IAEA Safety Standards

for protecting people and the environment

Regulatory Control of Radiation Sources

Jointly sponsored by
FAO, IAEA, ILO, PAHO and WHO

Safety Guide
No. GS-G-1.5

IAEA
International Atomic Energy Agency

IAEA SAFETY RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (i.e. all these areas of safety). The publication categories in the series are **Safety Fundamentals, Safety Requirements** and **Safety Guides**.

Safety standards are coded according to their coverage: nuclear safety (NS), radiation safety (RS), transport safety (TS), waste safety (WS) and general safety (GS).

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

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

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

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

OTHER SAFETY RELATED PUBLICATIONS

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

Reports on safety and protection in nuclear activities are issued in other publications series, in particular the **Safety Reports Series**. Safety Reports provide practical examples and detailed methods that can be used in support of the safety standards. Other IAEA series of safety related publications are the **Provision for the Application of Safety Standards Series**, the **Radiological Assessment Reports Series** and the International Nuclear Safety Group's **INSAG Series**. The IAEA also issues reports on radiological accidents and other special publications.

Safety related publications are also issued in the **Technical Reports Series**, the **IAEA-TECDOC Series**, the **Training Course Series** and the **IAEA Services Series**, and as **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. Security related publications are issued in the **IAEA Nuclear Security Series**.

REGULATORY CONTROL OF RADIATION SOURCES

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REGULATORY CONTROL OF RADIATION SOURCES

SAFETY GUIDE

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INTERNATIONAL ATOMIC ENERGY AGENCY,
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FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting Parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

PREFACE

The basic requirements for the protection of persons against exposure to ionizing radiation and for the safety of radiation sources were established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards), jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO) (the Sponsoring Organizations). The application of the Basic Safety Standards is based on the presumption that national infrastructures are in place to enable governments to discharge their responsibilities for radiation protection and safety. Requirements relating to the legal and governmental infrastructure for the safety of nuclear facilities and sources of ionizing radiation, radiation protection, the safe management of radioactive waste and the safe transport of radioactive material are established in the Safety Requirements on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1.

This Safety Guide, which is jointly sponsored by the FAO, the IAEA, the International Labour Office, the PAHO and the WHO, gives detailed guidance on the key elements for the organization and operation of a national regulatory infrastructure for radiation safety, with particular reference to the functions of the national regulatory body that are necessary to ensure the implementation of the Basic Safety Standards. The Safety Guide is based technically on material first published in IAEA-TECDOC-1067[1], which was jointly sponsored by the FAO, the IAEA, the OECD/NEA, the PAHO and the WHO. The requirements established in GS-R-1 have been taken into account.

The Safety Guide is oriented towards national regulatory infrastructures concerned with protection and safety for radiation sources used in medicine, industry, agriculture, research and education.

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources, IAEA-TECDOC-1067, Vienna (1999).

IAEA SAFETY STANDARDS

SAFETY THROUGH INTERNATIONAL STANDARDS

While safety is a national responsibility, international standards and approaches to safety promote consistency, help to provide assurance that nuclear and radiation related technologies are used safely, and facilitate international technical cooperation and trade.

The standards also provide support for States in meeting their international obligations. One general international obligation is that a State must not pursue activities that cause damage in another State. More specific obligations on Contracting States are set out in international safety related conventions. The internationally agreed IAEA safety standards provide the basis for States to demonstrate that they are meeting these obligations.

THE IAEA STANDARDS

The IAEA safety standards have a status derived from the IAEA's Statute, which authorizes the Agency to establish standards of safety for nuclear and radiation related facilities and activities and to provide for their application.

The safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment.

They are issued in the IAEA Safety Standards Series, which has three categories:

Safety Fundamentals

— Presenting the objectives, concepts and principles of protection and safety and providing the basis for the safety requirements.

Safety Requirements

— Establishing the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements, which are expressed as 'shall' statements, are governed by the objectives, concepts and principles of the Safety Fundamentals. If they are not met, measures must be taken to reach or restore the required level of safety. The Safety Requirements use regulatory language to enable them to be incorporated into national laws and regulations.

Safety Guides

— Providing recommendations and guidance on how to comply with the Safety Requirements. Recommendations in the Safety Guides are expressed as 'should' statements. It is recommended to take the measures stated or equivalent alternative measures. The Safety Guides present international good practices and increasingly they reflect best practices to

help users striving to achieve high levels of safety. Each Safety Requirements publication is supplemented by a number of Safety Guides, which can be used in developing national regulatory guides.

The IAEA safety standards need to be complemented by industry standards and must be implemented within appropriate national regulatory infrastructures to be fully effective. The IAEA produces a wide range of technical publications to help States in developing these national standards and infrastructures.

MAIN USERS OF THE STANDARDS

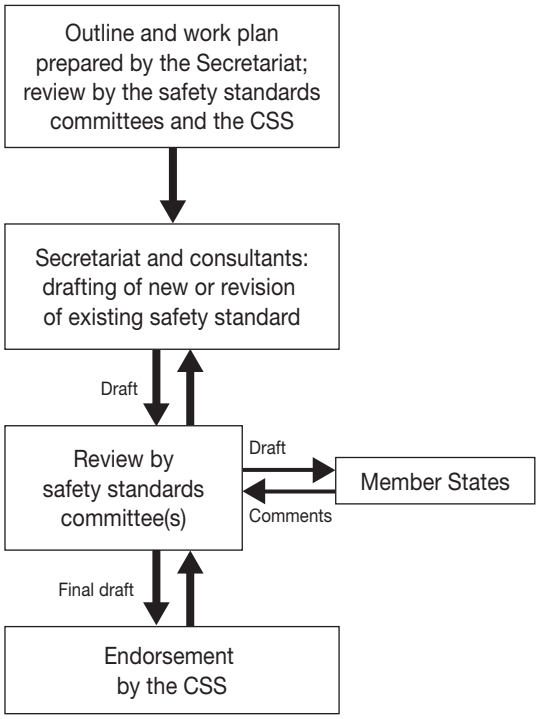
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture for and apply nuclear and radiation related technologies, including operating organizations of facilities of various types; by users and others involved with radiation and radioactive material in medicine, industry, agriculture, research and education; and by engineers, scientists, technicians and other specialists. The standards are used by the IAEA itself in its safety reviews and for developing education and training courses.

DEVELOPMENT PROCESS FOR THE STANDARDS

The preparation and review of safety standards involves the IAEA Secretariat and four safety standards committees for safety in the areas of nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS), which oversees the entire safety standards programme. All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the CSS is appointed by the Director General and includes senior government officials having responsibility for establishing national standards.

For Safety Fundamentals and Safety Requirements, the drafts endorsed by the Commission are submitted to the IAEA Board of Governors for approval for publication. Safety Guides are published on the approval of the Director General.

Through this process the standards come to represent a consensus view of the IAEA's Member States. The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the standards. Some standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the International



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

Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

The safety standards are kept up to date: five years after publication they are reviewed to determine whether revision is necessary.

APPLICATION AND SCOPE OF THE STANDARDS

The IAEA Statute makes the safety standards binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA concerning any form of Agency assistance is required to comply with the requirements of the safety standards that pertain to the activities covered by the agreement.

International conventions also contain similar requirements to those in the safety standards, and make them binding on contracting parties. The Safety Fundamentals were used as the basis for the development of the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The Safety

Requirements on Preparedness and Response for a Nuclear or Radiological Emergency reflect the obligations on States under the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The safety standards, incorporated into national legislation and regulations and supplemented by international conventions and detailed national requirements, establish a basis for protecting people and the environment. However, there will also be special aspects of safety that need to be assessed case by case at the national level. For example, many of the safety standards, particularly those addressing planning or design aspects of safety, are intended to apply primarily to new facilities and activities. The requirements and recommendations specified in the IAEA safety standards might not be fully met at some facilities built to earlier standards. The way in which the safety standards are to be applied to such facilities is a decision for individual States.

INTERPRETATION OF THE TEXT

The safety standards use the form 'shall' in establishing international consensus requirements, responsibilities and obligations. Many requirements are not addressed to a specific party, the implication being that the appropriate party or parties should be responsible for fulfilling them. Recommendations are expressed as 'should' statements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures) for complying with the requirements.

Safety related terms are to be interpreted as stated in the IAEA Safety Glossary (http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard within the Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the main text, or describes methods of calculation, experimental procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the standard. Material in an appendix has the same status as the main text and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. An annex is not an integral part of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material published in standards that is under other authorship may be presented in annexes. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The achievement and maintenance of a high level of safety in the use of radiation sources depend on there being a sound legal and governmental infrastructure, including a national regulatory body with well-defined responsibilities and functions. An appropriately organized and staffed regulatory body with access to adequate resources is a key element of such an infrastructure.

1.2. The Safety Requirements publication entitled Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [1] establishes the requirements for such an infrastructure. The term 'infrastructure' refers to the underlying structure of systems and organizations. This includes requirements concerning the establishment of a regulatory body for radiation sources and the responsibilities and functions to be assigned to it.

1.3. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards) [2] establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may give rise to such exposure (hereinafter the term 'radiation safety' is used to cover both these aspects). The Basic Safety Standards are not intended to be applied as they stand in all States and regions, but should be adapted to take account of local conditions. The ways in which States apply the Basic Safety Standards will vary depending on their legal systems, their technical resources, the scale of the installations concerned and related factors.

1.4. The Basic Safety Standards [2] can be applied only by means of an effective infrastructure for radiation safety, which includes adequate legislation and regulations, an efficient regulatory system, supporting experts and services, and a commitment to safety shared by all those with responsibilities for protection and safety, including both management and workers.

OBJECTIVE

1.5. This Safety Guide is intended mainly to assist States to implement the requirements established in Ref. [1] for a national regulatory infrastructure to

regulate any practice involving radiation sources in medicine, industry, agriculture, research and education.

1.6. Member States receiving assistance from the IAEA in the application of nuclear energy or radiation technology are expected to implement the Basic Safety Standards [2] or equivalent standards for radiation protection and safety as may be appropriate for the conditions. This can only be ensured by means of an adequate regulatory system, which is a key element of the national infrastructure for radiation safety. The other sponsors of the Basic Safety Standards — the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Pan American Health Organization (PAHO), the World Health Organization (WHO) and the OECD Nuclear Energy Agency (OECD/NEA) — apply them in their respective spheres of activity.

SCOPE

1.7. This Safety Guide covers the elements of a national regulatory infrastructure necessary to achieve an appropriate level of protection and safety for radiation sources used in medicine, industry, agriculture, research and education. It also provides guidance on the organization and implementation of a system for the regulatory control of radiation sources.

1.8. The guidance given in this Safety Guide is not oriented towards nuclear facilities. Although it is relevant to these facilities, they require a more elaborate and technically advanced safety infrastructure, as set out in four interrelated Safety Guides [3–6]. In using this Safety Guide, regulatory bodies should be aware of the current IAEA safety standards (and relevant national documents) concerning nuclear safety, radiation protection, the transport of radioactive material and the management of radioactive waste. This Safety Guide does not cover the safety infrastructures at the operator[1] level. These

[1] An operator is defined as any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc. It is synonymous with operating organization. This Safety Guide uses the term operator in the same sense as it is used in GS-R-1, and with the same meaning as for the term legal person as used in the Basic Safety Standards [2].

will be considered by the IAEA in practice specific publications on radiation safety. However, the present Safety Guide does cover the interactions between the government and those operators subject to its control.

