SAFETY SERIES No. 120

SAFETY FUNDAMENTALS

safety series

Radiation Protection and the Safety of Radiation Sources

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INTERNATIONAL ATOMIC ENERGY AGENCY, VIENNA, 1996

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RADIATION PROTECTION AND THE SAFETY OF RADIATION SOURCES

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Printed by the IAEA in Austria
January 1996

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RADIATION PROTECTION AND THE SAFETY OF RADIATION SOURCES

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

THIS SAFETY SERIES PUBLICATION IS ALSO ISSUED IN FRENCH, RUSSIAN AND SPANISH

VIC Library Cataloguing in Publication Data

Radiation protection and the safety of radiation sources. — Vienna : International Atomic Energy Agency, 1996.
p. ; 24 cm. — (Safety series, ISSN 0074-1892 ; 120)
STI/PUB/1000
ISBN 92-0-105295-2
Includes bibliographical references.

1. Radiation—Safety measures. I. International Atomic Energy Agency. II. Series.

VICL 95-00137

FOREWORD

The discipline of radiation protection embodies a coherent set of objectives and principles. These, together with corresponding principles to ensure safety in the use of radiation sources, are set out in this publication, which reflects an international consensus on the subject.

The totality of measures taken to ensure protection against exposure to radiation and the safety of radiation sources is both detailed and technically complex. This publication explains the fundamental basis for those approaches to protection and safety over a broad range of applications. It also provides an insight concerning protection and safety for those at senior levels in government and regulatory bodies and those who, while responsible for making decisions relating to the uses of radiation in medicine, industry, agriculture and other areas, may not be specialists in protection and safety matters.

This Safety Fundamentals publication is a primary publication in the IAEA Safety Series and provides the basis for the requirements in Safety Standards for the control of occupational, public and medical exposures and for the safety of radiation sources. Safety Guides and Safety Practices provide guidance and information on how to implement the requirements.

These Safety Fundamentals 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).

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. This Safety Fundamentals publication presents the principles of protection and safety[1] and explains the rationale for the application of radiation safety standards in a broad range of situations in which measures for protection and safety often differ in detail.

1.2. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), which compiles, assesses and disseminates information on the health effects of radiation and on levels of radiation exposure due to different sources, provided the scientific information on which these Fundamentals are based. The Fundamentals also draw upon information derived from extensive research and development by scientific and engineering organizations at the national and international levels, as well as upon experience in many countries in the use of radiation and nuclear techniques. The objectives and principles presented here are based upon the recommendations of the International Commission on Radiological Protection (ICRP), developed over a period of more than 60 years, in the area of radiation protection and upon an international consensus derived from experience gained in relation to the safety of radiation sources.

1.3. Protection and safety is relevant to all activities that involve or could involve radiation exposure. However, additional aspects relevant to the safety of nuclear installations and to the safe management of radioactive waste are discussed specifically in two previous Safety Fundamentals publications[2].

1.4. On the basis of the principles and objectives defined in the Fundamentals, requirements are established in the International Basic Safety Standards for Protection against

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[1] Protection and safety is defined as "The protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping people's doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur."

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, The Safety of Nuclear Installations, Safety Series No. 110, IAEA, Vienna (1993); INTERNATIONAL ATOMIC ENERGY AGENCY, The Principles of Radioactive Waste Management, Safety Series No. 111-F, IAEA, Vienna (1995).

Ionizing Radiation and for the Safety of Radiation Sources (BSS)[3], the Regulations for the Safe Transport of Radioactive Material[4] and other IAEA Safety Standards. IAEA Safety Guides and Practices as well as publications of other international organizations provide guidance and information on how to implement the requirements.

OBJECTIVE

1.5. The purpose of this Safety Fundamentals publication is to define principles whose effective application will ensure appropriate protection and safety in any situation which involves or might involve exposure to radiation. It is intended to be used, as appropriate, by the Sponsoring Organizations in their international assistance operations and by national authorities and national organizations in their programmes. Moreover, it also provides a concise statement of the principles of protection and safety for decision makers in technical and policy matters.

SCOPE

1.6. These Safety Fundamentals cover the protection of human beings against ionizing radiation (gamma and X rays and alpha, beta and other particles that can induce ionization as they interact with biological materials), referred to herein subsequently as radiation, and the safety of sources that produce ionizing radiation. The Fundamentals do not apply to non-ionizing radiation such as microwave, ultraviolet, visible and infrared radiation. They do not apply either to the control of non-radiological aspects of health and safety. They are, however, part of the overall framework of health and safety.

