## **FOREWORD**

by the Directors General of the Sponsoring Organizations

[To be prepared after approval]

#### **PREFACE**

The basic requirements for protection against exposure to ionizing radiation and radioactive materials and for the safety of radiation sources are presented in these Basic Safety Standards: International Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (hereinafter called the Standards). The Standards are a joint publication of the Food and Agricultural 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), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), hereinafter referred to as the Sponsoring Organizations (see the List of Sponsoring Organizations, Participants, Consultants and Contributors included at the end). The Standards are intended for the use of the Sponsoring Organizations; however, they are also recommended for use by Member States, regulatory authorities and radiation protection specialists in formulating national or institutional radiation protection regulations.

There have been continuing efforts over the last several decades to harmonize radiation health and safety standards internationally. The Board of Governors of the LAEA first approved radiation health and safety measures in March 1960<sup>1</sup>, 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 approved the first version of the Basic Safety Standards for Radiation Protection in June 1962<sup>2</sup>, and approved a revised version in 1965.<sup>3</sup> The last revision of the Standards was published as LAEA Safety Series No. 9 (1982 Edition) on behalf of the sponsoring organizations.<sup>4</sup> The philosophy underlying each edition of the Standards has been that of the latest Recommendations of the ICRP. The ICRP issued new Recommendations in 1991<sup>3</sup>.

An Inter-Agency Committee on Radiation Safety (IACRS) was constituted in 1990 as a forum for consultation and collaboration in radiation safety matters between international organizations. The IACRS consists of the Commission of the European Communities (CEC), (formerly) the Council for Mutual Economic Assistance (CMEA), the FAO, the IAEA, the ILO, the OECD/NEA, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the WHO. These organizations were subsequently joined by the PAHO. The ICRP, the International Commission on Radiological Units and Measurements (ICRU), the International Electrotechnical Commission (IEC), the International Radiation Protection Association (IRPA) and the International Standards Organization (ISO) have observer status in the IACRS. The objective

International Atomic Energy Agency, The Agency's Health and Safety Measures, IAEA/INFCIRC/18, Vienna (1960), The Agency's Safety Standards and Measures, IAEA/INFCIRC/18/Rev.1, Vienna (1976).

International Atomic Energy Agency, Basic Safety Standards for Radiation Protection, Safety Series No. 9, IAEA, Vienna (1962).

International Atomic Energy Agency, Basic Safety Standards for Radiation Protection, 1967 Edition, Safety Series No. 9, IAEA, Vienna (1967).

International Atomic Energy Agency, Basic Safety Standards for Radiation Protection, 1982 Edition, jointly sponsored by IAEA, ILO, NEA/OECD and WHO. Safety Series 9, IAEA, Vienna (1982).

<sup>&</sup>lt;sup>5</sup> INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, Publication 60, Pergamon Press, Oxford and New York (1991).

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

of the IACRS is to promote consistency and co-ordination of policies with respect to the following areas of common interest: applying radiation safety fundamentals (including principles, criteria and standards) and their transformation into regulatory terms; co-ordinating research and development; advancing education and training; promoting widespread information exchange; facilitating the equitable transfer of technology and know-how; and providing radiation safety services.

Within this framework, the Sponsoring Organizations established a Joint Secretariat (hereinafter the Joint Secretariat), co-ordinated by the IAEA, to prepare these Standards.

The Standards include a Preamble, the Requirements and a Glossary of Terms and Definitions, together with Appendices and Annexes and a List of the Sponsoring Organizations, Participants, Consultants and Contributors. The Preamble states the aims and the basis of the Standards and describes appropriate governmental organizations for protection and safety. The Requirements specify what is imperative in order to fulfil the aims of the Standards and include general framework, requirements for practices and requirements for interventions. Indicative numerical guidance is provided in the Appendices, and the Annexes contain some explanatory material on the underlying principles and philosophy.