1.9. While the guidance is intended primarily to assist in establishing a national regulatory infrastructure for regulating the safety of radiation practices and sources, it is also generally applicable for a regulatory infrastructure appropriate for regulating intervention. The latter type of infrastructure is different in some respects, however, and those aspects of the regulatory infrastructure that are unique to intervention are covered elsewhere.

STRUCTURE

1.10. Section 2 provides general information about the legal framework necessary to establish and maintain a regulatory infrastructure for radiation safety. The principal functions and activities of the regulatory body are identified in Section 3. Section 4 provides advice on the regulatory control of consumer product supply. Section 5 examines those functions of the regulatory body that are shared with other governmental organizations. The requirements applicable to the staffing of the regulatory body are reviewed in Section 6. Section 7 discusses the documentation of the regulatory body's functions and activities. Section 8 addresses the support services and the procedures to be established for ensuring that the regulatory body maintains an effective regulatory system. Section 9 outlines the content of a quality management system for the regulatory body.

2. LEGAL FRAMEWORK FOR A REGULATORY INFRASTRUCTURE

SCOPE OF THE BASIC LEGAL FRAMEWORK

2.1. A legislative and statutory framework (e.g. an act, law or decree; hereinafter termed 'the legislation') which allows for the beneficial use of ionizing radiation and regulates the safety of facilities and activities is required to be established by the legislative and governmental mechanisms of States

(Ref. [1], para. 2.2(1)). The enabling legislation should be as straightforward as feasible, consistent with the national situation, so that the need for its subsequent amendment is minimized. This is important because the process of amending the legislation is usually a slow and resource intensive one. In contrast, regulations, which contain administrative and technical requirements, can be amended as knowledge is gained from scientific and technical developments and experience is gained from regulated practices and in intervention situations.

2.2. The legislation "shall specify facilities, activities and materials that are included in the scope of the legislation" (Ref. [1], para. 2.4(2)). The legislation should be applicable to occupational, public and medical exposure, and to all sources of ionizing radiation (in use or disused). Thus, it should apply both to radiation sources containing radionuclides and to radiation generating machines (e.g. X ray equipment, particle accelerators), even those not in use. The legislation should also make reference to the radiation protection requirements established in the Basic Safety Standards [2] (i.e. requirements for the justification of practices, the limitation of doses, the optimization of protection and safety, dose constraints and guidance levels for medical exposure).

2.3. While it is required that the legislation specify facilities, activities and materials that are included in its scope, and this may be done by specifying exclusions from its requirements, it should also confer on the regulatory body authority to exclude certain exposures on the grounds of their being considered unamenable (not amenable) to regulatory control by any practicable means [2]. The regulatory body should also be granted authority to exempt certain practices from the requirements of the regulations when the imposition of such requirements is unnecessary. Such provisions for exemption should be in line with the provisions in Schedule I of the Basic Safety Standards [2].

PRIME RESPONSIBILITY FOR SAFETY

2.4. A fundamental concept that is required to be made clear in the legislation is that prime responsibility for radiation safety resides with those authorized to possess and to use, manufacture, supply or install radiation sources. "The prime responsibility for safety shall be assigned to the operator" (Ref. [1], para. 2.3). In relation to medical exposures, the final responsibility is placed on the medical practitioner. "Registrants and licensees shall ensure that (a) no patient is administered a diagnostic or therapeutic medical exposure unless the

exposure is prescribed by a medical practitioner; (b) medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure" (Ref. [2], para. II.1(a), (b)).

LEGISLATIVE BASIS FOR A REGULATORY BODY

2.5. Government is required to establish through legislation a national regulatory body to regulate the introduction and conduct of any practice involving sources of radiation (Ref. [1], para. 2.2(4)). The term 'regulatory body' [2] means an authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. Although it is preferable for a single body to have regulatory responsibilities for radiation safety, especially in States with no nuclear power programme, such responsibilities are often divided among several bodies already having responsibilities for protection and safety in general, e.g. a ministry of health regulating medical practices, a ministry of labour regulating industrial and research practices, and a ministry of transport regulating the transport of hazardous materials. In legislating to establish the governmental infrastructure, it should be ensured that the regulation of all aspects of radiation safety is covered and that the responsibilities of the governmental bodies involved are clearly specified and allocated. Where regulatory responsibilities for radiation safety are divided, the legislation should establish clear lines of authority and responsibility so as to avoid gaps or overlaps, and so that those operators that use or possess sources know which parts of their activities are within the remit of the various governmental bodies. For these purposes, the legislation should require that the regulatory bodies formally establish a system of liaison and working procedures so as to ensure an appropriate degree of co-ordination and co-operation between regulatory bodies sharing responsibilities.

2.6. The regulatory body is required (Ref. [1], para. 2.6) to have the authority to:

(a) Develop safety principles and criteria;

[2] The term regulatory body and the term Regulatory Authority as used in Ref. [2] are equivalent.

(b) Establish regulations and issue guidance;
(c) Require any operator to conduct a safety assessment;
(d) Require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary;
(e) Issue, amend, suspend or revoke authorizations and to set conditions;
(f) Require an operator to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
(g) Enter a site or facility at any time to carry out an inspection;
(h) Enforce regulatory requirements;
(i) Communicate directly with governmental authorities at higher levels when such communication is considered to be necessary for exercising effectively the functions of the body;
(j) Obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate;
(k) Communicate independently its regulatory requirements, decisions and opinions and their basis to the public;
(l) Make available to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
(m) Liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security and transport of dangerous goods;
(n) Liaise with regulatory bodies of other States and with international organizations to promote co-operation and the exchange of regulatory information.

2.7. The regulations and guidance that the regulatory body is required to establish should cover such matters as:

(a) Technical, administrative and competence requirements governing radiation safety;
(b) Administrative requirements governing notification and authorization;
(c) Criteria for exemption from regulatory requirements;
(d) Management of radioactive waste;
(e) Transport of radioactive material;
(f) Supporting codes of practice and guides, as appropriate, to assist in implementing the regulatory body's regulations and in enhancing radiation safety.

2.8. The legislation is required to establish a procedure for the review of, and appeal against, regulatory decisions (Ref. [1], para. 2.4(7)). The lodging of such an appeal, however, should not absolve operators from complying with safety requirements and conditions as specified by the regulatory body pending the result of the appeal.

2.9. In order to ensure the effective discharge of its responsibilities and performance of its functions, the legislation should also empower the regulatory body, within its sphere of responsibility, as appropriate:

(a) To establish arrangements with other governmental and non-governmental bodies, when it is necessary to discharge regulatory responsibilities, for performing essential activities and providing services (e.g. individual monitoring, training in radiation safety, calibration of radiation measuring equipment) that are beyond the capabilities required of operators and which are not otherwise available;
(b) To make arrangements for the approval of dosimetry services to undertake the assessment of and/or make and keep records of individual doses for the types of practice authorized;
(c) To co-ordinate its emergency preparedness and response arrangements with national and local plans and to fulfil its related international agreements and obligations, and to participate in the development and implementation of the more generic plans, to the extent that they concern aspects of radiation safety.

REGULATORY INDEPENDENCE

2.10. The importance of regulatory independence is reflected in the Safety Requirements (Ref. [1], para. 2.2(2)), which require the establishment of a regulatory body and its separation and independence from any governmental departments or agencies and other organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. The primary reason for this independence is that it should be ensured that regulatory judgements can be made, and regulatory enforcement actions taken, without pressure from interests that may conflict with safety. Furthermore, the credibility of the regulatory body will depend in large part upon whether it is considered to be independent of the organizations that it regulates, as well as independent of the governmental agencies and industry groups that develop and promote the practices being regulated.

2.11. It is recognized that a regulatory body cannot in every respect be absolutely independent of other areas of government; it must function within a national system of legislation and policies, just as other governmental bodies and private organizations do. Nevertheless, for the credibility and effectiveness of the regulatory body, it should have effective independence so as to be able to take the necessary decisions with regard to the protection of workers, patients, the public and the environment.

2.12. The need for the independence of the regulatory body should not be interpreted to mean that it ought to have an adversarial relationship with operators or with any other party.

Aspects of regulatory independence

2.13. *Political aspects.* The political system is required to ensure the clear and effective separation of responsibilities and duties between the regulatory body and the organizations promoting or furthering the development of the practices being regulated. In this regard, the distinction between independence and accountability should be made. The regulatory body should not be subject to political influence or pressure in taking decisions relating to safety. The regulatory body should, however, be accountable in respect of fulfilling its mission to protect workers, patients, the public and the environment from undue radiation exposure. One way of providing this accountability is by establishing a direct reporting line from the regulatory body to the highest levels of government. Where a regulatory body reports to a government agency that has responsibility for utilizing or promoting the practices being regulated, there should be channels for reporting to higher authorities so as to be able to resolve any conflicts of interest that may arise. This accountability should not compromise the independence of the regulatory body in taking decisions relating to safety with neutrality and objectivity.

2.14. *Legislative aspects.* The functions, competence and independence of the regulatory body in respect of safety should be defined in the legislative framework of a national regulatory system (that is, in legislation relating to radiation protection). The regulatory body is required to have the authority and responsibility to adopt or to develop regulations relating to safety to effect the legislation enacted by the legislature. The regulatory body is also required to have the authority to take decisions, including decisions on enforcement actions. There should be a formal mechanism for appeal against regulatory decisions, with predefined conditions that must be met for an appeal to be considered.

2.15. *Financial aspects.* "The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities" (Ref. [1], para. 2.2(4)). While it is recognized that the regulatory body is in principle subject, as is the rest of government, to financial controls, the budget of the regulatory body should not be subject to review and approval by the government departments or agencies and other organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities.

2.16. *Competence aspects.* The regulatory body should have independent technical expertise available to it in the areas relevant to its responsibilities for safety. The management of the regulatory body should therefore have the authority and responsibility to recruit staff with the skills and technical expertise it considers necessary to enable the regulatory body to perform its functions. In addition, the regulatory body should maintain an awareness of the 'state of the art' in safety related technology. In order to have access to external technical expertise and advice that is independent of any funding or support from operators, in support of its decision making on regulatory matters, the regulatory body is required to be able to set up and fund independent advisory bodies to provide expert opinion and advice (Ref. [1], para. 2.4(9)) and to award contracts for research and development projects. In particular, the regulatory body is required to be able "to obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate" (Ref. [1], para. 2.6(10)).

2.17. *Public information aspects.* One of the responsibilities of the regulatory body is to inform the public. "The regulatory body shall have the authority to communicate independently its regulatory requirements, decisions and opinions and their basis to the public" (Ref. [1], para. 2.6(11)). The public will have greater confidence in the safe use of nuclear and radiation related technologies if regulatory processes are open and decisions are made public. The governmental authorities should set up a system to allow independent experts and experts from major interested parties (e.g. operators, the workforce and the public) to give their views. The experts' findings should be made public.