1.7. The activities to which protection and safety provisions apply are defined as 'practices' or 'interventions'. A practice involves the introduction of a new source of exposure or a new exposure pathway, resulting in an increase in exposure or the likelihood of exposure, or in the number of persons exposed. Practices are those human activities involving radiation exposure, or the potential for exposure, for which radiation

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

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990), Safety Series No. 6, IAEA, Vienna (1990).

safety provisions can be planned in advance. They include the use of radiation or radioactive substances, both natural and man-made, in medicine, research, industry, agriculture, veterinary practice and teaching; the generation of electricity by nuclear power, including all related fuel cycle activities, from the mining of radioactive ores to the operation of nuclear reactors and other installations; the management of radioactive wastes; and activities such as the underground mining of coal and of phosphatic and other minerals that may increase exposure to naturally occurring radioactive substances. Practices also include the related transport of radioactive materials.

1.8. A source is broadly defined as anything that may cause radiation exposure. The definition includes radioactive substances and devices that contain radioactive substances or produce radiation. It also includes installations and facilities that contain radioactive substances or devices that produce radiation, including irradiation installations, mines and mills processing radioactive ores, installations processing radioactive substances, nuclear installations and radioactive waste management facilities. These Fundamentals apply to each individual source of radiation within an installation or to the installation as a whole considered as a source. For the purposes of the Fundamentals, these sources and installations are all referred to as sources.

1.9. Interventions are those human activities that seek to reduce or avert radiation exposures, or reduce the likelihood of incurring exposure, in situations in which the sources are not part of a currently controlled practice or are out of control as a consequence of an accident. Intervention actions may be prepared in advance and incorporated into an emergency plan. In addition to actions in relation to the radiological consequences of an accident or to chronic exposure due to natural sources of radiation, the term intervention is also used for actions in relation to residual contamination from previous events or situations. In all these situations, the circumstances giving rise to exposure, or to the likelihood of exposure, already exist and its reduction can only be achieved by means of remedial or protective actions. These may include actions for eliminating the causes of the exposure, modifying existing exposure pathways, or changing people's habits and circumstances so as to reduce their exposure or likelihood of exposure. In these existing situations the focus of decisions on protection and safety is on the features and the degree of intervention.

1.10. The system of protection described in these Fundamentals is intended to be as general as possible so as to achieve consistency of approach in different circumstances. However, exposures resulting from practices and exposures that require interventions are amenable to control to different extents, which necessitates different approaches to the management of protection and safety.

1.11. It is virtually certain that some exposures will result from practices and that their magnitudes will be broadly predictable: such expected exposures are referred to as

normal (i.e. actual) exposures. However, exposure scenarios can also be foreseen for which there is a potential for exposure, but no certainty that it will occur. Such unexpected but plausible exposures are termed potential exposures. Other distinctions relate to the circumstances under which the exposure occurs, hence: occupational exposure, medical exposure and public exposure.

1.12. These Fundamentals cover all people who may be exposed to radiation, including those in future generations who could be affected by present practices or interventions.

1.13. In some cases the exposure is essentially not amenable to control and is therefore excluded from these Fundamentals. Examples of excluded exposures are exposure to certain natural sources such as cosmic rays at ground level or to radionuclides that are natural constituents of the body.

STRUCTURE

1.14. Section 2 describes the biological effects of radiation as the scientific basis for various objectives and principles; Section 3 sets forth the objectives and Sections 4 and 5 set out the principles in accordance with which the objectives are to be achieved for the two broad areas of application — practices and interventions; Section 6 supplements these basic principles with the major implementation principles; and Section 7 outlines those aspects of infrastructure that are common and needed for the application of principles in both areas.

2. BIOLOGICAL EFFECTS OF IRRADIATION

2.1. The process of ionization induced by irradiation changes atoms and molecules, at least transiently, and may thus damage cells. If cellular damage does occur and is not adequately repaired, it may prevent the cell from surviving or reproducing or may result in a viable but modified cell. The two outcomes have profoundly different implications for the organism as a whole. Most organs and tissues of the body are unaffected by the loss of even a substantial number of cells but, if the number lost is large enough, there will be observable harm to the individual, namely tissue damage and a consequent loss of tissue function. The likelihood of such harm being caused will be zero at low doses but, above some level of threshold dose, the damage will occur almost with certainty. Above the threshold, the severity of the harm increases

with the dose. This type of outcome, which includes acute radiation syndromes such as burns, is called 'deterministic' because harm is almost bound to occur in an exposed individual if the dose exceeds the threshold dose. This threshold dose is substantially higher than the doses expected from practices and sources in normal operation. Only a severe accident with a source having the potential for delivering high doses can cause deterministic effects.