The Standards are published in the IAEA's Safety Series. This Series encompasses Fundamentals. Standards, Guides and Practices documents relating to nuclear safety, radiation protection and radioactive waste management. The Series includes other related international standards, codes, guides and regulations such as the Nuclear Safety Standards (NUSS) of the IAEA's Nuclear Safety Standards Advisory Group (NUSSAG), the Regulations for the Safe Transport of Radioactive Materials of the IAEA's Standing Advisory Group on the Safe Transport of Radioactive Materials (SAGSTRAM) and the forthcoming Waste Management Standards (RADWASS) of the IAEA's Waste Management Advisory Group. The other organizations of the Joint Secretariat have also produced codes and guides in their spheres of activity: the ILO has issued a code of practice for the radiation protection workers and 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 OECD/NEA has published documents on specific topics relating to radiation safety.

The Standards are limited to specifying basic radiation safety requirements, with little guidance on how to apply them. Some general guidance on applying some of the requirements is already available in the publications of the Sponsoring Organizations and additional guidance will be developed as needed. More detailed guidance on some specific areas will be developed in the light of experience.

#### CONTENTS

#### PREFACE

#### **PREAMBLE**

**GOVERNMENTAL REGULATION** National Infrastructure for Protection and Safety

Regulatory Authorities Application of the Standards

#### REQUIREMENTS

#### 1. GENERAL FRAMEWORK FOR REQUIREMENTS

- 11 PURPOSE
- 1.2 SCOPE
  - 1.2 1
  - Application
  - 1.2.2 Practices
  - 1.2.3 Interventions
- 1.3 EXCLUSIONS
- 1.4 RESPONSIBILITIES
- 1.5 RECORDS
- 16 INSPECTIONS
- 1.7 VIOLATIONS
- 18 ENTRY INTO FORCE
- 1.9 RESOLUTION OF CONFLICT
- 1.10 INTERPRETATION
- 1.11 COMMUNICATIONS

#### 2. REQUIREMENTS FOR PRACTICES

- 2.1 BASIC OBLIGATIONS
- 2.2 SOURCES
- 2.3 EXPOSURES
- 2.4 PARTIES
- 2.5 REGULATORY SYSTEM FOR PRACTICES
  - 2.51 Notification and Registration
  - 2.5.2 Authorization and Licensing
  - Exemptions 25.3

#### 2.6 THE SYSTEM OF PROTECTION AND SAFETY FOR PRACTICES

- 26.1 Justification of Practices
- 2.6.2 Optimization of Protection and Safety
- 2.6.3 Individual Limits
- 2.6.4 Constraints
- 26.5 Technical Principles
- 2.6.6 Assessment of Effectiveness

#### 2.7 GENERAL REQUIREMENTS FOR PROTECTION

- 27.1 Practices deemed to be not justified
- 2.7.2 Optimization of Protection and Safety
- 2.7.3 Individual Pelated Limits to Dose and Risk
- 2.7.4 Source Related Constraints on Dose and Risk
- 2.7.5 Operational Restrictions

#### 2.8 REQUIREMENTS FOR CONTROLLING OCCUPATIONAL EXPOSURES

- 2.8.1 Responsibilities of Employers
- 282 Special Administrative Arrangements
- 2.8.3 Classification of Areas
- 284 Local Rules and Supervision

