangement whereby the parties request the IAEA to provide for the application of the Standards.

EXCLUSIONS

1.4. Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards is deemed to be excluded from the Standards².

² Examples are exposure from ⁴⁰K in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials.

RESPONSIBLE PARTIES

1.5. The Regulatory Authority and, in the case of intervention, the Intervening Organizations shall be responsible for the enforcement of the Standards.

1.6. The principal parties having the main responsibilities for the application of the Standards shall be:

- (a) registrants or licensees; and
- (b) employers.

1.7. Other parties shall have subsidiary responsibilities for the application of the Standards. These parties may include, as appropriate:

- (a) suppliers;
- (b) workers;
- (c) radiation protection officers;
- (d) medical practitioners;
- (e) health professionals;
- (f) qualified experts;
- (g) Ethical Review Committees; and
- (h) any other party to whom a principal party has delegated specific responsibilities.

1.8. The parties shall have the general and specific responsibilities set out in the Standards.

1.9. The general responsibilities of principal parties, within the requirements specified by the Regulatory Authority, are:

- (a) to establish protection and safety objectives in conformity with the relevant requirements of the Standards; and
- (b) to develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks associated with the practices and interventions under their responsibility and sufficient to ensure compliance with the requirements of the Standards, and, within this programme:
 - (i) to determine the measures and resources needed to achieve the protection and safety objectives and to ensure that the resources are provided and the measures properly implemented;
 - (ii) to keep such measures and resources continually under review, and regularly to verify that the protection and safety objectives are being achieved;
 - (iii) to identify any failures and shortcomings in the protection and safety measures and resources, and to take steps to correct them and prevent their recurrence;

- (iv) to establish arrangements, through representatives if appropriate, for facilitating consultation and co-operation between all relevant parties with respect to protection and safety; and
- (v) to keep appropriate records regarding the discharge of their responsibilities.

INSPECTIONS

1.10. The principal parties shall permit duly authorized representatives of the Regulatory Authority, and of the relevant Sponsoring Organizations when applicable, to inspect their protection and safety records and to carry out appropriate inspections of their authorized activities.

NON-COMPLIANCE

1.11. In the event of a breach of any applicable requirement of the Standards, principal parties shall, as appropriate:

- (a) investigate the breach and its causes, circumstances and consequences;
- (b) take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;
- (c) communicate to the Regulatory Authority, and to the relevant Sponsoring Organizations when applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and
- (d) take whatever other actions are necessary as required by the Standards.

1.12. The communication of a breach of the Standards shall be prompt and it shall be immediate whenever an emergency exposure situation has developed or is developing.

1.13. Failure to take corrective or preventive actions within a reasonable time in accordance with national regulations shall be grounds for modifying, suspending or withdrawing any authorization that had been granted by the Regulatory Authority or, when applicable, by the relevant Sponsoring Organization.

1.14. Wilful breach of, attempted breach of or conspiracy to breach any requirement of the Standards shall be subject to the provisions for such infractions by the appropriate national legislation of the State, or by the Regulatory Authority or, when applicable, by the relevant Sponsoring Organization.

ENTRY INTO FORCE

1.15. The Standards shall come into force one year after the date of their adoption or acknowledgement, as appropriate, by the relevant Sponsoring Organization.

1.16. Should a State choose to adopt the Standards, the Standards shall come into force at the time indicated in the formal adoption by that State.

1.17. If a modification to an existing practice or source is required by the Regulatory Authority or, where applicable, by the relevant Sponsoring Organization, in order to comply with some requirement of the Standards, such a requirement shall take effect within an approved period if such a period is required for the modification.

RESOLUTION OF CONFLICTS

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

1.19. In cases of conflict between the requirements of the Standards and other applicable requirements, the Regulatory Authority shall determine which requirement is to be enforced.

1.20. Nothing in the Standards shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

INTERPRETATION

1.21. Except as specifically authorized by the statutory Governing Body of a relevant Sponsoring Organization, no interpretation of the 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.

COMMUNICATIONS

1.22. The appropriate responsible party, as established by the Standards, shall report on compliance with the requirements of the Standards.