2.2. There is a major difference if the irradiated cell is modified rather than killed. Despite the existence of highly effective defence mechanisms, the cloning of cells resulting from the reproduction of a modified but viable cell may, after a prolonged and varying delay called the latency period, result in the manifestation of a cancer. This induction of a cancer is assumed to take place over the entire range of doses without a threshold and the probability of induction is taken to be proportional to the dose received. The probability of occurrence of a cancer is therefore higher for higher doses, but the severity of any cancer is independent of the dose from which it results. Such effects are called 'stochastic'.

2.3. If damage due to irradiation occurs in a cell whose function is to transmit genetic information to later generations, it is presumed that some harm, which may be of many different kinds and degrees of severity, might be expressed in the descendants of the exposed person. The damage might be too severe for a descendant to be viable, however. This type of stochastic outcome is known as a 'hereditary' effect. The probability of hereditary harm is taken to be proportional to the dose received. In addition, irradiation in utero may lead to effects in children, notably an increase in the stochastic risk of childhood leukaemia and tumours. Irradiation in early to mid-pregnancy might also result in deterministic effects in the foetus and the newborn child. The effects include malformations and brain damage which may lead to a greater likelihood of mental retardation. Doses above the thresholds for these effects are not encountered in normal practices; however, they may result from serious accidents and from irradiation of the foetus in radiotherapy.

2.4. The likelihood of stochastic outcomes due to normal levels of exposure is very small. For average exposure to natural background radiation, this probability is estimated to be of the order of one in 10 000 per year, and for average exposures in the population from many current practices it is orders of magnitude lower. It is difficult to determine whether cancers observed in an irradiated population are related to the exposure or arose 'naturally' or 'from other causes'. Indeed, stochastic effects are detectable only by epidemiological studies having sufficient statistical power, and usually this would require a large population exposed to high levels of radiation. Even in this case, the result would be a small increase in the incidence of those cancers over the incidence of the same cancers in a similar non-irradiated population. Stochastic outcomes cannot be assigned individually, with a causal relation, to the individual's

exposure. This means that they can only be attributed probabilistically in a population group. The epidemiological data therefore need considerable interpretation, and not all studies yield reliable information, particularly if doses are small. This is because cancer and hereditary disorders are common in human populations.

3. OBJECTIVES OF PROTECTION AND SAFETY

3.1. The primary aim of protection and safety is to provide an appropriate standard of protection and safety for humans without unduly limiting the benefits of practices giving rise to exposure or incurring disproportionate costs in interventions.

3.2. This primary aim is expressed by the following specific protection and safety objectives:

> ***Protection objective:*** *to prevent the occurrence of deterministic effects in individuals by keeping doses below the relevant threshold and to ensure that all reasonable steps are taken to reduce the occurrence of stochastic effects in the population at present and in the future.*
>
> ***Safety objective:*** *to protect individuals, society and the environment from harm by establishing and maintaining effective defences against radiological hazards from sources.*

3.3. These objectives are achieved by the application of the principles set out in the following sections.

4. PRINCIPLES FOR PRACTICES

4.1. To achieve the objectives specified in Section 3 as they relate to practices, a system of protection founded on basic principles is needed. The conceptual framework developed by the ICRP and used here includes justification of practices, optimization of protection, dose limitation and safety of sources. The dose limitation principle does not apply to medical exposures.

JUSTIFICATION OF PRACTICES

4.2. A practice shall be justified on the grounds that it produce sufficient benefit to the exposed individual(s) and to society to outweigh the radiation detriment that it

may cause. The likelihood and magnitude of exposures expected from a practice shall be explicitly taken into account in the justification process. The justification of a practice, however, usually goes beyond the scope of protection and safety because the radiation detriment is often just one of many considerations. Decisions on justification are largely influenced by broader political, economic and social concerns.

4.3. Some practices are not justified in terms of radiation protection because they result in frivolous exposure. Examples of such practices are the incorporation of radioactive substances into foods, cosmetics and toys.