	and the second of the second o
2 8.5 2.8.6	Information, Instruction and Training Personal Protective Equipment
2.8.7	Duties of Workers
2.8.8	Co-operation between Employers and Operators
2.8.9	Personal Monitoring and Exposure Assessment
2.8.10	Workplace Monitoring
2.8.11	Health Surveillance
2.8.12	Dose Records
2.8.13	Control of Natural Sources of Radiation in Workplaces
2.8.14	Radiation Protection in Uranium and Thorium Mines and Mills
2.8.15	Exposure of Workers Not Involved in Radiation Work
2 8.16	Reference Exposure Levels for Workers Undertaking Protective Actio
29 REQUIREMEN	ITS FOR CONTROLLING MEDICAL EXPOSURES
2.9 1	Responsibilities
2.9.2	Requirements
2.9.3	Justification of Medical Exposures
2,9.4	Optimization of Protection for Medical Exposures
2.9.5	Exposure Constraints and Reference Levels
296	Potential Medical Exposures
2,9.7	Training
2.9.8	Design Requirements related to Medical Exposures
2.9.9	Clinical Dosimetry
2.9.10	Calibration
2 9.11	Quality Assurance for Medical Exposures
2.9.12	Investigations of Medical Exposures
2 10 REQUIREME	NTS FOR PUBLIC EXPOSURE
2.10.1	Control of External Radiation
2.10.2	Control of Radioactive Effluents
2.10.3	Management of Radioactive Waste other than Effluents
2.10.4	Environmental Monitoring
2.10.5	Consumer Products
2.11 GENERAL RE	EQUIREMENTS FOR THE SAFETY OF SOURCES
2.11.1	Requirements for the Control of Potential Exposures
2.11.2	Safety Assessment
2 11 3	Human Factors
2 11.4	Quality Assurance
2.12 DESIGN AND	OTHER PRE-OPERATIONAL SAFETY REQUIREMENTS
2.12.1	Responsibilities of Suppliers
2 12.2	Design Requirements
2.12.3	Location of Sources
2.12,4	Siting of Installations
2.12.5	Requirements for the Prevention and Mitigation of Accidents
2.13 OPERATION	AL SAFETY REQUIREMENTS
2.13.1	Responsibilities of the Operator
2.13 2	Qualified Experts
2.13.3	Safety Assessments
2,13.4	Maintenance, Testing and Inspection
2.13.5	Records of Sources
2,13.6	Monitoring
2.13.7	Investigations and Follow-up
2 13.8	Emergency Preparedness
2 13.9	Accident Management
2.13.10	Feedback of Operational Experience
2.14 SECURING (	DE SOUBCES

#### 2 14 SECURING OF SOURCES

#### 3. REQUIREMENTS FOR INTERVENTION

- 3.1 INTERVENTION SITUATIONS
- 3.2 BASIC OBLIGATION
- 33 REGULATORY SYSTEM FOR INTERVENTION
  - 3.3.1 Organizations and Responsibilities
  - 3 3.2 Notification
- 3.4 THE SYSTEM OF PROTECTION FOR INTERVENTION SITUATIONS
  - 3.4.1 Justification of Interventions
  - 3.4.2 Optimization of Interventions
- 3.5 ASSESSMENTS
- 3.6 REQUIREMENTS FOR LONG STANDING SITUATIONS
  - 3.6.1 Remedial Action Plans
  - 3.6.2 Dwellings
  - 3.6.3 Intervention Levels
- 3.7 REQUIREMENTS FOR ACCIDENTS AND EMERGENCIES
  - 3.7.1 Emergency Plans
  - 3.7.2 Intervention Levels for Accidents and Emergencies
- 3.8 TRANSITION FROM INTERVENTION TO NORMAL SITUATIONS
  - 3.8.1 Continuation of Intervention
  - 3.8.2 Return to Normal after an Emergency Intervention Situation
- 3.9 ASSESSMENT AND MONITORING DURING AN EMERGENCY INTERVENTION SITUATION

#### **APPENDICES**

: Exemptions

Table of Appendix I: Exempt Activity and Exempt Activity Concentration of Radionuclides

- II: Dose Limits for Exposure due to Practices
  - Table 1. Committed effective dose per unit intake via ingestion
  - Table 2: Committed effective dose per unit intake via inhalation
  - Table 3. Annual limits of intake and exposure for radon and thoron daughters
- III: Indicative Dose Constraints
- IV: Constraints on the Probability of Accident Sequences leading to Potential Exposures
- V: Reference Values for Medical Diagnostic Exposures for a Standard Size Patient
- VI: Levels of Doses at which Intervention is nearly always Justified
- VII. Intervention Levels
  - A) Generic Intervention Levels for Long Standing Situations
  - B) Indicative Guidance on Intervention Levels for Urgent Countermeasures
  - C) Generic Intervention Levels for Withdrawal and Substitution of Food and Drinking Water following an Accident or Emergency
  - Codex Alimentarius Commission Guideline Levels for Radionuclides in Foods for Use in Foods in International Trade following Accidental Nuclear Contamination
  - E) Generic Intervention Level for Temporary Relocation following an Accident or Emergency
  - F) Generic Intervention Level for Permanent Resettlement following an Accident or Emergency