1.23. Reports on compliance and other communications on official interpretation of the Standards shall be addressed to the Regulatory Authority or the relevant Sponsoring Organizations, as appropriate.

2. REQUIREMENTS FOR PRACTICES

APPLICATION

Practices

- 2.1. The practices to which the Standards shall apply include:
- (a) the production of sources and the use of radiation or radioactive substances for medical, industrial, veterinary or agricultural purposes, or for education, training or research, including any activities related to that use which involve or could involve exposure to radiation or radioactive substances;
 - (b) the generation of nuclear power, including any activities in the nuclear fuel cycle which involve or could involve exposure to radiation or radioactive substances;
 - (c) practices involving exposure to natural sources specified by the Regulatory Authority as requiring control; and
 - (d) any other practice specified by the Regulatory Authority.

Sources

- 2.2. The sources within any practice to which the requirements for practices of the Standards shall apply include:
- (a) radioactive substances and devices that contain radioactive substances or produce radiation, including consumer products, sealed sources, unsealed sources, and radiation generators, including mobile radiography equipment;
 - (b) installations and facilities which contain radioactive substances or devices which produce radiation, including irradiation installations, mines and mills processing radioactive ores, installations processing radioactive substances, nuclear installations, and radioactive waste management facilities; and
 - (c) any other source specified by the Regulatory Authority.

2.3. The requirements of the Standards shall apply to each individual source of radiation within an installation or facility and to the complete installation or facility regarded as a source, as appropriate, according to the requirements of the Regulatory Authority.

Exposures

2.4. The exposures to which the requirements of the Standards apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or source within the practice, including both normal exposures and potential exposures.

2.5. Exposure to natural sources shall normally be considered as a chronic exposure situation and, if necessary, shall be subject to the requirements for intervention, except that³:

- (a) public exposure delivered by effluent discharges or the disposal of radioactive waste arising from a practice involving natural sources shall be subject to the requirements for practices given here, unless the exposure is excluded or the practice or the source is exempted; and
- (b) occupational exposure of workers to natural sources shall be subject to the requirements for practices given in this section if these sources lead to:
 - (i) exposure to radon required by or directly related to their work, irrespective of whether the exposure is higher or lower than the action level for remedial action relating to chronic exposure situations involving radon in workplaces⁴, unless the exposure is excluded or the practice or the source is exempted; or
 - (ii) exposure to radon incidental to their work, but the exposure is higher than the action level for remedial action relating to chronic exposure situations involving radon in workplaces⁴; unless the exposure is excluded or the practice or the source is exempted; or
 - (iii) exposure specified by the Regulatory Authority to be subject to such requirements.

2.6. The detailed requirements for occupational exposures, medical exposures, public exposures and potential exposures are specified in Appendices I, II, III and IV respectively. These shall be considered consequential requirements subsidiary to those established in this Section, unless other more desirable options for protection and safety are established by the Regulatory Authority or, where applicable, by the relevant Sponsoring Organization.

³ At the time of the endorsement of the Standards, the available quantitative recommendations of the ICRP for protection against exposure to natural sources were confined to radon. It was therefore decided that the General Obligations for practices concerning protection against natural sources will be that exposure to natural sources, which is normally a chronic exposure situation, should be subject to intervention and that the requirements for practices should be generally limited to exposure to radon, the exposure to other natural sources being expected to be dealt with by exclusion or exemption of the source or otherwise at the discretion of the Regulatory Authority.

⁴ See Schedule VI, Guidelines for Action Levels in Chronic Exposure Situations, para. VI-3.

BASIC OBLIGATIONS

General obligations

2.7. No practice shall be adopted, introduced, conducted, discontinued or ceased and no source within a practice shall, as applicable, be mined, milled, processed, designed, manufactured, constructed, assembled, acquired, imported, exported, distributed, sold, loaned, hired, received, sited, located, commissioned, possessed, used, operated, maintained, repaired, transferred, decommissioned, disassembled, transported, stored or disposed of, except in accordance with the appropriate requirements of the Standards, unless the exposure from such practice or source is excluded from the Standards or the practice or source is exempted from the requirements of the Standards, including the requirements of notification and authorization.