4.4. Some activities, such as the disposal of radioactive wastes and the transport of radioactive materials, are consequences or parts of practices that need to be justified in their entirety with these activities taken into account.

4.5. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits they are expected to produce against the radiation detriment they might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.

Principle 1: Justification of practices

A practice shall be justified on the grounds that it produces sufficient benefit to the exposed individual(s) and to society to offset the radiation detriment that it may cause.

LIMITATION OF DOSES AND RISKS

4.6. Even if a practice is justified, restrictions are required on the dose that individuals may incur or on their likelihood of exposure (potential exposure) in order to ensure that no person be subject to an unacceptable risk attributable to radiation from all relevant sources. These limitations do not apply to medical exposure since such exposure, if administered on the basis of proper indications, is intended to lead to a net benefit to the patient or has been accepted voluntarily.

4.7. Dose limits do not apply directly to potential exposures. Ideally, dose limits would be supplemented by risk limits, which take account of both the probability of incurring a dose and the detriment associated with that dose if it were to be received. However, risk limits differ from dose limits in that the probability of occurrence and the magnitude of the potential exposure cannot be determined: they can only be estimated from an assessment of scenarios of the future.

4.8. Because the same individual may be exposed to more than one source, the dose limit applies to the total dose from exposure to all sources. Moreover, for sources that

release to the environment radionuclides with long half-lives, limitation of dose applies to people regardless of where they are or when in the future their exposure will occur. In order to fulfil an ethical obligation to protect future generations, the buildup of doses due to releases caused by the continuation of current practices shall be limited to a level judged to be acceptable for the current generation.

Principle 2: Dose limits

For justified practices, other than those involving medical exposures, restrictions on the dose that an individual may incur (dose limits) shall be imposed to ensure that no person be subject to an unacceptable risk attributable to radiation exposure.

OPTIMIZATION OF PROTECTION

4.9. In relation to exposures from any particular source within a practice, except for medical exposures in radiodiagnosis and radiotherapy, 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, with the restriction that the doses delivered to individuals by the source be subject to dose constraints.

4.10. Since radiodiagnosis and radiotherapy necessitate medical exposure of patients, optimization objectives shall be adapted for the protection of patients. Doses shall be optimized consistent with obtaining the desired result from the examination or treatment, and the risk of errors in the delivery of such doses shall be maintained as low as reasonably achievable.

4.11. A dose constraint is the value of an individual dose not to be exceeded in the individual dose distribution considered in the optimization process. It is a source related quantity, i.e. it refers to the source, practice or task to which the optimization process is applied. As a ceiling on the individual dose, the constraint is used to restrict the inequity of the distribution of benefits and detriments amongst the population that could result from economic and social judgements. The value of the dose constraint shall not exceed an appropriate fraction of the relevant dose limit, to take account of the fact that individuals may also accumulate doses from other sources.

4.12. Dose constraints are not limits. They are used purely prospectively in the planning of protection. For occupational exposure, they may be applied to the dose to a worker from a specified task or operation or from an entire job. For public exposure, dose constraints may be applied to the members of a critical group summed over all exposure pathways arising from the current and future operations of a controlled facil-

ity. For diagnostic medical exposures of patients, guidance levels rather than dose constraints shall be established to better ensure protection consistent with obtaining the desired medical information. However, constraints shall be applied to certain medical exposures, such as in medical research or the non-occupational exposure of individuals who provide aid or comfort to patients undergoing radiodiagnosis or radiotherapy.

Principle 3: Optimization of protection

For exposures from any source, except for therapeutic medical exposure, the doses, the number of people exposed and the likelihood of incurring exposures shall all be kept as low as reasonably achievable.

SAFETY OF SOURCES

4.13. Measures shall be taken to reduce the probability of abnormal operating situations or events that could lead to unintended exposures, and in addition to mitigate the consequences of any such situations or events should they nonetheless occur. These measures for prevention and mitigation may be identical in some cases to those providing protection during normal operations, but in other cases different or additional measures may be needed.

4.14. Approaches to the prevention and mitigation of accidents have been highly developed in the area of nuclear power. The elaboration of these principles for the safety of nuclear installations is discussed specifically in a Safety Fundamentals publication on the safety of nuclear installations (see footnote 2 on p. 1). However, similar approaches have been taken to varying degrees for all types of sources. Typically, these approaches have included consideration of the location of the source, its design and its construction to ensure the integrity of the source, and operational procedures and standards to ensure that abnormal situations will not arise.