2.18. *International aspects.* "The regulatory body shall have the authority to liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information" (Ref. [1], para. 2.6(14)).

LEGISLATION FOR FUNDING

2.19. According to the Safety Requirements publication GS-R-1 (Ref. [1], para. 2.2(4)), one requirement is to ensure that the regulatory body has adequate financial resources to enable it to discharge its assigned responsibilities. Specific provision is required to be made either through the enactment of legislation or in the national fiscal process to budget for the conduct of regulatory activities, including staffing and staff training, facilities, equipment, logistical support, documentation and the use of consultants, that allow the regulatory body to discharge its responsibilities and maintain its independence. If costs are to be recovered by means of authorization and inspection fees, the authority to levy charges should be granted by the legislation. To the extent that the regulatory body levies charges for authorizations and inspections and fines relating to enforcement, the link between the funds generated and the regulatory body's budget should be made public to help prevent abuses, or the appearance of abuses, by the regulatory body. One approach to take to avoid abuses is to set up a mechanism whereby the funds generated are payable to the general treasury and the parliament is the body that funds the regulatory body's operations.

LEGISLATIVE FOCUS ON INTERAGENCY CO-OPERATION

2.20. "The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary (Ref. [1], para. 3.4):

(a) environmental protection;
(b) public and occupational health;
(c) emergency planning and preparedness;
(d) radioactive waste management (including determination of national policy);
(e) public liability (including implementation of national regulations and international conventions concerning third party liability);
(f) physical protection and safeguards;
(g) water use and consumption of food;
(h) land use and planning; and
(i) safety in the transport of dangerous goods."

2.21. In preparing legislation, special consideration should be given to the establishment of a system of strict regulatory control for protection and safety,

security and accountability in relation to radiation sources. Likewise, attention should be paid to how governmental agencies sharing responsibilities will co-operate so that this system of regulatory control works effectively and so that timely, effective enforcement and corrective actions are taken. In this regard, and to the extent warranted, the legislation is required to provide for the establishment of a direct link to encourage co-operation and co-ordination between the regulatory body and other relevant governmental agencies. For example, this link could extend to customs authorities to ensure that there is adequate regulatory control over the import and export of radiation sources, and that the persons importing or receiving the sources are identified and authorized; or to transport authorities to ensure that transport authorizations for radioactive material are issued in accordance with the applicable radiation safety requirements. In addition, the regulatory body should also implement co-operation agreements with governmental agencies responsible for matters relating to the regulation of security and fire protection.

3. PRINCIPAL FUNCTIONS AND ACTIVITIES OF THE REGULATORY BODY

3.1. The functions and activities of the regulatory body are described in Sections 3 and 5 of the Safety Requirements publication No. GS-R-1 [1] and include, in particular, establishing regulations that set out requirements for radiation safety; establishing a process for notification and authorization for control over radiation sources, including a system of review and assessment of applications for authorization; carrying out regulatory inspections; taking necessary enforcement actions; and investigating accidents or circumstances potentially giving rise to accidents.

ESTABLISHING REGULATIONS AND GUIDES

3.2. One of the prerequisites for the safety of facilities and activities, as set out in the Safety Requirements publication No. GS-R-1, is to establish and maintain a regulatory body with the responsibility "for establishing safety principles, criteria, regulations and guides" (Ref. [1], para. 2.2(3)). The legislation shall establish a regulatory body (Ref. [1], para. 2.4(4)) with "the authority to establish regulations and issue guidance" (Ref. [1], para. 2.6(2)).

Scope of regulations and exclusion from the regulatory scope

3.3. The legislation "shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements for any particular part of the legislation" (Ref. [1], para. 2.4(2)).

3.4. The first step towards the development of radiation safety regulations should be to identify clearly the practices, sources and/or exposures to which regulatory requirements are to be applied; that is, the scope of the regulations. The scope should be as unambiguous as practicable; anything that is not included in the scope is excluded or is considered outside the boundary of the regulations.

3.5. For reasons of clarity, some things that are excluded from the scope should be specified. According to Ref. [2] (para. 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 Standards." Examples of such exposures are those due to ^{40}K in the body, cosmic radiation at the surface of the Earth and unmodified concentrations of radionuclides in most raw materials.

Development and use of regulations

3.6. "In fulfilling its statutory obligations, the regulatory body shall establish, promote or adopt regulations and guides upon which its regulatory actions are based" (Ref. [1], para. 3.2(1)). "The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated" (Ref. [1], para. 5.25).

3.7. "The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations" (Ref. [1], para. 5.26).

3.8. Regulatory bodies should establish a basic foundation of performance regulations[3] that is consistent with the general principles of radiation safety. Regulations should be based on the Basic Safety Standards [2] and other international standards for radiation protection and the safety of radiation sources. "Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards" (Ref. [1], para. 5.28).

3.9. Regulatory bodies should also give consideration to the establishment of prescriptive regulations, although the degree to which this is done will depend on national approaches. In some States, for example, detailed guidance would be preferred to prescriptive regulations.

3.10. The regulatory body should ensure that the following administrative and procedural topics and requirements are covered in the regulations:

(a) The exact name and location of the regulatory body;
(b) The purpose of the regulations, their scope and their date of entry into force;
(c) The powers of the regulatory body, such as powers of authorization, inspection and enforcement;
(d) The relationship of a given set of regulations to other governmental regulations in force;
(e) The criteria to be met in an application for exemption from certain procedural aspects of the regulatory requirements;
(f) The requirements for occupational radiation exposure, public radiation exposure, dose limits, medical exposure, management of radioactive

[3] A performance regulation is general and simply specifies the overall radiation safety requirement and basic operational parameters. A prescriptive regulation is more specific and states how to achieve radiation safety. The development of any particular radiation safety regulation will involve a balance between two concerns — the need for flexibility to permit easy adaptation of the regulations to evolving circumstances and technology (performance regulations) versus the need to include detailed requirements for safety which also make it easier to determine whether the requirements are being met (prescriptive regulations). Most regulations contain both performance requirements and prescriptive requirements. However, the general national approach to regulations and the results achieved by the regulatory body will often dictate whether the regulations are either predominantly performance oriented or predominantly prescriptive in nature.

waste, transport of radioactive material and emergency exposure situations;

(g) The financial assurance for dealing with orphan sources, radiological accidents and waste management (including decommissioning and waste disposal).

Development and use of guidance documents

3.11. "Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary" (Ref. [1], para. 5.27). Irrespective of the degree to which the regulatory body has developed prescriptive regulations, the regulatory body is required to give consideration to supplementing its regulations with guidance documents, where appropriate, based on those of the IAEA and of the other joint sponsoring organizations of this Safety Guide. Guides directed at those practices that have the greatest potential to cause exposure are a useful supplement to the performance regulations. There may be a need to provide for some flexibility in their application.

3.12. Guides are intended for use by the regulatory body, operators, technical service providers and equipment manufacturers, or combinations of these. Their purpose is to provide guidance on how to implement regulatory requirements, thus enhancing radiation safety and improving effectiveness and efficiency. The regulatory body should also support the production of guidance documents by professional bodies wishing to help their members in the discharge of their regulatory responsibilities regarding safety. Guides should be grouped into several broad categories as follows:

(a) Detailed or specific recommendations, concerning facilities and equipment, operating procedures and protocols (e.g. for nuclear medicine, radiotherapy, diagnostic and interventional radiology, dental radiology, industrial radiography, industrial irradiation, well logging), and the qualification and training of personnel, that pertain to a specific radiation practice and that can be adopted by operators as a means of meeting performance regulations;

(b) Practical radiation safety manuals covering various practices and procedures that serve as aids for the training of workers and for management in setting up local radiation safety rules;

(c) Procedural guides such as those pertaining to instrument calibration, individual monitoring, environmental surveys and radioactive waste management, for use by operators and/or technical service providers;

(d) Guidance relating to the protection of persons undergoing medical exposure;
(e) Safety assessment plans that identify areas that need to be evaluated or reviewed for the authorization and inspection of radiation sources;
(f) Guidance on the safe transport of radioactive material;
(g) Procedures for the conduct of investigations;
(h) Plans and procedures for emergency preparedness and response.

3.13. The regulatory body should also prepare detailed guidance for operators on how to notify and how to apply for authorization. This may include printed (or electronic) forms to be completed by operators in a question and answer format, so that all relevant information is gathered.

Exemption from regulatory requirements

3.14. The legislation "shall establish authorization and other processes (such as notification and exemption)… and shall specify the steps of the processes" (Ref. [1], para. 2.4(3)).

3.15. Exemption is a regulatory mechanism that provides operators with relief from regulatory requirements, including those for notification and authorization of practices or sources within a practice. Where exemption is considered appropriate, the exemption criteria presented in Schedule I of the Basic Safety Standards [2] should be applied for such purposes. This Schedule describes those practices or sources within a practice that can be automatically exempted without further consideration from the requirements of the Basic Safety Standards and those sources for which a conditional exemption may be granted.

Clearance from regulatory requirements

3.16. Clearance is a regulatory mechanism similar to exemption and relates to the removal of radioactive material or radioactive objects within authorized practices from any further control by the regulatory body. It relieves operators that wish to release substances, material or objects from further regulatory requirements subject to compliance with clearance levels approved by the regulatory body. Both exemption and clearance are essentially generic authorizations.

3.17. Clearance applies mainly, however, to radioactive residues that are an undesirable consequence of conducting a practice, and it allows the release of

such residues from further regulatory control, provided that the residues meet the specified criteria. Clearance criteria given in Ref. [2] are the same as those applicable for the purpose of exemption to practices and to sources within practices, except for bulk amounts. The Basic Safety Standards [2] indicate that bulk amounts of materials with activity concentrations lower than the guidance exemption levels specified in Ref. [2] may need further consideration by the regulatory body.

Process for developing regulations and guides

3.18. The regulatory body should follow a consistent procedure for establishing, revising and revoking regulations and guides. A general procedure should be prepared that details the general format and style of language to be used in the regulations and guides. This procedure should be distributed to members of working groups engaged in drafting and should be adhered to by all parties involved. These procedures should be efficient and flexible enough to permit revisions to be made to take account of changing conditions, or as justified by advances in technology. Because of differences in the legal systems and practices of States, it is impossible to provide detailed procedural guidance for establishing regulations and guides that can be used by all States. However, certain basic steps for establishing regulations and guides can be specified. The procedure used by the regulatory body to establish regulations and guides should include the following steps:

(a) *Determination of the need for the regulations and guides.* The need for the regulations and guides may arise from the regulatory body's activities within its sets of responsibilities and functions as specified in Ref. [1], and from the inventory of radiation sources and practices using radiation sources in the State.
(b) *Setting the priority for the development of regulations and guides.* The regulatory body should consider the advantages and disadvantages of the proposed regulations and guides, including such matters as: the risk associated with the facility or activity; the need for improvements in safety; the number of operators to be affected; the effects on the efficiency of the authorization process; and the feedback of information and experience from inspections, investigations and enforcement activities.
(c) *Determination of the scope of the regulations and guides.* This includes the identification of the type of facility or activity to be covered.

(d) *Determination of the resources necessary.* This will depend on the resources available and on the timescale for the preparation and establishment of the regulations and guides.