2.8. The application of the requirements of the Standards to any practice or any source within a practice or to any of the actions specified in para. 2.7 shall be commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures and shall also conform to any requirements specified by the Regulatory Authority or, whenever applicable, by the relevant Sponsoring Organizations. Not all the requirements are relevant for every practice or source, nor for all the actions specified in para. 2.7.

2.9. The transport of radioactive sources shall be subject to the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material⁵ and any applicable international convention.

ADMINISTRATIVE REQUIREMENTS

Notification

2.10. Any legal person intending to carry out any of the actions specified under the General Obligations for practices of the Standards (see paras 2.7 and 2.8) shall submit a notification to the Regulatory Authority of such an intention⁶. Notification for consumer products is required only with respect to manufacturing, assembling, importing and distributing.

⁵ See the most recent edition of the IAEA Regulations for the Safe Transport of Radioactive Material (published as IAEA Safety Series No. 6 (1990); 1996 edition to be issued).

⁶ Notification alone is sufficient provided that the normal exposures associated with the practice or action are unlikely to exceed a small fraction, specified by the Regulatory Authority, of the relevant limits, and that the likelihood and expected amount of potential exposure and any other detrimental consequence are negligible.

Authorization: registration or licensing

2.11. The legal person responsible for any sealed source, unsealed source or radiation generator shall, unless the source is exempted, apply to the Regulatory Authority for an authorization which shall take the form of either a registration⁷ or a licence.

2.12. The legal person responsible for any irradiation installation, mine or mill processing radioactive ores, installation processing radioactive substances, nuclear installation or radioactive waste management facility, or for any use of a source which the Regulatory Authority has not designated as suitable for registration, shall apply to the Regulatory Authority for an authorization which shall take the form of a licence.

2.13. Any legal person applying for an authorization shall:

- (a) submit to the Regulatory Authority and, if applicable, the relevant Sponsoring Organization relevant information necessary to support the application;
- (b) refrain from carrying out any of the actions described in the General Obligations for practices of the Standards (see paras 2.7 and 2.8) until the registration or licence, as appropriate, has been granted;
- (c) make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for the protection and safety of both workers and the public; and
- (d) if the potential for an exposure is greater than any level specified by the Regulatory Authority, have a safety assessment made and submitted to the Regulatory Authority as part of the application.

2.14. The legal person responsible for a source to be used for medical exposure shall include in the application for authorization:

- (a) the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or
- (b) a statement that only medical practitioners with the qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized source.

⁷ Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly.

Authorized legal persons: registrants and licensees

2.15. Registrants and licensees shall bear the responsibility for setting up and implementing the technical and organizational measures that are needed for ensuring protection and safety for the sources for which they are authorized. They may appoint other people to carry out actions and tasks related to these responsibilities, but they shall retain the responsibility for the actions and tasks themselves. Registrants and licensees shall specifically identify the individuals responsible for ensuring compliance with the Standards.

2.16. Registrants and licensees shall notify the Regulatory Authority of their intentions to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modification unless specifically authorized by the Regulatory Authority.

Exemption

2.17. Practices and sources within a practice may be exempted from the requirements of the Standards provided that such sources comply with:

- (a) the requirements on exemption specified in Schedule I, or
- (b) any exemption levels defined by the Regulatory Authority on the basis of the exemption criteria specified in Schedule I.

2.18. Exemption shall not be granted for practices deemed not to be justified.

Clearance

2.19. Sources, including substances, materials and objects, within notified or authorized practices may be released from further requirements of the Standards subject to complying with clearance levels approved by the Regulatory Authority. Such clearance levels shall take account of the exemption criteria specified in Schedule I and shall not be higher than the exemption levels specified in Schedule I or defined by the Regulatory Authority on the basis of the criteria specified in Schedule I, unless otherwise approved by the Regulatory Authority⁸.

⁸ Clearance of bulk amounts of materials with activity concentrations lower than the guidance exemption levels specified in Table I-I of Schedule I may require further consideration by the Regulatory Authority.

RADIATION PROTECTION REQUIREMENTS

Justification of practices

2.20. No practice or source within a practice should be authorized unless the practice produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause; that is: unless the practice is justified, taking into account social, economic and other relevant factors.