Principle 4: Safety of sources

All reasonably practicable measures shall be taken to enhance operational safety, to prevent radiation accidents and to mitigate their consequences should they occur.

5. PRINCIPLES FOR INTERVENTION

5.1. As is the case with practices, to achieve the objectives set out in Section 3 as they relate to intervention, a system of protection founded on basic principles is needed. Intervention may be necessary to deal with the radiological consequences of an

accident, with the chronic exposure from natural sources of radiation and with residual contamination from previous events or situations. The conceptual framework formulated by the ICRP is used here.

JUSTIFICATION OF INTERVENTION

5.2. The protective actions forming a programme of intervention, which always have some economic and social costs, shall be justified in the sense that they do more good than harm. In some situations, mainly those resulting from an emergency, intervention cannot be applied at the source but has to be applied in the environment in a manner which can give rise to non-radiological risks or serious social impacts. The dose limits recommended for the control of doses from practices cannot be used as a basis for deciding on the reduction of doses by intervention since they might invoke measures with economic and social costs that could be out of all proportion to the reduction obtained in the radiation detriment. This would conflict with the principle of justification.

5.3. There will, however, be some level of dose, approaching the levels at which serious deterministic effects may be induced, for which the principle of justification will imply that some kind of intervention will almost certainly be required.

Principle 5: Justification of intervention

Any proposed intervention shall do more good than harm.

OPTIMIZATION OF PROTECTIVE ACTIONS IN INTERVENTION

5.4. While the basis for intervention is justification, the form, scale and duration of an intervention shall be optimized so that the benefit of the reduction in dose is balanced against the harm and the financial and social costs associated with the intervention in such a way that the net benefit is maximized (optimization of intervention). The practical application of optimization of intervention is influenced by subjective considerations, including how to measure costs and benefits, who is to receive the benefit and who is to bear the costs. Any decision about the withdrawal of a protective action shall be part of the process of optimization.

5.5. In implementing programmes for intervention or emergency plans, pre-established intervention or action levels should be used. These may be derived from the optimization process or from generic international or national guidance. They should be applied flexibly; they may be modified to take account of local and specific conditions and should be reconsidered during the intervention, with account also

taken of factors and experience unique to the actual situation, and uncertainties in future conditions.

Principle 6: Optimization of intervention

The form, scale and duration of any intervention shall be optimized so that the net benefit is maximized.

6. IMPLEMENTATION PRINCIPLES

6.1. The following implementation principles are linked to the principles for protection and safety stated in Sections 4 and 5. They specify what must be accomplished technically for the safe design, construction and use of sources. Protection and safety are ensured by a combination of design features and operational procedures and conditions. The relative importance of design and of operation depends on the type of source. Consideration shall first be given to ensuring protection and safety through design features, but these shall be complemented by operational procedures and conditions to ensure the required level of protection and safety.

LOCATION OF SOURCES

6.2. In choosing the location of any source within a facility, account shall be taken of factors that could affect levels of exposure and the safety of the source as well as the likelihood of potential exposures.

6.3. The location of a source having the potential to give rise to a major release of radioactive substances, and the location of the facility housing it, shall be evaluated. In this evaluation, account shall be taken of the effects the source may have on the surrounding population and the uses of environmental features. Moreover, man-made and natural factors that could adversely affect the safety of such a source shall also be taken into account. The density and distribution of the local population shall be evaluated periodically over the lifetime of the source to ensure the continued feasibility and applicability of emergency plans.

Principle 7: Location of sources

In locating a source, account shall be taken of those factors which affect the exposure, or potential exposure, of individuals and populations.

DESIGN AND CONSTRUCTION OF SOURCES

6.4. The design and construction of a source and the associated facilities and equipment shall provide for reliable, stable and easily manageable operation of the source.

This shall ensure, as far as reasonably achievable, the control of radiation exposures, of radioactive releases and of the generation of radioactive wastes for all anticipated operational states, and control at the end of the useful life of the source. The design and construction shall also ensure, to the extent possible, the prevention of accidents that could affect site personnel, patients, the public and the environment, as well as mitigate the consequences of accidents if they do occur.

6.5. Despite the precautions taken, engineered systems may still fail, and it is therefore a basic design concept to provide backup safety features. If this is not practicable or appropriate, compensating operational procedures are needed. This shall create a combination of engineered design features and operating procedures based on defence in depth to prevent accidents and mitigate their consequences.