These four steps should form the basis for a decision on whether or not to prepare the proposed regulations and guides, including the adoption or adaptation of regulations issued by others. These additional steps should follow a positive decision:

(e) *Collection of information.* The information necessary to prepare the proposed regulations and guides should be collected. This would include collecting regulations, guides or recommendations from other States or from international organizations such as the IAEA, the International Commission on Radiological Protection (ICRP), the International Commission on Radiological Units and Measurements (ICRU), the International Electrotechnical Commission (IEC), the ILO, the International Organization for Standardization (ISO), the OECD/NEA, the PAHO and the WHO.

(f) *Drafting of the regulations and guides.* The staff of the regulatory body, consultants, professional societies or advisory committees may draft the initial versions of the regulations and guides. Regulations and guides should be written in a style that is clear and easy to understand. They should be relevant, precise and unambiguous so as to be readily applicable and enforceable.

(g) *Review of the regulations and guides.* Although practices vary widely, legal staff and special advisory committees, as appropriate, would usually review the initial versions of the proposed regulations and guides. "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience" (Ref. [1], para. 5.28). In some States, operators, professional societies or other organizations participate in these reviews. A draft version may also be published provisionally with an invitation for comment from the public. Comments received as a result of the review should be analysed, evaluated and resolved as appropriate. Whichever review process is adopted, a formal procedure should be established to ensure that advice on the proposed regulations is obtained from all concerned parties. The regulatory body should then make a final decision with regard to the advice before the regulations are finalized. At this stage consideration should also be given to the implications of the regulations for existing facilities.

(h) *Establishing and issuing the regulations and guides.* The regulations should be established and promulgated in a manner that makes them legally binding according to the national legal system, thereby ensuring that their provisions can be enforced by the regulatory body. Guides may be formally issued with a lower level of approval, however, since they are only advisory in nature.

Process for review and revision of regulations and guides

3.19. The regulatory body should ensure that regulations and guides are kept up to date and should establish procedures for their periodic review. Experience in implementing the regulations should be examined and any problems or difficulties that may arise should be duly considered. The status of applicable requirements should also be examined in the light of new, safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. However, events may occasionally occur that necessitate more frequent revisions. The reasons for revising regulations may include: changes in legislation; feedback of information and experience from events, incidents and accidents; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.

3.20. The procedures applicable in the development of regulations can also be followed when making any necessary revisions. Advice should be obtained from all parties concerned. Operators and others potentially affected by the revised regulations should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.

NOTIFICATION AND AUTHORIZATION (BY REGISTRATION OR LICENCE)

3.21. "The regulatory body shall establish a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption, or for removal from regulatory control" (Ref. [1], para. 3.3(1)). In addition, "the regulatory body shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information" (Ref. [1], para. 3.3(3)).

3.22. "Any legal person applying for an authorization shall make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source. " In addition, "if the potential for an exposure is greater than any level specified by the [regulatory body, the legal person shall] have a safety assessment made and submitted to the [regulatory body] as part of the application" (Ref. [2], para. 2.13).

3.23. The Basic Safety Standards apply the terms notification, and authorization by registration or licence to indicate broadly an appropriate type of control based upon the levels of risk or complexity associated with non-exempted practices, notification being applied to the lowest level of risk or complexity and licence to the highest. A categorization system for sealed radioactive sources based on considerations of health detriment, among other factors, has been published by the IAEA [7]. This categorization should be used to assist regulatory bodies in determining the graded approach to notification and authorization that should be adopted. The regulatory body should establish criteria for determining whether notification only is sufficient, or whether an authorization is required.

Notification

3.24. Notification is the mechanism that provides initial information to the regulatory body about the possession of a source or the intention to conduct a practice. The Basic Safety Standards [2] require that the regulatory system itself requires that any such possession of a source or intention to conduct a practice, unless exempted, be notified to the regulatory body. For those sources and sources within practices for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible, but which are not suitable for exemption for some reason (e.g. to prevent uncontrolled waste disposal), the regulatory body may only require notification.

3.25. The regulatory body should maintain a national register of radiation sources. The main input of data to the inventory is provided via notification.

3.26. For radiation sources and sources within practices for which registration or a licence is required, an application for either may also serve as notification.

Registration

3.27. Registration may be employed as a relatively simple and efficient method of authorization if certain criteria can be met. General criteria that should be used to assess the suitability of a practice as a candidate for registration are: "(a) safety can largely be ensured by the design of 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" (Ref. [2], footnote 7).

3.28. The information required from the applicant for registration should be sufficient to allow the regulatory body to form a judgement on the basis of the above criteria. Examples of practices or sources within practices that may be candidates for registration, in accordance with the criteria given in para. 3.27, are:

(a) Industrial gauges in permanent locations,
(b) Dental diagnostic X rays,
(c) Radio-immunoanalysis,
(d) Diffractometry apparatus.

Licensing

3.29. Authorization by licensing is required by the regulatory body for all practices, other than those to which an exemption applies, that are not otherwise designated as suitable for notification alone or registration [2]. In principle, a licence should be required for the higher risk or more complex practices, including those for which the radiation protection depends significantly or largely on human performance, as with some medical applications (e.g. radiotherapy) and industrial radiography, for example. The information required from the applicant will be more detailed than for registration and should include a more detailed assessment of the nature, magnitude and likelihood of potential exposures arising from the source or sources within the practice.

Documents submitted by applicants for authorization

3.30. "Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and

assessed by the regulatory body in accordance with clearly defined procedures" (Ref. [1], para. 5.3).

3.31. "The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed timescales, all information that is specified or requested" (Ref. [1], para. 5.4). "The regulatory body shall establish a process for dealing with applications" (Ref. [1], para. 3.3(1)).

3.32. In all cases the operators should, as a minimum, be required to submit in support of notification and for application for authorization the following information:

(a) Clear identification of the applicant for authorization, i.e. the operator and/or the actual person applying;
(b) Specification of the system to be used for source accounting;
(c) Clear specification of the source(s) and associated facilities and equipment to be used in the practice;
(d) The location(s) where the radiation source(s) will be stored and where they will be used.

3.33. In addition, an application for authorization should include:

(a) Identification of the individual(s) representing the operator;
(b) Identification and details of qualifications of the radiation protection officer and, where appropriate, qualified expert(s);
(c) Details of qualifications and training in radiation protection of workers engaged in activities that involve or could involve occupational exposure;
(d) For practices involving medical exposure, "the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or a statement that only medical practitioners with 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" (Ref. [2], para 2.14);
(e) For significant risk sources, unusual or complex practices, or consumer products, a justification for engaging in the regulated activity or practice;
(f) For significant risk sources, copies of the operating and maintenance procedures that will be followed;

(g) A plan of the premises with an assessment of the nature, magnitude and likelihood of exposures attributable to the radiation source(s) made by the radiation protection officer or a qualified expert;
(h) For significant risk sources or unusual or complex practices, a safety assessment that states the probability and magnitude of potential exposures (e.g. a safety assessment should be made for Category 1 and 2 sources, as defined in Ref. [7]);
(i) The occupational radiation protection programme, including arrangements for monitoring of workers and the workplace, and the provision and maintenance of personal protective equipment and equipment for radiation detection;
(j) For practices involving medical exposure, information relating to the radiological protection of patients, including arrangements for the calibration of sources used for medical exposure, clinical dosimetry and quality assurance programmes;
(k) Radiation protection of the public, where appropriate, with all pathways of exposure taken into account;
(l) Arrangements to ensure safety and security of sources;
(m) Arrangements for the management of radioactive waste, including the management of disused sources (disused sources should either be managed in the State concerned or be returned to the supplier or manufacturer), and information on the financial arrangements for such purposes;
(n) Emergency arrangements and financial arrangements for a radiological emergency, where appropriate.

3.34. "For complex facilities… authorization may be carried out in several stages" (Ref. [1], para. 5.4). For facilities such as industrial irradiators and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistage process of authorization (e.g. it may require the submission of an application to construct before construction can begin). The regulatory body may also prohibit the procurement of radiation sources (including their import) until a particular stage of construction has been completed and the safe and secure storage of sources can be ensured. The authorization process may also be subdivided into various steps (e.g. acceptance tests and commissioning, for which the regulatory body may require additional information before the authorization process can be completed).

3.35. Certain information submitted by the operator should be considered confidential, either because of its proprietary nature, or for security reasons, or

because of the rights of the individual to privacy, in accordance with national legislation and regulations.

Review and assessment of applications for authorization

3.36. "A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator, to satisfy itself that:

(a) the available information demonstrates the safety of the facility or proposed activity;
(b) the information contained in the operator's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements; and
(c) the technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety" (Ref. [1], para. 5.9). Additionally, the justification for engaging in the practice should be evaluated.[4]

3.37. "In undertaking its own review and assessment of a safety submission presented by the operator, the regulatory body shall not rely solely on any safety assessment performed for it by consultants or on that conducted by the operator. Accordingly, the regulatory body shall have a full time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants" (Ref. [1], para. 4.8).

3.38. The regulatory body should establish internal procedures to be followed in the review and assessment of an application for authorization, to provide assurance that all topics significant to safety will be covered and that operators for similar facilities or activities will be treated equally. The regulatory body should request any additional information to rectify deficiencies in the information provided by the applicant. The scope and depth of the review and

[4] The justification of some practices may well be matters of national policy and not the direct responsibility of the regulatory body.

assessment will depend on several factors such as the complexity of the practice and the associated risks.

3.39. The regulatory body should establish which requirements, regulations, guides and industrial standards are applicable to each type of facility or activity, and should determine the requirements to be placed on operators for each type of facility or activity. Where there are no such requirements, regulations, guides or industrial standards in force, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the applicable requirements as a reference for deciding on the acceptability of an operator's submission.

3.40. To facilitate the review and assessment process, the regulatory body may develop lists of approved equipment containing radiation sources, based on the submission of a certificate confirming compliance with the international industry standards (of the IEC and the ISO). An expert with the appropriate skills or an independent accreditation laboratory of the State concerned, or of another State or an international organization, would issue the certificate after reviewing a generic safety assessment. The generic safety assessment would be documented, together with a summary of the conditions of use of the device and any appropriate limitations on its use.

3.41. It would be inappropriate for the regulatory body to issue an authorization solely because a model of equipment was 'type approved' or carried a certificate of compliance, in accordance with IEC standards or nationally recognized equivalent standards in the State of use. The safety of each facility or activity will depend on many factors in addition to the design and manufacture of the radiation source or equipment, such as the design and construction of the building housing the radiation source, the qualification and training of the staff using the equipment, and operational aspects.

Regulatory inspection for review and assessment of an application for authorization

3.42. A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant. For significant risk sources or unusual or complex practices, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used. These inspections will also allow the regulatory body to supplement the information and data needed for

review and assessment. Additionally, the regulatory body will be able to extend its practical understanding of the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization.

Issuing an authorization

3.43. "The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either: (1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or (2) the refusal of such an authorization. The regulatory body shall formally record the basis for these decisions" (Ref. [1], para. 5.5). Its decisions should be based on the legislation and regulations.