2.21. Detailed requirements for the justification of practices involving medical exposures are given in Appendix II.

2.22. Except for justified practices involving medical exposures, the following practices are deemed to be not justified whenever they would result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products:

- (a) practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being; and
- (b) practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments.

Dose limitation

2.23. The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, exceeds any relevant dose limit specified in Schedule II, except in special circumstances provided for in Appendix I. Dose limits shall not apply to medical exposures from authorized practices.

Optimization of protection and safety

2.24. In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimized in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the doses to individuals delivered by the source be subject to dose constraints.

2.25. The process of optimization of protection and safety measures may range from intuitive qualitative analyses to quantitative analyses using decision aiding

techniques, but shall be sufficient to take all relevant factors into account in a coherent way so as to contribute to achieving the following objectives:

- (a) to determine optimized protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and
- (b) to establish criteria, on the basis of the results of the optimization, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences.

Dose constraints

2.26. Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints which:

- (a) do not exceed either the appropriate values established or agreed to by the Regulatory Authority for such a source or values which can cause the dose limits to be exceeded; and
- (b) ensure, for any source (including radioactive waste management facilities) that can release radioactive substances to the environment, that the cumulative effects of each annual release from the source be restricted so that the effective dose in any year to any member of the public, including people distant from the source and people of future generations, is unlikely to exceed any relevant dose limit, taking into account cumulative releases and the exposures expected to be delivered by all other relevant sources and practices under control.

Guidance levels for medical exposure

2.27. Guidance levels for medical exposure shall be established for use by medical practitioners. The guidance levels are intended:

- (a) to be a reasonable indication of doses for average sized patients;
- (b) to be established by relevant professional bodies in consultation with the Regulatory Authority following the detailed requirements of Appendix II and the guidance levels given in Schedule III;
- (c) to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance;
- (d) to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement; and
- (e) to be revised as technology and techniques improve.

MANAGEMENT REQUIREMENTS

Safety culture

2.28. A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency, which shall ensure that:

- (a) policies and procedures be established that identify protection and safety as *being of the highest priority*;
- (b) problems affecting protection and safety be promptly identified and corrected in a manner commensurate with their importance;
- (c) the responsibilities of each individual, including those at senior management levels, for protection and safety be clearly identified and each individual be suitably trained and qualified;
- (d) clear lines of authority for decisions on protection and safety be defined; and
- (e) organizational arrangements and lines of communications be effected that result in an appropriate flow of information on protection and safety at and between the various levels in the organization of the registrant or licensee.

Quality assurance

2.29. Quality assurance programmes shall be established that provide, as appropriate:

- (a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and
- (b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.

Human factors

2.30. Provision shall be made for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures, by ensuring that:

- (a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures;
- (b) sound ergonomic principles be followed as appropriate in designing equipment and operating procedures, so as to facilitate the safe operation or use of equipment, to minimize the possibility that operating errors will lead to accidents, and to reduce the possibility of misinterpreting indications of normal and abnormal conditions; and

- (c) appropriate equipment, safety systems, and procedural requirements be provided and other necessary provisions be made:
- (i) to reduce, as far as practicable, the possibility that human error will lead to inadvertent or unintentional exposure of any person;
 - (ii) to provide means for detecting human errors and for correcting or compensating for them; and
 - (iii) to facilitate intervention in the event of failure of safety systems or of other protective measures.

Qualified experts

2.31. Qualified experts shall be identified and made available for providing advice on the observance of the Standards.

2.32. Registrants and licensees shall inform the Regulatory Authority of their arrangements to make available the expertise necessary to provide advice on the observance of the Standards. The information provided shall include the scope of the functions of any qualified experts identified.

TECHNICAL REQUIREMENTS

2.33. Relevant principal parties shall ensure that the protection and safety measures for practices and sources for which they have responsibilities, other than nuclear installations and radioactive waste management facilities, are governed by the interrelated technical requirements of paras 2.34–2.36. These technical requirements shall be applied when appropriate and to an extent commensurate with the magnitude and likelihood of the exposures expected from the practice or source. Nuclear installations and radioactive waste management facilities, including disposal facilities, are typically subject to more specific technical and other requirements such as those issued under the IAEA's Nuclear Safety Standards (NUSS)⁹ Programme and Radioactive Waste Safety Standards (RADWASS)¹⁰ Programme, as well as other relevant requirements of the Sponsoring Organizations. As these more specific requirements are generally consistent with the Standards, it follows that, in complying with them, such more complex installations should also generally comply with the Standards.