6.6. Human interactions with equipment (human factors) are extremely important. Design and construction need to take account of human capabilities and performance and the capability of the source to tolerate and withstand human errors.

6.7. An appropriate radiation safety analysis of the behaviour of the source under a range of anticipated conditions is necessary. It shall be consistent with the safety significance and shall include an assessment of a wide range of events to ensure that accidents, including those of low probability, can be effectively dealt with and their consequences mitigated by means of installed radiation safety systems, sound procedures and accident management. Operational experience, where available, shall be analysed to provide indications for improving design features.

Principle 8: Design and construction of sources

The design and construction shall be such that a source is suited for reliable, stable and easily manageable operation that ensures protection and safety with a high level of confidence. For this purpose, consideration shall be given to defence in depth, human factors, system testing and feedback of operational experience.

OPERATION AND MAINTENANCE OF SOURCES

6.8. The operation of sources and associated facilities and equipment shall be controlled in accordance with a set of operational procedures and conditions, derived from a radiation safety analysis, that cover the safety of the source, the protection of individuals (including patients undergoing radiodiagnosis or radiotherapy) and of populations, and the generation of wastes. These procedures and conditions should be revised as necessary in the light of experience. Minimum requirements should be set for the availability of adequately trained staff and appropriate equipment.

6.9. The source and associated facilities and equipment shall be regularly inspected, tested and maintained in accordance with approved procedures and quality assurance programmes to ensure that components, structures and systems continue to be available and to operate as intended. Modifications to the source and associated equipment shall be conditional on the results of an assessment of their safety implications. Operating procedures shall provide staff with instructions for the conduct of normal operations and for managing foreseeable and reasonably plausible accidents. Lessons learned from operating experience should be considered in order to determine whether equipment, procedures and/or training or related safety requirements need to be modified.

6.10. A system of source security comprising measures to prevent loss, theft, damage or unauthorized use of sources is an important aspect of safety. An inventory of sources shall be maintained and periodic checks conducted to confirm that they are in their assigned locations and are secure. This procedure is especially important for multiple individual sources or particularly hazardous sources.

Principles 9: Operation and use of sources

The operation and use of sources shall be based upon procedures and conditions that ensure the safety and security of the source and the optimization of radiation protection and that take into account the lessons learned from operational experience.

7. INFRASTRUCTURE FOR PROTECTION AND SAFETY

7.1. Infrastructure is the term used for the basic organization and management needed to discharge functions related to protection and safety. It includes a legal framework, a Regulatory Authority, supporting governmental services and employers, registrants and licensees, as well as others bearing responsibility for safety.

LEGAL FRAMEWORK

7.2. A legal framework needs to be established that provides for the regulation of practices and interventions and for the clear assignment of responsibilities for protection and safety. The government is responsible for the adoption of a legal framework which allocates responsibilities for protection and safety and establishes a Regulatory Authority responsible for the regulatory control of practices and interventions and for the enforcement of the regulations. The framework shall provide for a clear separation of the Regulatory Authority from organizations that conduct or promote activities involving radiation exposure.

7.3. Because of the nature of situations of emergency exposure and chronic exposure that require intervention, governmental organizations of several kinds and at different levels are likely to be involved in the intervention. Responsibilities shall be clearly allocated, including those for co-ordination of the intervention measures.

Principle 10: Legal framework

The government shall establish a legal framework for the regulation of practices and interventions, with a clear allocation of responsibilities, including those of a Regulatory Authority.

RESPONSIBILITIES WITHIN THE LEGAL FRAMEWORK

7.4. The Regulatory Authority is responsible for ensuring regulatory control over practices and for contributing to timely and appropriate intervention consistent with national policies and objectives for protection and safety.

7.5. For practices, the Regulatory Authority shall establish a programme of control for sources through notification, registration and/or licensing; conduct an inspection programme to assess protection and safety; and take enforcement action in the event of non-compliance with requirements.

7.6. The principal parties having responsibility to provide for protection and safety, under the control regime established by the Regulatory Authority, are registrants, licensees and employers. Medical practitioners are assigned the primary task and obligation of ensuring the protection and safety of patients in the prescription of, and during the delivery of, medical exposure. Other persons, such as designers, manufacturers and suppliers, may have professional and legal responsibilities that are significant for protection and safety.