3.44. "The regulatory body shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified):

(a) the facilities, activities or inventories of sources covered by the authorization;
(b) the requirements for notifying the regulatory body of any modifications to safety related aspects;
(c) the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel;
(d) any limits on operation and use (such as dose or discharge limits, action levels or limits on the duration of the authorization);
(e) conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;
(f) any additional separate authorizations that the operator is required to obtain from the regulatory body;
(g) the requirements for incident reporting;
(h) the reports that the operator is required to make to the regulatory body;
(i) the records that the operator is required to retain and the time periods for which they must be retained; and
(j) the emergency preparedness arrangements" (Ref. [1], para. 3.2(3)).

3.45. The regulatory body should issue the authorization certificate to the operator. The designated officer of the regulatory body should sign the authorization certificate.

Amending or renewing an authorization

3.46. "Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations" (Ref. [1], para. 5.6).

3.47. The regulatory body should require the renewal of an authorization after a set time interval. In such instances, a review would usually be made of the findings of inspections and of other information on performance, and its results would be documented as part of the revalidation process. Authorization details should be kept up to date.

3.48. The regulatory body should require the operator to notify any significant changes to safety related aspects of the practice and to apply, where necessary, for an amendment to, or a renewal of, the authorization. Any modification to safety related aspects of a facility or an activity with radiation sources should be subject to an assessment by the operator, with account taken of the possible magnitude and nature of the associated risk. The regulatory body is required to review this assessment.

Cancellation of authorization and authorization of transfer or disposal

3.49. An authorization for a practice involving the use of radiation sources may be cancelled because the radiation sources are no longer required or because the regulatory body has taken an enforcement action. The regulatory body is required to ensure that the radiation sources are transferred to an operator that possesses a valid authorization (Ref. [2], para. 2.34(b)), or are disposed of to an authorized waste management facility. The regulatory body should provide guidance on radiological criteria for the removal of regulatory control from materials, facilities and sites. Further information is provided in Ref. [8].

Financial assurance

3.50. Regulations should require, as a condition for granting an authorization for select facilities and/or sources, that adequate funds be made available for the timely decommissioning of facilities and the management of radioactive waste and/or spent radiation sources, including disposal. The arrangements for financial assurance proposed by an applicant should be incorporated as a condition of the authorization.

Authorization of suppliers of equipment or radiation sources

3.51. Suppliers are one of the parties identified as having responsibilities for the application of the Basic Safety Standards (Ref. [2], para. 1.7). "The regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator" (Ref. [1], para. 5.12). The regulatory body should require suppliers of sources and equipment, as well as companies that provide maintenance services, to be authorized. The regulatory body should, as necessary, require these organizations to:

(a) Ensure that the design, construction and safety of equipment conform with the relevant standards of the IEC and the ISO or equivalent national standards;
(b) Ensure the availability of spare parts relating to safety and the provision of technical assistance for a reasonable period after the supply of the equipment;
(c) Provide assistance when unplanned events occur in the operation of the equipment supplied, even if there is no immediate danger to health;
(d) Accept the return of spent sealed radioactive sources that were originally provided by the supplier;
(e) Provide relevant safety related information on the use and maintenance of the radiation sources.

3.52. The regulatory body should require the manufacturer, in its application for authorization to supply equipment or radiation sources, to submit detailed information on:

(a) The design, construction and safety of the facility, equipment or radiation source, as appropriate;
(b) The procedures and the results of prototype tests for demonstrating that the equipment will maintain its integrity under conditions of normal use, possible misuse and accidental damage;
(c) The procedures for installation and for acceptance tests, as appropriate;
(d) The quality control procedures to ensure that the equipment meets the relevant national and international standards and codes for design;
(e) The specifications for operating and maintenance instructions in a language understandable to the operator, as determined by the regulatory body.

INSPECTION

3.53. "The regulatory body shall carry out regulatory inspections" (Ref. [1], para. 3.2(4)) to verify that practices are carried out, and that sources are used within practices, in accordance with the relevant regulations and with any conditions of the registration or licence. The regulatory body's inspection programme should include as key elements: a system of prioritizing inspections based on a categorization system such as that established for sealed radioactive sources [7]; on-site visits of inspectors; the review of radiation safety assessments made by the operators; the investigation and follow-up of accidents; and the submission of information on key operational safety parameters by operators. On-site inspection is the one element of the regulatory regime closest to actual operations, and a significant proportion of the regulatory body's resources should be allocated to this task.

3.54. "The main purposes of regulatory inspection and enforcement are to ensure that:

(a) facilities, equipment and work performance meet all necessary requirements;
(b) relevant documents and instructions are valid and are being complied with;
(c) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;
(d) deficiencies and deviations are identified and are corrected or justified without undue delay;
(e) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate; and
(f) the operator is managing safety in a proper manner.

Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out" (Ref. [1], para. 5.13).

Types of inspection

3.55. The regulatory body should conduct two general types of inspection, namely, planned inspections and reactive inspections or investigations. Inspections may be conducted by individuals or teams and may be announced in advance or unannounced, as part of a general programme or with specific aims.

3.56. Planned inspections are those carried out in fulfilment of, and in conformity with, a structured and largely prearranged inspection programme developed by the regulatory body. They differ from reactive inspections in that they are necessarily scheduled in advance by the regulatory body and are not prompted by unusual or unexpected circumstances.

3.57. "The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity" (Ref. [1], para. 5.14). The priority and frequency of such inspections should reflect the risk associated with the radiation source and the complexity of the practice, as well as the possible consequences of an accident and the type and frequency of any violations found by inspections. The regulatory body should also compile and analyse data on the performance of operators.

3.58. An announced inspection is an inspection visit of which the operator has been notified in advance by the regulatory body. The main advantage of announced inspections is that the regulatory inspector is able to discuss plans and needs in advance with the operator's personnel, and to secure assurances that documentation or personnel will be available for inspection or interview, and that activities can be inspected as scheduled.

3.59. The advantage of unannounced inspections is that the actual state of the facility or activity and the way in which it is being operated can be observed. The disadvantage of unannounced inspections is that key personnel may not be available and it may not be possible to inspect parts of the facility that are not in operation at the time.

Preparation for an inspection

3.60. Before an inspection is carried out, the regulatory inspector should be thoroughly prepared. The type of preparation will depend on the type and method of inspection to be used. However, preparation may include a review of the following:

(a) Regulatory requirements relating to the authorized facility or activity, and conditions on the authorization issued to the operator;
(b) Findings of previous inspections and previous enforcement actions, and any unresolved issues from previous inspections;

(c) Correspondence between the regulatory body and the operator;
(d) Documentation on design and operation of the facility.

Internal guidance

3.61. To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. The procedures should be such as to ensure a systematic and consistent approach to inspection, allowing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. Appropriate information and guidance should be provided to the inspectors concerned and each inspector should be given adequate training in following the procedures. Appropriate subjects for the inspection procedures could include:

(a) The legal basis of inspection and the extent of the inspector's authority;
(b) The use of regulatory requirements, regulations, guides and industrial standards;
(c) The implementation of the inspection programme, including persons to be interviewed, documents to be reviewed, measurements to be made, equipment to be used, and the use of checklists and technical information;
(d) Reporting requirements and practices for inspectors;
(e) Standards of conduct for inspectors;
(f) Enforcement policy, procedures and practices.

3.62. Inspectors, owing to the authority vested in them, should conduct themselves in a manner that inspires confidence and respect concerning their competence and integrity. They should, for example, make adequate preparation by gathering and reviewing all relevant information and data, and they should be knowledgeable about the facility or activity that they are required to inspect. The regulatory body should stress in its guidance the importance of objectivity and fairness on the part of inspectors, together with the need to respect the rules for the facility as established by the operator.

Methods of inspection

3.63. The inspection programme of the regulatory body should incorporate and use a variety of methods, as follows:

(a) *Direct observation of working practices and equipment.* Such observation is aimed at gaining a general impression of the operator's capabilities and

performance, and may include determining whether: personnel follow documented procedures; suitable warning signs are displayed at required locations; radiation sources and their containers are correctly identified and labelled; the storage area for radiation sources is appropriate and secure; the storage area for radioactive waste is appropriate and secure; and equipment for radiation detection is appropriate, functioning, calibrated and maintained.

(b) *Discussion and interviews.* The inspectors should conduct discussions and interviews with the operator's personnel.

(c) *Examination of procedures, records and documentation.* Documentation and records examined by a regulatory inspector may cover: the radiation source inventory and the inventory controls that are to be conducted on a regular basis by operators; utilization logs; waste management procedures; records of the disposal of radioactive sources; qualification and training of personnel; records of incidents and accidents; quality assurance records; test results and data; the results of calibrations, clinical dosimetry and periodic checks of the relevant physical and clinical parameters used in medical exposure for diagnostic examinations and treatments; operational and maintenance records; and records of individual exposure.

(d) *Tests and measurements.* The extent to which the regulatory body carries out its own tests and measurements independently of the operator varies greatly between States, depending on such factors as the qualifications of the regulatory inspectors, its regulatory philosophy, and the experience and demonstrated performance of the operators. The regulatory body should not carry out tests and measurements that are the responsibility of the operator. In most instances, tests and measurements carried out by the regulatory body should serve as an independent verification of those tests and measurements performed by the operator.

Indicators of degraded safety performance

3.64. In addition to verifying compliance with all applicable regulatory requirements, the regulatory body's inspection programme should be such as to provide a general sense of the 'safety' of operations. Perspectives on safety in general should be aided by the use of indicators of the potential for degraded safety performance. The more common indicators of degraded performance include: poor housekeeping; poor financial stability; insufficient staffing; high turnover of staff; poor record retrieval systems; lack of set investigation levels; lack of procedures to be followed in the event that investigation levels are exceeded; inadequate training; lack of retraining of staff; and higher than

average occupational exposures for the type of practice. These indicators could be used as a basis to inform operators of the need to improve and as a basis for establishing the frequency of inspections for any particular operator. The regulatory body should require operators to pay attention to such indicators of degraded safety performance and this should enhance the safety culture.

Inspection reports and findings

3.65. "Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process" (Ref. [1], para. 5.17). The purpose of the inspection report is to:

(a) Record the results of all inspection activities relating to safety, including actions taken on recommendations made following previous inspections;
(b) Document an assessment of the operator's activities in relation to safety;
(c) Provide a basis for notifying the operator of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;
(d) Document any recommendations by inspectors for future actions by the operator or the regulatory body.

3.66. Inspection reports typically should include:

(a) Details of the operator inspected, the purpose and date of the inspection, and the inspector's name;
(b) Reference to applicable regulations and authorization conditions;
(c) Details of the radiation sources inspected;
(d) Details of the qualification and training of the personnel using the radiation sources;
(e) Details of the management of the radioactive waste generated by the operator;
(f) A record of any deficiencies or violations found in the regulatory inspections, including a record of any regulations or authorization conditions that have been contravened;
(g) A record of the findings and conclusions of the regulatory inspector, including any corrective or enforcement actions that should be taken;
(h) A record of the recommendations made by the inspector for future actions.