#### **ANNEXES**

ANNEX I

EXPLANATORY MATERIAL ON THE 1990 RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

Quantities used in Radiological Protection Biological Effects of Radiation Exposure The Conceptual Framework of Radiological Protection The System of Protection to Practices

#### ANNEX II

BASIC SAFETY PRINCIPLES - adapted excerpts from two reports of the INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP: 'Basic Safety Principles for Nuclear Power Plants' (Safety Series No. 75 INSAG-3, 1988) and 'Safety Culture' (Safety Series No. 75-INSAG-4, 1991)

#### **GLOSSARY**

DEFINITIONS

QUANTITIES AND UNITS

Basic Dosimetric Quantities Dosimetric Quantities for Monitoring Collective Dosimetric Quantities Other Radiological Quantities

LIST OF SPONSORING ORGANIZATIONS, PARTICIPANTS, CONSULTANTS AND CONTRIBUTORS

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#### PREAMBLE

Over the 20th century, a vast amount of information has been gained on levels of exposure to ionizing radiation (hereinafter referred to as radiation) and their health effects and on technologies for controlling radiation sources. Comprehensive understanding has been gained from extensive research and development programmes and from operating experience around the world. The results of this unprecedented effort have been regularly compiled by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) as well as by scientific and engineering professional organizations at both the national and the international level.

On this basis, radiation protection and nuclear safety objectives have been formulated for (a) the adoption and continuation of human activities that can increase the exposure of people to radiation (socalled 'practices') and (b) processes for reducing existing levels of exposure through 'interventions'. Although practices and interventions may differ enormously in scale and technical complexity, they have in common the agent giving rise to the risk and necessitating safety provisions: radiation.

The common objective of radiation protection and nuclear safety is to protect people and the environment -- and populations of other species -- from adverse effects of radiation, while still allowing justified activities from which radiation exposure may result. Complementary objectives are to keep risks caused by radiation exposure as low as reasonably achievable and, within prescribed constraints, to prevent accidental radiation exposures and to mitigate the consequences of any accident that does occur. The objectives encompass the safety of all people exposed or potentially exposed to radiation, and include the ethical obligation to protect future generations, which could be affected by present practices.

In order to achieve these objectives, a number of general and fundamental protection and safety principles have been developed on an international level. A global consensus on such principles has been achieved by expert bodies, notably the long established International Commission on Radiological Protection (ICRP), which has issued recommendations on radiation protection since its inception in 1928, and by the relatively new International Nuclear Safety Advisory Group (INSAG), which has been formulating nuclear safety concepts since 1985 under the auspices of the IAEA. These principles provide the basis for the Standards.

These Standards have been developed within this framework. They establish requirements for protection against radiation risks arising from practices giving rise to exposure to radiation and for the safety of radiation sources within these practices, as well as for intervention in situations involving existing sources of radiation. The practices of concern for these Standards include: the use of radiation sources and radioactive substances in medicine, research, industry, agriculture and teaching; the generation of electricity by nuclear power, including the entire cycle of activities from the mining of radioactive ores to the operation of nuclear reactors and fuel cycle facilities and the management and disposal of radioactive wastes; practices involving exposure to natural radiation such as the industrial use of materials such as phosphatic minerals which contain naturally occurring radioactive substances; and the transport of radioactive substances. Situations that may require intervention include exposure to existing natural sources of radiation, such as radon in dwellings, and to radioactive contamination following an accident

The relevant exposures encompass the expected and potential exposures of radiation workers, of patients in diagnosis or treatment, and of members of the public. 'Potential' exposures are those which would occur only in the event of unplanned occurrences such as equipment failures, accidents, errors or the failure of protective measures.