⁹ Publications within the IAEA's NUSS Programme, Safety Series No. 50.

¹⁰ Publications within the IAEA's RADWASS Programme, Safety Series No. 111.

Security of sources

2.34. Sources shall be kept secure so as to prevent theft or damage and to prevent any unauthorized legal person from carrying out any of the actions specified in the General Obligations for practices of the Standards (see paras 2.7–2.9), by ensuring that:

- (a) control of a source not be relinquished without compliance with all relevant requirements specified in the registration or licence and without immediate communication to the Regulatory Authority, and when applicable to the relevant Sponsoring Organization, of information regarding any decontrolled, lost, stolen or missing source;
- (b) a source not be transferred unless the receiver possesses a valid authorization; and
- (c) a periodic inventory of movable sources be conducted at appropriate intervals to confirm that they are in their assigned locations and are secure.

Defence in depth

2.35. A multilayer (defence in depth) system of provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of:

- (a) preventing accidents that may cause exposure;
- (b) mitigating the consequences of any such accident that does occur; and
- (c) restoring sources to safe conditions after any such accident.

Good engineering practice

2.36. As applicable, the siting, location, design, construction, assembly, commissioning, operation, maintenance and decommissioning of sources within practices shall be based on sound engineering which shall, as appropriate:

- (a) take account of approved codes and standards and other appropriately documented instruments;
- (b) be supported by reliable managerial and organizational features, with the aim of ensuring protection and safety throughout the life of the sources;
- (c) include sufficient safety margins for the design and construction of the sources, and for operations involving the sources, such as to ensure reliable performance during normal operation, taking into account quality, redundancy and inspectability, with emphasis on preventing accidents, mitigating their consequences and restricting any future exposures; and

- (d) take account of relevant developments in technical criteria, as well as the results of any relevant research on protection or safety and lessons from experience.

VERIFICATION OF SAFETY

Safety assessments

2.37. Safety assessments related to protection and safety measures for sources within practices shall be made at different stages, including siting, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning, as appropriate, in order:

- (a) to identify the ways in which normal exposures and potential exposures could be incurred, account being taken of the effect of events external to the sources as well as events directly involving the sources and their associated equipment;
- (b) to determine the expected magnitudes of normal exposures and, to the extent reasonable and practicable, to estimate the probabilities and the magnitudes of potential exposures; and
- (c) to assess the quality and extent of the protection and safety provisions.

Monitoring and verification of compliance

2.38. Monitoring and measurements shall be conducted of the parameters necessary for verification of compliance with the requirements of the Standards.

2.39. For the purposes of monitoring and verification of compliance, suitable equipment shall be provided and verification procedures introduced. The equipment shall be properly maintained and tested and shall be calibrated at appropriate intervals with reference to standards traceable to national or international standards.

Records

2.40. Records shall be maintained of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with the Standards.

3. REQUIREMENTS FOR INTERVENTION

APPLICATION

- 3.1. The intervention situations to which the Standards apply are:
- (a) emergency exposure situations requiring protective action to reduce or avert temporary exposures, including:
 - (i) accidents and emergencies in which an emergency plan or emergency procedures have been activated; and
 - (ii) any other temporary exposure situation identified by the Regulatory Authority or the Intervening Organization as warranting intervention; and
 - (b) chronic exposure situations requiring remedial action to reduce or avert chronic exposure, including:
 - (i) natural exposure, such as exposure to radon in buildings and workplaces;
 - (ii) exposure to radioactive residues from past events, such as to the radioactive contamination caused by accidents, after the situation requiring protective action has been terminated, as well as from the conduct of practices and the use of sources not under the system of notification, and authorization; and
 - (iii) any other chronic exposure situation specified by the Regulatory Authority or the Intervening Organization as warranting intervention.
- 3.2. The detailed requirements relating to emergency exposure situations and chronic exposure situations are set out in Appendices V and VI respectively. These shall be considered as consequential requirements subsidiary to those specified in this Section, unless other more desirable options for protection and safety are established by the Regulatory Authority or, where applicable, by a relevant Sponsoring Organization.