3.67. Inspection reports should be distributed according to established procedures in order to:

(a) Provide a basis for future regulatory action;
(b) Document the regulatory history of a facility by maintaining a record of inspections and their findings and conclusions;
(c) Provide a basis for identifying major or generic issues that necessitate special inspections, changes to inspection plans or regulatory action;
(d) Provide a basis for the periodic review of the findings of inspections, including trends and root causes;
(e) Inform the regulatory staff responsible for the development of requirements for authorizations or new regulations;
(f) Provide a means of passing information to governmental bodies or interested parties;
(g) Provide a basis for self-assessment activities.

3.68. Inspection findings should be submitted to the operator for any necessary corrective action. Whenever corrective action is needed, a formal communication that includes the inspection findings should be sent to the operator as part of the enforcement procedure. In some States, the full inspection report is sent to the operator.

INVESTIGATION OF ACCIDENTS

3.69. "In addition to routine inspection activities, the regulatory body shall carry out inspections at short notice if an abnormal occurrence warrants immediate investigation. Such regulatory inspection shall not diminish the responsibility of the operator to investigate any such occurrence immediately" (Ref. [1], para. 5.16).

3.70. The regulatory body should require operators to carry out an investigation of any accident, to determine how it occurred and how to prevent its recurrence. Accidents involving a radiation source that are minor and confined to the workplace are usually investigated by the operator only and the findings, together with the corrective actions taken, are reported to the regulatory body. In addition to the investigation of accidents, operators should investigate instances where investigation levels are exceeded and, depending on the circumstances, may be required to submit a report to the regulatory body.

3.71. For more serious accidents or potentially serious accidents, or when operational parameters (e.g. doses) exceed regulatory limits or are significantly elevated, an independent investigation should be conducted by the regulatory body and in some cases by other governmental bodies, in addition to the investigation to be conducted by the operator. There are usually two main objectives in an investigation of a serious accident by the authorities, which are not completely separable but which need to be distinguished:

(1) Determination of the reasons why the accident happened so as to take measures to prevent its recurrence,
(2) Consideration of the legal aspects concerning liability for the accident.

3.72. The extent to which the regulatory body is involved, as an authority or as an advisor to other governmental agencies, in the investigations relating to the legal aspects and the liabilities is likely to vary depending on the national legislation. The regulatory body should establish procedures for discharging its responsibilities in its role in investigations.

3.73. To the extent practicable, the technical aspects of an accident investigation should be separated from the legal aspects, so that timely information can be provided to those who need it while protecting the legal rights of those involved in the accident or who have responsibilities in relation to the accident.

3.74. The former objective — determining why the accident happened — is of central interest with regard to radiation safety. Investigations should be carried out by, or in consultation with, a person with appropriate knowledge and experience. With regard to the accident, the regulatory body should require the following:

(a) The determination of the root causes, the sequence of events and the contributory factors;
(b) The assessment of the consequences in terms of exposure and the likelihood of exposure;
(c) The identification of preventive and corrective actions;
(d) The documentation of lessons to be learned;
(e) The recommendations of measures to be taken for the prevention of similar accidents in the future, including changes in the regulatory programme, as well as any adjustments in the radiation safety programmes of operators;

(f) The dissemination of all findings, lessons to be learned and recommendations to relevant operators, manufacturers and suppliers, both nationally and internationally.

ENFORCEMENT

3.75. "The regulatory body shall have the authority to enforce regulatory requirements" (Ref. [1], para. 2.6(8)), as laid down in regulations and conditions of authorization. "In fulfilling its statutory obligations, the regulatory body shall ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected; and shall take the necessary enforcement action in the event of violations of safety requirements" (Ref. [1], para. 3.2(5, 6)). Within the legal framework within which it is established, the regulatory body may draft and issue enabling regulations that detail procedures for determining and exercising enforcement actions as well as the rights and obligations of the operator.

3.76. "Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The regulatory body shall ensure that the operator has effectively implemented any remedial actions" (Ref. [1], para. 5.18).

Factors to be considered in determining enforcement actions

3.77. The factors to be taken into account by the regulatory body in deciding which enforcement action is appropriate in each case should include:

(a) The safety significance of the deficiency and the complexity of the corrective action needed,
(b) The seriousness of the violation,
(c) Whether the violation is a repeat violation of a less serious nature,
(d) Whether there has been a wilful violation of the limits and conditions specified in the authorization or in regulations,
(e) The identity of the person who noted and reported the non-conformance,

(f) The past performance of the operator and the performance trend,
(g) The need for consistency and openness in the treatment of operators.

Methods of enforcement

Written warnings or directives

3.78. "Deviations from, or violations of, requirements [of the authorization], or unsatisfactory situations which have minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body shall issue a written warning or directive to the operator which shall identify the nature and regulatory basis of each violation and the period of time permitted for taking remedial action" (Ref. [1], para. 5.19). This is the most common form of enforcement action and will, in most cases, suffice to remedy the safety issue.

Orders to curtail specific activities

3.79. "If there is evidence of a deterioration in the level of safety, or in the event of serious violations which in the judgement of the regulatory body pose an imminent radiological hazard to workers, public or environment, the regulatory body shall require the operator to curtail [specific] activities and to take any further action necessary to restore an adequate level of safety" (Ref. [1], para. 5.20).

Modification, suspension or revocation of the authorization

3.80. "In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the regulatory body shall direct the operator to curtail activities and may suspend or revoke the authorization. The operator shall be directed to eliminate any unsafe conditions" (Ref. [1], para. 5.21). In considering the withdrawal of an authorization, the regulatory body should ensure that activities important to safety continue to be performed by an authorized operator.

Penalties

3.81. The regulatory body should have the authority to impose or to recommend penalties, for example, fines on the operator, whether a corporate body or an individual, or to institute prosecution through the legal process,

depending on the legal system and the authorization practices of the State. The use of penalties is usually reserved for serious violations, for repeated violations of a less serious nature, or for wilful non-compliance. Experience in some States suggests that imposing penalties on the operator rather than on individual workers is preferable and is more likely to lead to improved safety performance.

The inspector's authority in relation to enforcement

3.82. "The extent of the authority of the regulatory inspectors to take on the spot enforcement actions shall be determined by the regulatory body" (Ref. [1], para. 5.23). The authority given to an inspector may depend on the structure of the regulatory body and on the inspector's duties and experience.

3.83. "Where on the spot enforcement authority is not granted to individual inspectors, the transmission of information to the regulatory body shall be suited to the urgency of the situation so that necessary actions are taken in a timely manner; information shall be transmitted immediately if the inspectors judge that the health and safety of workers or the public are at risk, or the environment is endangered" (Ref. [1], para. 5.24).

3.84. Enforcement actions taken on the spot by regulatory inspectors are appropriate only in unusual situations. In normal situations, decisions concerning enforcement actions, particularly those involving fines, the curtailment of activities or the suspension of authorization, should be approved by the regulatory body according to its established procedures.

Use of the enforcement process

3.85. The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures. The procedures should specify the policy of the regulatory body with regard to the use of regulatory actions and enforcement measures, and the associated delegated authority given to inspectors and to other staff of the regulatory body. Depending on national practices, the procedures should take account of the need to allow the operator to state a point of view on a regulatory decision, to respond to enforcement notifications and to appeal against enforcement decisions. The procedures should cover in detail the decision making approach of the regulatory body in determining the level of action to take and the way in which actions should be taken, including dealing

with the failure of the operator to comply with the regulatory enforcement requirements.

3.86. If there is no immediate risk to safety, the regulatory body should allow the operator a reasonable period of time in which to complete a corrective action. The time period should reflect the seriousness of the issue and the complexity of the corrective action required. However, in an integrated approach to safety, the contribution of each deficiency requiring a corrective action to the total risk for the facility should be considered.

3.87. Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement notifications being made.

3.88. Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the operator has responded to regulatory and enforcement measures. The purpose of these inspections should be to:

(a) Confirm that the operator has complied with the enforcement measures within the periods of time specified;
(b) Check that enforcement measures intended to protect the workers, patients, the public and the environment against an imminent radiological hazard have been taken by the operator, even though the operator may intend to appeal against the decision of the regulatory body.

Records of enforcement

3.89. "All enforcement decisions shall be confirmed to the operator in writing" (Ref. [1], para. 5.22). Internal records of decisions relating to enforcement actions and any supporting documentation should be kept in such a way that it is easily accessible and retrievable when required.

DISSEMINATION OF INFORMATION

3.90. The regulatory body is required to establish and implement a system for the timely dissemination of information on radiation safety, including modifications to regulatory requirements, to operators, manufacturers and suppliers in order to ensure that those persons who may be affected are made aware of the problems they may encounter and of the consequences if those problems are not properly addressed [1]. Information should be exchanged in

meetings or by means of the periodic mailing of notices. However, these means should not be used as a substitute for the rapid actions that may need to be taken following an actual or potential accident that may have significant and urgent implications for safety elsewhere. In this connection, Member States of the IAEA, through their contact points established pursuant to international agreements, are requested to notify the Emergency Response Centre of the IAEA of any events or circumstances that seem to have consequences or implications for safety at the national or international level.

3.91. The regulatory body is required to establish a public information programme concerning its functions and responsibilities, its policies, the uses of radiation sources and the ways in which sources are regulated for safety purposes [1]. In this respect, the regulatory body should also disseminate information on its own initiative to the public (e.g. by means of press releases) on exposure situations and accidents, and provide any information relating to radiation safety that may be of interest to the public. For this purpose, the regulatory body should establish channels of communication through which interested or affected members of the public can be informed of the duties and responsibilities of the regulatory body and of its operational activities. These channels of communication should be such that members of the public can request and be provided with specific information about radiation safety. The channels of communication should also enable members of the public to interact with the regulatory body on matters of public policy and other issues that can affect their welfare.

4. REGULATORY CONTROL OF THE SUPPLY OF CONSUMER PRODUCTS

REGULATORY APPROACH TO THE GENERIC APPROVAL OF CONSUMER PRODUCTS

General

4.1. There are some types of practice for which the associated risks are so small that a system of regulatory control is not required. In addition, there are some types of practice for which there is no effective way of exercising regulatory control after large numbers of sources have been supplied to the

public. Consumer products containing radioactive substances[5] have the first characteristic, the second characteristic being an inevitable consequence of the availability of such consumer products.

4.2. Paragraph 2.4 notes that the prime responsibility for radiation safety resides with those operators authorized to possess and to use a source. Consumer products constitute a special category of source, however, in that persons possessing them, and the public at large, may well not know that the product contains a radioactive substance and, in general, they will not be able to evaluate the significance of any radiation exposure incurred. The only method of control is by means of the authorization of their supply. In authorizing the supply of such consumer products, the regulatory body should therefore ensure the appropriate protection of the public.

4.3. The regulatory body should specify the conditions under which such consumer products may be made available to members of the public, who, for reasons of practicability, cannot be subject to regulatory control and so need to be exempted from regulatory control. The regulatory body is also required to exercise control over the supply of consumer products by requiring manufacturers to be authorized to supply such products to the public (Ref. [2], para. III.14.(c)). Authorization should be based on a prior assessment of the individual and collective doses that may be received to determine whether the criteria for exemption are likely to be met. Account should be taken of normal use, misuse and accidents and of likely methods of disposal.