7.7. In the organization of a registrant or a licensee, it is the management's responsibility to recognize the significance for protection and safety of its activities, and to promote a radiation safety culture aimed at developing and maintaining an attitude of rigour and thoroughness towards safety that permeates the entire organization. This approach shall include the participation of workers and their representatives, as appropriate. Management shall ensure that lines of authority and communication are clear and responsibilities are well defined; and that safety policies, requirements and procedures are well established, understood and observed. An important aspect of this effort is the establishment of programmes for verification and quality assurance.

7.8. Protection and safety shall be organized in such a way that non-radiological safety is not compromised.

7.9. Registrants, licensees, employers and governmental organizations, as well as other intervening organizations, need to make preparations for accident situations that are commensurate with the risk. In particular, the registrant or licensee shall prepare accident management procedures and on-site emergency plans before the commencement of operation of any source having the potential for significant uncontrolled releases of radioactive substances to the environment. When the magnitude of the source requires it, off-site emergency procedures shall be prepared, with the participation of the registrants, licensees or employers and competent authorities, including the intervening organizations, and in compliance with national regulations and international agreements.

Principle 11: Responsibilities within the legal framework

Parties responsible within the legal framework shall, as appropriate, provide for protection and safety, verify its effectiveness and prepare adequate emergency plans.

DEFINITIONS

Action level

The level of dose rate or activity concentration above which remedial actions or protective actions should be carried out in chronic exposure or emergency exposure situations.

Critical group

A group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathway and is typical of individuals receiving the highest effective dose or equivalent dose (as applicable) by the given exposure pathway from the given source.

Defence in depth

The application of more than a single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fails.

Deterministic effect

A radiation effect for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose.

Detriment

The total harm that would eventually be experienced by an exposed group and its descendants as a result of the group's exposure to radiation from a source.

Dose

A measure of the radiation received or 'absorbed' by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. The modifying terms are often omitted when they are not necessary for defining the quantity of interest.

Dose constraint

A prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the

source. For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The exposure to which the dose constraint applies is the annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the controlled source. The dose constraint for each source is intended to ensure that the sum of doses to the critical group from all controlled sources remains within the dose limit. For medical exposure the dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

Dose limit

The value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.

Employer

A legal person with recognized responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both an employer and a worker.)

Excluded

Outside the scope of the Standards.

Guidance level for medical exposure

A value of dose, dose rate or activity selected by professional bodies in consultation with the Regulatory Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgement.

Intervention

Any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

Ionizing radiation

For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s).

Licence

An authorization granted by the Regulatory Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.

Licensee

The holder of a current licence granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection and safety.

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

Medical practitioner

An individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is a registrant or licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure.

Natural sources

Naturally occurring sources of radiation, including cosmic radiation and terrestrial sources of radiation.

Normal exposure

An exposure which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control.

Occupational exposure

All exposures of workers incurred in the course of their work, with the exception of exposures excluded from the Standards and exposures from practices or sources exempted by the Standards.

Potential exposure

Exposure that is not expected with certainty to be delivered but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Practice

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

Protection and safety

The protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping people's doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur.

Public exposure

Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.

Radiation generator

Device capable of generating radiation, such as X rays, neutrons, electrons or other charged particles, which may be used for scientific, industrial or medical purposes.

Registrant

An applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety.

Regulatory Authority

An authority or authorities designated or otherwise recognized by a government for regulatory purposes in connection with protection and safety.

Risk

A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

Sealed source

Radioactive material that is (a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leaktightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps.

Source

Anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment, a sterilization gamma irradiation unit is a source for the practice of radiation preservation of food, an X ray unit may be a source for the practice of radiodiagnosis, and a nuclear power plant is a source for the practice of generating electricity by nuclear power. A complex or multiple installation situated at one location or site may, as appropriate, be considered a single source for the purposes of application of the Standards.

Sponsoring Organizations

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).

Stochastic effects of radiation

Radiation effects, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose.

Unsealed source

A source that does not meet the definition of a sealed source.

Worker

Any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker.)

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Consultants Meeting

Vienna: 15–18 November 1993

Technical Committee Meeting Sub-group

Vienna: 13–17 December 1993

Advisory Group Meetings

Vienna: 14–16 March 1994, 23–27 January 1995

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No. 3, July 1996

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SPAIN	Díaz de Santos, Lagasca 95, E-28006 Madrid Díaz de Santos, Balmes 417, E-08022 Barcelona
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ISBN 92-0-105295-2
ISSN 0074-1892