The Standards cover such a broad range of practices and sources that involve or could involve exposure to radiation that many of their requirements are necessarily drafted in general terms in order to cover the entire range of activities to be regulated. It follows that a given requirement will have to be fulfilled differently for different types of practices and sources, according to the nature of the operations involved and the potential for large exposures. Not all the requirements will apply to every practice or to every source. It is up to the regulatory authority to specify which of the requirements are applicable in each case.

The Standards do not apply to non-ionizing radiation nor to the control of non-radiological aspects of health and safety. Such matters should nevertheless be kept in mind when applying the Standards and, conversely, these Standards should be taken into account in applying safety measures in these areas.

The radiation protection parts of the Standards are based primarily on the 1990 Recommendations of the ICRP (see footnote 5). In the safety area the available international recommendations include those of INSAG<sup>7</sup> and although these were developed for nuclear power plants, they have been incorporated into the Standards to the extent that they are applicable. Other standards, guides and recommendations of the Sponsoring Organizations have also been used as source material, notably those from the Nuclear Safety Standards (NUSS) programme of the IAEA.

Explanatory material on the radiobiological evidence and the radiation protection principles of the 1990 Recommendations of the ICRP on which the Standards are based is included in Annex I. A summary of relevant principles of safety and safety culture adapted from INSAG publications is given in Annex II.<sup>7,8</sup>

The basic principles of radiation protection and safety may be summarized as follows:

- No practice that involves or could involve exposure to radiation should be adopted unless it yields sufficient benefit to the exposed individuals and to society to offset the radiation detriment it causes.
- Sources should be accorded the best protection and safety measures that are reasonably achievable under the prevailing circumstances, such that the magnitude and likelihood of individual exposures and the number of people exposed are as low as reasonably achievable and are within the dose limits and the specified dose and risk constraints.
- Individual doses due to the combination of all relevant practices should not exceed predetermined limits.
- Protection and safety should be ensured by sound engineering and management, quality assurance, trained and qualified personnel, comprehensive safety assessments, and lessons learned from experience and research.
- Defence in depth measures should be applied to compensate for potential failures in protection or safety measures.

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

<sup>8</sup> INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Safety Culture, Safety Series No.75-INSAG-4, IAEA, Vienna (1991)

- Radiation exposure due to existing sources of radiation should be reduced by intervention when justified.
- Practices should not jeopardize the general natural state of the environment.
- -- Safety culture should be developed which governs the safety attitudes, actions and interactions of all persons and organizations engaged in activities concerned with sources of radiation.
- -- The operator of a source should bear the ultimate responsibility for protection and safety.

Although operators have the ultimate responsibility for applying these principles, governments also help to ensure their proper application, generally through a regulatory system. Governments also usually provide for certain essential radiation safety services, that are beyond the capabilities of [operators] or that complement the capabilities of operators. The purpose of these Standards is to specify the basic radiation safety requirements for operators and other related parties rather than for governments, and therefore governmental responsibilities are not included under the requirements. However, some elements of regulatory systems and of other governmental responsibilities in radiation safety are outlined in the following to provide a context for the basic requirements of the Standards.

#### **GOVERNMENTAL REGULATION**

[Note that governmental responsibilities presented under this heading are not framed as requirements but, described as good regulatory practices.]

#### National infrastructure for protection and safety

A national infrastructure, including legislation and regulations, a regulatory authority, certain essential radiation protection and safety facilities, equipment and services, and an adequate number of trained people, is needed to ensure that all aspects of radiation safety are adequately dealt with.