4.4. The first step towards authorizing any particular manufacturer to supply a type of consumer product is for the regulatory body to consider the justification and safety as a whole of the practice involving the consumer product (e.g. the manufacture of consumer products of an approved type, and their distribution, sale, use and disposal on a national scale). The national regulations should state

[5] A 'consumer product' is a device such as a smoke detector, luminous dial or ion generating tube that contains a small amount of radioactive substance(s). More generally, it is an item that is readily available to members of the public without any requirements being imposed in relation to any radiation source therein. They may be available through commercial outlets where personal and household products are normally purchased, and there is a reasonably large market for such products, resulting in their wide scale distribution. The term 'manufacturer' as used in relation to consumer products includes importers or other legal persons authorized by the regulatory body to supply consumer products to persons who have no regulatory obligations with respect to the product.

the general principles for authorization and the criteria for consumer products of specific types should be provided in the regulations or in guides. Since control cannot reasonably be exercised over consumer products once they have been supplied to the public, and since such products may be used within practices, approval should be dependent on compliance with the criteria for exemption given in Schedule I of the Basic Safety Standards [2].

Justification and optimization of protection

4.5. Various factors influence decisions about justification. Some may be characterized as reflecting societal values independent of the associated risk, whereas others are more oriented towards safety. For instance, a regulatory body may decide to approve certain uses of radiation sources or radioactive materials if the associated doses are trivial; another may decide to discourage or not to approve the same product because members of the public would then be exposed to radiation, irrespective of the magnitude of the exposure. As a consequence, there will be differences in national attitudes; there will probably also be differences in points of view even within the same regulatory body. National guidelines on the acceptability would therefore be useful in order to provide a consistent approach. To help in the establishment of these guidelines, the Basic Safety Standards [2] stated that practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys or jewellery are deemed to be not justified.

4.6. Important factors that are relevant to justification in relation to safety and which may lead to optimized protection, as required in the Basic Safety Standards (Ref. [2], para. III.15), include the following:

(a) Selection of the most appropriate radionuclides with respect to the half-life, radiation type, energy and amount of radioactive material necessary for the product to function effectively;
(b) Selection of the chemical and physical forms of the radionuclide that provide the highest degree of intrinsic safety under both normal and accident conditions and for disposal;
(c) Construction of the product;
(d) Prevention of access to the radioactive substance without the use of special tools;
(e) Experience with other products, particularly similar products, that have previously been assessed;
(f) Verification of quality.

Safety assessment

4.7. The responsibility for conducting a generic safety assessment for a given type of practice in relation to a consumer product should rest with the manufacturer which, on the basis of the assessment, should apply to the regulatory body for an authorization to supply the consumer product. The regulatory body should establish criteria for the approval of consumer products and should compare the findings of the generic safety assessment with these approval criteria. It should verify any safety assessment provided by the manufacturer.

4.8. In general, authorization to supply consumer products will depend on an assessment of the doses that may arise from the practice in relation to the consumer product. If a generic assessment indicates, in its early stages, that the likely consequences in terms of radiation doses are within the criteria for exemption, the regulatory body may well decide to authorize the supply of the product without further analysis. In cases where such a simplified procedure does not show that doses are within these exemption criteria, more detailed assessments, including comparisons with other available options, should be required. The focus of any analysis for the authorization of consumer products should be on the individual dose criterion. While regulations may include a collective dose criterion, it has not proved to be a useful criterion for the purpose of controlling consumer products because in general it would be unreasonable to limit the number of products supplied.

4.9. The assessment should be carried out using exposure models that take account of the characteristics of the:

(a) Product to be authorized,
(b) Sources involved in the product.

4.10. Simple deterministic models may suffice for the purposes of a generic study concerning a well-defined use of the product. For other situations, more elaborate models that cover in detail a sufficient number of exposure scenarios should be used.

4.11. The choice of scenarios should be such as to cover all the reasonably likely exposure pathways and exposure situations that arise with the consumer product. Situations of potential exposure, such as accidents and misuse, should be considered to assess whether the product is inherently safe. Conditions of both actual exposures and potential exposures should therefore be covered; the

latter, although unlikely, may have consequences that are serious enough to preclude granting an authorization to supply.

4.12. In considering the construction of the product, account should be taken of its ability to withstand the rigours of use. The product should also be able to withstand misuse without damage to the source or source assembly. A compass incorporating a gaseous tritium light source, for example, should be constructed to withstand frequent transport in a backpack without incurring damage to the source or its mounting. The anticipated use of a product and its possible misuse should be considered in the selection of prototype tests for the product.

4.13. For reasons of general policy, some regulatory bodies have in the past advised members of the public using consumer products to dispose of them at the end of their useful lifetime by means other than as household refuse. It is likely, however, that users would not follow this advice, nor should it be necessary to do so. Following such advice could in fact lead to higher exposures than would otherwise occur, owing to the collection of ageing sources in a particular location. In calculating doses, it is therefore necessary to take into account the radiological consequences resulting from disposal in landfills and those resulting from incineration and other forms of disposal.

4.14. The supply of a new consumer product should not be authorized if it is considered that it would be necessary to specify operational procedures to be followed for its disposal so as to limit doses to acceptable levels. In practice, no administrative system for ensuring the controlled disposal of products that are in the public domain seems feasible. However, if consumer products that are no longer used are returned to the original supplier or to a central point, the accumulated sources are likely to require regulatory control and should properly be managed as radioactive waste.

AUTHORIZATION FOR THE SUPPLY OF CONSUMER PRODUCTS

4.15. The regulatory body should require the manufacturer of consumer products to apply to the regulatory body and receive authorization to supply products to the public to ensure that consumer products meet all the requirements for design and performance that were taken into account in the generic safety assessment. The manufacturer should provide the regulatory body with sufficient documentation and certification to enable it to review and assess the proposed product. The documentation should include the following:

(a) A description of the product, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive substance fulfils its function should also be provided.
(b) The activity of the radionuclide(s) to be used in the product.

4.16. The following additional information should be provided as may be appropriate or as required by the regulatory body:

(a) Justification of the choice of a radionuclide, particularly in relation to other radionuclide(s) that could be of lower toxicity (e.g. emit less penetrating radiation and/or have a shorter half-life). The reason for choosing the radioactive substance in preference to a non-radioactive alternative should also be justified.
(b) The chemical and physical forms of the radionuclide(s) contained in the product.
(c) Details of the construction and design of the product, particularly as related to the containment and shielding of the radionuclide in normal and adverse conditions of use and disposal, and the degree of access to the radioactive substance.
(d) The quality testing and verification procedures to be applied to radioactive sources, components and finished products to ensure that the maximum specified quantities of radioactive substances or the maximum specified radiation levels are not exceeded, and that devices are constructed according to the design specifications.
(e) A description of the prototype tests for demonstrating the integrity of the product in normal use and for possible misuse and accidental damage, and the results of these tests.
(f) External radiation levels arising from the product and the method of measurement.
(g) Dose assessments, including individual doses and, if appropriate, collective doses arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing and repair.
(h) The anticipated useful lifetime of the product and the total number of items of the product expected to be distributed annually.
(i) Information about any advice to be provided to customers on the correct use, installation, maintenance, servicing and repair of the product.
(j) An analysis to demonstrate that the product is inherently safe.
(k) Information on how the product is intended to be labelled.

4.17. A manufacturer should satisfy the regulatory body that the assumptions made in the safety assessment in relation to the design of the product are valid for any particular proposal. This is usually accomplished by means of a system of regulatory control, which often includes:

(a) Specifications for radiation levels or the radionuclide content, durability and integrity of the source, the solubility or dispersibility of the radionuclide, and the fire resistance.
(b) Prototype tests developed to determine that the materials of construction and the methods of manufacture are such that the ultimate product or its components will meet the specifications for safety performance as well as any other design requirements that are imposed on the product. Certification of prototype testing may form a part of the conditions applying to an authorization.
(c) Quality assurance consisting of statistical sampling of products, components, materials and manufacturing methods together with a test regime sufficient to confirm that products are within the specifications of the prototype. The number of products selected for testing should be such that there is only a small probability that a defective product would be distributed to the public.

4.18. Instructions relating to the use of consumer products are required to be provided with the product (Ref. [2], para. III.17), as they are with any other product. Labels are also required to be provided on the products to indicate the presence and the nature of the radiation source (Ref. [2], para. III.16) and thereby meet the public's demand for information about the goods that they purchase. However, it should be noted that if particular instructions or labels are considered necessary to ensure that the dose criterion for the exemption of the product is met, then the product should not be approved for distribution to the public, since there is no practical way of ensuring that the public using the products will heed the instructions or the labels.

4.19. Authorizations granting manufacturers permission to supply consumer products should require record keeping, particularly for those records relating to quality control and the amounts of the product distributed. Record keeping for the former is to help the regulatory body verify compliance with the criteria. For the latter, it is to assess whether or not the amounts and patterns of distribution of the product remain valid as projected in the generic safety assessment for the practice relating to the consumer product.

4.20. To the extent appropriate for any particular type of consumer product, the conditions for the control of product specifications should be stated in the authorization granted to a manufacturer and/or included in regulations issued by the regulatory body. The regulatory body should decide on the period of time for which authorization is granted for the supply of any product. The time-frame covered by the authorization may be a set number of years (e.g. five years) or it may be conditional on the proposal of any changes that could result in increased doses to members of the public using them or to others. The manufacturer authorized to apply consumer products should seek reapproval after a time to be decided on by the regulatory body or when any significant change to the product is proposed.

INSPECTION FOR THE SUPPLY OF CONSUMER PRODUCTS

4.21. Periodic inspections of the premises of manufacturers authorized to supply consumer products should be carried out so as to confirm that the products are being manufactured and distributed in accordance with the specifications and conditions established in the regulations and the authorization. The regulatory body should also conduct investigations, or review the results of investigations, of any accidents or instances of misuse. If the regulatory body receives new information that casts doubt on part or all of the original safety assessment, then appropriate measures should be taken.

5. FUNCTIONS OF THE REGULATORY BODY SHARED WITH OTHER GOVERNMENTAL AGENCIES

5.1. A shared function is one in which the regulatory body has partial, but not complete, regulatory responsibility for radiation safety. While many of the regulatory body's functions are shared with other governmental bodies, the ones specifically identified in this Safety Guide are those for which the regulatory body has an important role, often limited to providing expert guidance and assistance to the organization that has the lead responsibility. Where responsibilities are shared, the organizations involved should agree a memorandum of understanding or similar instrument that apportions clearly the responsibilities for all aspects of the shared functions.

5.2. The regulatory body is required to ensure (Ref. [1], para. 3.2(3)(x)) that the operators develop specific arrangements for preparedness and response for any practice or source that could necessitate an emergency intervention. Also, the regulatory body, together with other national and local intervening organizations, as appropriate, should participate in the development and implementation of the national emergency plan, and should have a general plan or plans to co-ordinate and support the protective actions foreseen by the emergency plans of operators [9]. The level of participation of the regulatory body will depend on the roles and responsibilities assigned to it in the State concerned. The plans should include a description of the co-ordination established with international organizations, as appropriate, to respond to situations that are not immediately or directly traced to a particular operator. The international requirements concerning emergency preparedness and response arrangements are given in Ref. [10].