BASIC OBLIGATIONS

- 3.3. In order to reduce or avert exposures in intervention situations, protective actions or remedial actions shall be undertaken whenever they are justified.
- 3.4. The form, scale, and duration of any such protective action or remedial action shall be optimized so as to produce the maximum net benefit, understood in a broad sense, under the prevailing social and economic circumstances.

3.5. In the case of emergency exposure situations, protective actions are not normally likely to be necessary unless intervention levels or action levels¹¹ are or may be exceeded.

3.6. In the case of chronic exposure situations, remedial actions are not normally likely to be necessary unless the relevant action levels¹¹ are exceeded.

ADMINISTRATIVE REQUIREMENTS

Responsibilities

3.7. For occupational exposures incurred by workers undertaking intervention, the responsibilities set forth in Appendix V shall be discharged by the registrant or licensee, the employer and the Intervening Organizations, as required by the Regulatory Authority.

3.8. For public exposure in intervention situations, responsibilities identified and assigned by the government for the various organizational arrangements and functions necessary for ensuring effective intervention shall be discharged:

- (a) by the appropriate national, regional or local Intervening Organizations; and,
- (b) if a practice or source that is registered or licensed is involved, by the registrant or licensee.

3.9. Each registrant or licensee responsible for sources for which prompt intervention may be required shall ensure that an emergency plan exists that defines on-site responsibilities and takes account of off-site responsibilities appropriate for the source and provides for implementation of each relevant form of protective action, as set out in Appendix V.

3.10. The relevant Intervening Organizations shall prepare a general plan or plans for co-ordinating and implementing the actions required for supporting protective actions under the emergency plans of registrants and licensees, as well as for other situations that may require prompt intervention. This includes situations involving such sources of exposure as sources illegally brought into the country, falling satellites equipped with sources or radioactive materials released in accidents beyond national borders.

¹¹ Intervention levels and action levels serve to protect members of the public and are specified separately for different protective actions and remedial actions. Optimized levels for justified interventions are normally selected for inclusion in emergency plans and remedial action plans, and, in the case of accidents, are re-evaluated at the time of their implementation on the basis of current conditions.

3.11. For chronic exposure situations in which the relevant action levels for remedial actions are or may be exceeded, the relevant Intervening Organizations shall ensure that generic or site specific remedial action plans, as necessary, are developed. When remedial action is to be undertaken, the legal person responsible for carrying out the remedial action shall ensure that it is in accordance with the generic remedial action plan or that specific remedial action plans are developed, approved and implemented.

Notification requirements

3.12. Registrants and licensees shall notify the Regulatory Authority and the relevant Intervening Organizations promptly when a situation requiring protective action has arisen or is expected to arise, and shall keep them informed of:

- (a) the situation as it develops and how it is expected to develop;
- (b) the measures taken for the protection of workers and members of the public; and
- (c) the exposures that have been incurred and that are expected to be incurred.

RADIATION PROTECTION REQUIREMENTS

3.13. Intervention is justified only if it is expected to achieve more good than harm, with due regard to health, social and economic factors. If the dose levels approach or are expected to approach the levels specified in Schedule IV, protective actions or remedial actions will be justified under almost any circumstances.

3.14. Optimized intervention levels and action levels shall be specified in plans for intervention situations, on the basis of the guidelines given in Schedules V and VI, modified to take account of local and national conditions, such as:

- (a) the individual and collective exposures to be averted by the intervention; and
- (b) the radiological and non-radiological health risks and the financial and social costs and benefits associated with the intervention.

3.15. During the response to an accident, justification of intervention and optimization of pre-established intervention levels shall be reconsidered, with account taken of:

- (a) those factors which are unique to the actual situation, such as the nature of the release, weather conditions and other relevant non-radiological factors; and
- (b) the likelihood that the protective actions will provide a net benefit, given that future conditions may be uncertain.