The purpose of the national infrastructures is to provide for addressing societal concerns which extend beyond the legal responsibilities of the operators authorized to conduct practices with sources of radiation. For example, national authorities can ensure that appropriate arrangements are made to detect any build-up of radioactive substances in the general environment, to dispose of radioactive wastes and to be prepared for emergencies that could result in exposure of the general public.

National infrastructure can also ensure that facilities and services that are essential for proper radiation protection and safety but are beyond the required capabilities of the persons who are authorized to conduct practices are provided. Such facilities include those for personnel dosimetry and environmental monitoring, for calibration and intercomparison of radiation measuring equipment, as well as central registries of occupational doses and of information on equipment reliability.

The components of a national infrastructure are generally provided by the government, either through governmental authorities or through organizations acting on behalf of the government. The government also ensures that the provision of such services at a national level does not detract from the primary responsibility for radiation safety of the operators and workers authorized to conduct the practices and operate the sources.

#### Regulatory authorities

National authorities that are established by governments regulate the introduction and conduct of any practice involving sources of radiation. Governments need to provide these regulatory authorities with sufficient powers and resources for effective regulation. Much of the Standards is drafted as if there

were a single regulatory authority for all aspects of radiation safety in each country; 'regulatory authority' as used in these Standards should generally be taken to mean the relevant regulatory authority for the particular source or aspect of radiation safety in question.

The type of regulatory system in a given country will depend on the size, complexity and protection 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 can vary, with some authorities being completely self-sufficient and others delegating some inspection, assessment or other duties to various government, public or private agencies. A regulatory authority might also be self-sufficient in specialist expertise or may augment its capabilities by expert advisors and advisory committees.

In general, regulatory authorities assess, as necessary, applications for conducting practices that involve exposure to radiation; authorize such practices and the sources associated with them, subject to certain specified conditions; and periodically inspect for compliance with these specified conditions. They also assess the overall effectiveness of radiation protection and safety measures for each authorized practice, as well as the combined health and environment impacts of all authorized practices.

For these purposes, regulatory authorities need to establish regulations and standards for protection and safety and provide for their enforcement. They institute formal systems for notification, registration and licensing, as well as provisions for exclusion or exemption from regulatory requirements, and make provisions for surveillance, monitoring, review, verification and inspection of practices and sources. They also prescribe intervention.

The government needs to ensure that the regulatory authorities are independent, particularly of designers, constructors and operators. The separation of the responsibilities is made clear so that the regulators retain their independence as safety authorities. The government also needs to ensure that some competent body is assigned responsibility for the regulatory surveillance of protection and safety measures for patients and of quality assurance measures for the equipment and techniques used for medical irradiation. The government also needs to ensure that adequate arrangements are provided by the operators, or that other arrangements are made, for the education and training of radiation protection and nuclear safety specialists and for fostering information exchange among specialists.

Regulatory authorities also need to provide for the control of certain natural sources of radiation for which no other organization has responsibility, such as radioactive residues from past practices and some cases of exposure to natural radiation. Duties of regulatory authorities include the setting of generic exposure constraints for broad types of sources such as X ray machines or nuclear reactors. They also ensure that adequate plans exist for dealing with radiation accidents, including emergency interventions.

Regulatory authorities may also specify additional requirements for specific sources and practices. Moreover, they provide guidance on how various types of operator may be expected to satisfy the regulatory requirements, such as in the form of regulatory guideline documents.

Regulatory authorities need inspection procedures to define the powers of inspectors, maintain consistency of enforcement, and provide for appeals by operators. They also need to ensure that directives to both their inspectors and their operators are clear and unambiguous and to develop appropriate mechanisms for informing the public, their representatives and the media about the health and safety aspects of radiation uses and about regulatory processes. This is helpful in assigning appropriate priorities and resources in relation to total allocations for health and safety and in making the regulatory process more readily understandable

The authorities would encourage operators to take due account of lessons learned from experience and of new developments in radiation protection and the safety of sources, in addition to applying the

basic requirements of these Standards. They also encourage the development of a safety culture in operators, which includes:

- individual and collective dedication to safety, on the part of both workers and management;
- accountability of all persons for safety, including those at corporate and management levels;
- encouraging a questioning attitude and discouraging complacency,
- -- openness and co-operation between operators and inspectors, which include facilitating the access by inspectors to premises and to relevant information.

## REQUIREMENTS

### 1. GENERAL FRAMEWORK FOR REQUIREMENTS

#### 1.1. PURPOSE

(1) The purposes of the Standards are to specify basic requirements for the <u>protection</u> of health from harm due to exposure to radiation and for the <u>safety</u> of radiation sources (hereinafter, protection and safety).

#### 1.2. SCOPE

#### 1.2.1 Application

- (2) The Standards apply to:
  - (a) any practice or intervention in any State that adopts the Standards or requests any of the sponsoring organizations to provide for the application of these Standards;
  - (b) any practice or intervention undertaken by States with the assistance of the FAO, the IAEA, the ILO, the PAHO, or the WHO, in conjunction with relevant national rules and regulations;
  - (c) operations carried out by the IAEA, or making use of materials, services, equipment, facilities and information made available by the IAEA or at its request or under its control or supervision, or under any bilateral or multilateral arrangement where the parties request the IAEA to provide for the application of these Standards, and to any of an IAEA Member State's activities in the field of nuclear energy where the State requests the IAEA to provide for the application of these Standards, whereby the Standards are applied under the provisions of "The Agency's Safety Standards and Measures".9

International Atomic Energy Agency: "The Agency's Safety Standards and Measures"; INFCIRC 18/REV.1; IAEA (April 1976)

#### 1.2.2 Practices

- (3) For the purpose of the Standards, the term <u>practice</u> is used to mean any activity that introduces additional sources of exposure, exposure pathways or scenarios, or extends exposure to additional people, or modifies the network of pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people, or the number of people exposed.
- (4) The practices to which the Standards apply include, but are not limited to, the following:
  - (a) Practices causing exposure to natural sources of radiation whenever the adoption or introduction of such practices is a matter of choice and results in an increase in exposure of people over the background exposure that they would inevitably incur.
  - (b) The use of artificially produced radiation and radioactive materials, including: medical practices such as radiodiagnosis, radiotherapy, nuclear medicine and clinical and laboratory testing and research for medical purposes; industrial practices such as radiopreservation of food, industrial gauging, and non-destructive testing by radiography; education and research; and agricultural and veterinary practices.
  - (c) The generation of energy by nuclear power, including any activity in the nuclear fuel cycle.

#### 1.2.3 Interventions

- (5) For the purposes of the Standards, the term <u>intervention</u> is used to mean any action intended to reduce exposures to existing sources, whether altering the causes of exposure, modifying the exposure pathways, or by changing people's habits, circumstances or actions so as to preclude them from exposure.
- (6) The intervention situations to which these Standards apply include, but are not limited to, the following situations:
  - (a) long standing situations involving exposure to natural sources of radiation, such as exposure to radon and other naturally occurring radioactive substances in [pre-existing]

buildings, fincluding the continuation of long standing practices involving only such 1 exposures and] whenever such continuation is unavoidable; and 2 (b) situations where exposures could occur due to the presence of radioactive residues 3 from previous events, such as contamination caused by accidents. 4 5 1.3 EXCLUSIONS 6 7 (7)These Standards do not apply to: 8 sources for which the exposure is essentially unamenable to the requirements of the 9 (a) Standards, such as naturally occurring radioactive substances in the concentrations 10 occurring in nature, cosmic radiation at low altitudes, and radioactive substances that 11 are natural constituents of the human body, such as potassium-40; 12 scenarios and accident sequences that may lead to potential exposures whose the 13 (b) magnitudes are essentially unamenable to the requirements of Standards; however, the 14 evidence of a very low probability of occurrence of a scenario or accident sequence 15 is not a sufficient condition for the exclusion of such scenarios or sequences. 16 17 1.4 RESPONSIBILITIES 18 19 (8) Besides the Sponsoring Organizations and the Regulatory Authorities, the Parties having 20 responsibilities for the application of these Standards are those indicated in the Requirements 21 for Practices and Requirements for Intervention respectively. 22 23 (9) The Parties shall discharge the general responsibilities given in this part and the specific 24 25 responsibilities set out in other parts of the Standards. 26 (10) The general responsibilities of each Party are: 27 (a) to establish protection and safety objectives relevant to the Party, in conformity with 28 29 the requirements of these Standards;

to determine the measures and provide the resources needed to achieve these (b) 1 objectives; 2 to ensure that these measures are properly taken; (c) 3 to make a continuing review of performance, including a programme of verification (d) 4 to determine how effectively the [original] objectives are being achieved; and 5 to identify failures and shortcomings and to take steps to prevent their recurrence. (e) 6 7 8 1.5 RECORDS 9 (11) Each Party shall keep general records on the discharge of its responsibilities as well as 10 specific records as required by these Standards. 11 12 (12) Unless otherwise specified by these Standards, all general records shall be retained for at 13 least ten years and summary records shall be retained for at least thirty years. 14 15 1.6 INSPECTIONS 16 17 (13) Each Party shall permit duly authorized representatives of the Regulatory Authority and -18 wherever applicable - of the relevant Sponsoring Organizations, to inspect, copy and take away 19

#### 1.7 VIOLATIONS

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(14) In the event of breach of any requirement of these Standards, the appropriate Party shall:

copies of its records and to inspect its premises, activities and personnel and any source under

its responsibility as may be necessary to fulfil the purposes and requirements of these Standards.

- (a) investigate the breach,
- (b) take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;

- (c) report to the Regulatory Authority and wherever applicable to the relevant Sponsoring Organizations on the causes of the breach as determined by the investigation and on the corrective or preventive actions taken or to be taken; and
- (d) take whatever other actions are necessary as required by these Standards.
- (15) Failure to take corrective or preventive actions within a reasonable time shall be grounds for modifying, suspending or withdrawing the relevant registration, authorization or licence.
- (16) Wilful violation, attempts to violate or conspiracy to violate any requirement of these Standards are subject to the provisions for breach of the Standards as provided by the appropriate national legislation, or by regulations or other administrative procedures promulgated by the Regulatory Authority and wherever applicable by the relevant Sponsoring Organizations.

#### 1.8 ENTRY INTO FORCE

- (17) For the Sponsoring Organizations, the Standards come into force six months after the date of their adoption by the statutory Governing Body(ies) of the relevant Sponsoring Organization; for a State, the Standards come into force at the time indicated by the formal adoption by the State.
- (18) Wherever a modification to a practice or source is required in order to comply with some requirement of the Standards, that requirement shall take effect within any approved period of up to five years after the date of adoption if such a period is required for the modification. During this period, interim dose limits may be used for some specified practices or for some sources with the practice, or for particular operations with a source, which may be higher than the limits specified by the Standards but which shall not exceed the limits specified in the 1982 Edition of the IAEA/ILO/NEA/WHO Basic Safety Standards for Radiation Protection.

#### 1.9 RESOLUTION OF CONFLICT

1 (19) The requirements of these Standards are in addition to and not in place of other applicable
2 requirements in international binding conventions and national regulations. In any case of
3 conflict between the requirements in these Standards and those in other applicable requirements,
4 the requirement that would achieve the best protection and safety shall apply.

#### 1.10 INTERPRETATION

(20) Except as specifically authorized by the Governing Bodies of the relevant Sponsoring Organizations, no interpretation of these Standards by any officer or employee of the relevant Sponsoring Organization(s) other than a written interpretation by the Director General of the Sponsoring Organization(s) will be binding upon the Organization(s).

#### 1.11 COMMUNICATIONS

(21) All reports and any other communication concerning these Standards shall be addressed to the Regulatory Authority and, whenever appropriate, to the relevant Sponsoring Organizations.