5.3. In general, abnormal situations that cause exposure or that have or even appear to have the potential to cause exposure can be a reason for an emergency response. In addition to more typical situations, such as a fire in a nuclear facility triggering an emergency response, the following may also, under certain circumstances, give rise to an emergency response or an intervention:

(a) Lost, stolen or abandoned sources of significant risk (see the categorization of sources [7]);
(b) Sources brought illegally into the State;
(c) Radioactive contamination from sources or from releases generated in accidents in other States;
(d) A discarded container with a radiation warning symbol and unknown contents;
(e) Malicious or criminal activity involving radiation exposure.

The response may be necessary owing to actual exposure or to an abnormal situation with a perceived potential for exposure.

5.4. The role of the regulatory body in an intervention in the case of an emergency involving radiation sources will vary, depending on national circumstances, and should be determined in advance at the stage of emergency planning. Its role can range from one in which it has responsibility for

participating directly in emergency response actions to one in which it acts mainly as an advisor. The regulatory body should:

(a) Have its role and responsibilities clearly defined and documented, including interaction with operators in the event of an on-site emergency, and interaction and co-ordination with authorities responsible for national and local off-site emergency response, where available, and with international agencies for a transboundary emergency;
(b) Have procedures to enable it to perform its role and discharge its responsibilities;
(c) Participate in appropriate regular emergency response exercises in order to assess preparedness and the effectiveness of procedures, infrastructure and personnel, as well as to ensure that response capabilities remain effective;
(d) Establish intervention criteria and action criteria for emergencies;
(e) Issue regulations consistent with Ref. [10], including emergencies involving the transport of radioactive material.

INTERVENTION IN CHRONIC EXPOSURE SITUATIONS

5.5. The role of the regulatory body in intervention to reduce or avert chronic exposure (i.e. exposure persisting in time) should be defined in terms of a broader governmental infrastructure for public health, since this kind of intervention often involves high costs and decisions on policy that go well beyond the regulatory body's powers and responsibilities for decision making. The regulatory body should be prepared to provide expert advice about individual and collective radiation doses and the associated radiological risks and, to the extent practicable, to identify situations where intervention to reduce chronic exposure should be considered. "The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities" (Ref. [1], para. 6.15). "Principles and criteria for intervention actions shall be established and the regulatory body shall provide any necessary advice in this regard" (Ref. 1, para. 6.16).

TRANSPORT SAFETY

5.6. The role of the regulatory body in relation to transport will normally include requirements relating to the approval of package designs, the approval

of transport and, as determined by national legislation, the tracking of sources. National infrastructures for transport safety, in general, can be very complex. The regulatory body's role for the safe transport of radioactive material may need to be shared with other governmental agencies having competences and responsibilities for the safe transport of other dangerous goods.

5.7. The regulations issued by the regulatory body are subject to the international IAEA Regulations for the Safe Transport of Radioactive Material [11]. If there is a memorandum of understanding between governmental agencies, those operators that are subject to the regulations should know which agency governs particular aspects of the requirements for safe transport, e.g. shipment approval.

WASTE SAFETY

5.8. The regulatory body, in co-ordination with other governmental bodies, as appropriate, should develop regulations on the safety of radioactive waste, in accordance with its legislative mandate. These requirements should apply to all aspects of radioactive waste management, including collection, segregation, characterization, classification, treatment, conditioning, storage, disposal and waste inventory, whenever such waste arises from medical, agricultural, industrial, research and educational applications.

5.9. "Prior to the authorization of activities that generate radioactive waste, the regulatory body shall ensure that appropriate consideration is given to making provision for the necessary capacity for processing and storage of the anticipated radioactive waste" (Ref. [1], para. 6.9(1)).

CO-ORDINATION AND CO-OPERATION

5.10. In addition to those specific functions discussed above, the regulatory body should identify areas where co-ordination and co-operation with other local, national and international organizations are needed to fulfil its mandate. When such needs are identified, the regulatory body, together with the other organizations involved at the local and national levels, should establish specific arrangements for co-ordination and co-operation. "Several international conventions relating to various aspects of safety are in force. National authorities, with the assistance of the regulatory body, as appropriate, shall establish arrangements for the exchange of safety related information,

bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation" (Ref. [1], para. 4.11).

6. ORGANIZATION AND STAFFING OF THE REGULATORY BODY

6.1. "The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model" (Ref. [1], para. 4.1).

6.2. In order to assess the staffing needs of a regulatory body, it is convenient to divide the activities of the regulatory body into four major areas:

(1) Development and maintenance of regulations and guides,
(2) Review and assessment of applications for authorization,
(3) Inspection and enforcement,
(4) Administrative and legal support.

6.3. Other functions of the regulatory body such as emergency response and investigation of accidents are not normally day to day activities, and related responsibilities should therefore be assigned according to where they best fit in the larger units of the organizational structure.

6.4. "The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions" (Ref. [1], para. 4.6).

6.5. The size of the regulatory body should depend on the magnitude and scope of the radiation related practices subject to regulation; that is, on an inventory of radiation sources and on practices using radiation sources. In larger regulatory bodies, regulatory staff may be assigned to perform within a specific functional area (e.g. review and assessment of applications for authorization). Alternatively, regulatory staff may specialize in particular kinds of practices (e.g. radiotherapy) and consequently their work assignments would cover more than one functional area in the organizational structure (e.g. assessing applications for authorization and conducting inspections of radiotherapy facilities).

6.6. The number and the specialized skills of the regulatory staff will also depend on decisions about the coverage of functional areas and on what should be referred to consultants and/or advisory committees. The regulatory body should have sufficient numbers of staff with the basic skills necessary to operate the regulatory system without depending on the immediate availability of consultants. It should, for example, be prepared to fulfil its pre-established role in emergency response at all times, despite the fact that some staff may be in the field conducting inspections or unavailable for personal reasons. Since the fundamental objective of a regulatory system governing radiation safety is to protect people from the harmful effects of ionizing radiation, a broad capability in radiation safety should be permanently available among the regulatory staff. Also, the staff should have a managerial capability sufficient to co-ordinate the contributions of various specialists. Similarly, staff should have sufficient technical knowledge to identify the need for specialists to evaluate or analyse recommendations on how individual contributions fit into the resolution of a complex issue.

6.7. Another aspect of the requirement for having a broad capability for radiation safety and project management among the regulatory staff is that radiation source technologies change, particularly those used in medicine. The regulatory body, therefore, should have sufficient technical and project management capability to identify new safety issues that may stem from technological developments and to bring specialized technical skills to bear in addressing problem areas.

6.8. In order to achieve the necessary kind of capability within the technical staff of the regulatory body, most regulatory staff should have an academic degree in the physical or biological sciences or in engineering. This should be supplemented with specialized university level training and/or professional work experience in radiation safety. Project management capability can usually

be developed through on the job training and work experience, and through specialized training for career development. The regulatory body should also have policies and programmes in place, offering salaries that are competitive in the industry and opportunities for training and career development, in order to avoid a high turnover of staff.

Conduct of regulatory staff

6.9. "Mutual understanding and respect between the regulatory body and the operator, and a frank, open and yet formal relationship, shall be fostered" (Ref. [1], para. 4.10).

6.10. Regulatory staff should be as objective as possible in discharging their responsibilities. They should be open to receiving information and opinions from others, and their regulatory positions and decisions should demonstrate transparency and clarity. Regulatory staff should not engage in, or hold a financial interest in, activities that may be the cause of a conflict of interest with the performance of regulatory functions. The regulatory staff should be formal and friendly but not familiar in their transactions with the regulated community.

6.11. Regulatory staff should have an enquiring disposition and should probe to learn more about areas where there may be problems. Staff should be confident with their assigned responsibilities so as to discharge them in a positive manner and without ambiguity, which is particularly important in the case of inspectors who might encounter hostility or circumstances in which their attention is being intentionally diverted.

6.12. A delicate balance should be struck between providing operators with sufficient information to enable them to carry out an adequate protection and safety programme, and becoming their 'consultant' by advising on the details of how best to organize and operate their programmes. Whether an appropriate balance can be struck depends on national situations such as the availability of qualified persons to provide advice and assistance outside the regulatory framework. If regulatory staff appear to become consultants and their recommendations are adopted, the operator may perceive that the responsibility for operational safety has shifted to the regulatory staff. This should be avoided to the extent practicable.

Use of consultants and advisory committees

6.13. "If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants. Whoever may provide such advice or assistance (such as a dedicated support organization, universities or private consultants), arrangements shall be made to ensure that the consultants are effectively independent of the operator. If this is not possible, then advice or assistance may be sought from other States or from international organizations whose expertise in the field concerned is well established and recognized" (Ref. [1], para. 4.3).

6.14. It is unlikely that the staff of any regulatory body, however large, will be able to embody the full range of skills and expertise necessary to resolve all the problems of each and every practice. The use of consultants possessing specialized expertise in particular subjects (e.g. mechanical engineering, medical physics) is a cost efficient and effective way to enhance the technical depth and breadth of knowledge of the regulatory body's staff. To the extent practicable, a pool of consultants with specialized skills should be identified well in advance of a specific need arising, and appropriate arrangements made so that they are available when needed.

6.15. With regard to the employment of consultants, the regulatory body should use consultants only for advice. "The use of consultants shall not relieve the regulatory body of any of its responsibilities. In particular, the regulatory body's responsibility for making decisions and recommendations shall not be delegated" (Ref. [1], para. 4.4). In addition, the regulatory body should ensure that consultants are free from any conflicts of interest so that they are able to provide impartial advice.

6.16. "The government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice… Any advice offered shall not relieve the regulatory body of its responsibilities for making decisions and recommendations" (Ref. [1], para. 4.9).

6.17. Advisory committees can support the regulatory body in various ways. Broadly based advisory committees with membership drawn from other governmental departments, scientific organizations and the industry being regulated should bring broad perspectives to bear on the formulation of regulatory policy and regulations. Another type of advisory committee is the technical committee composed of members offering a range of specialized skills needed to address complex technical issues. The latter are often formed ad hoc. They perform a function similar to that of consultants whenever different specialized skills are needed to address complex issues.

6.18. In establishing advisory committees, the relationship of such committees to the regulatory body and the need for the regulatory body to maintain its independence on matters concerning radiation safety should be taken into account. The regulatory body should prepare clearly defined terms of reference and specific criteria for the selection of its membership well before an advisory committee is established. When the advisory committee is formed, the regulatory body should have well focused agenda for its meetings and should place deadlines on any actions specified.

Legal support

6.19. The regulatory body should have the necessary legal support to carry out its legal mandate. A regulatory body is by its nature engaged in activities that require professional legal support. Although the need for legal support cuts across all regulatory functions, the two functions for which it is most commonly needed are in the preparation of regulations and in the initiation of enforcement actions. The regulatory body may either have professional legal personnel on its staff or obtain such services from a governmental organization that has a specific responsibility to provide legal advice to the government, or it may retain the services of a legal consultant, depending on the day to day need for legal advice and on the way in which government is organized.

Administrative support

6.20. The regulatory body should have sufficient administrative support to carry out its mission in a timely manner. The regulatory body may employ its own administrative staff to carry out the administrative functions, or it may rely on the administrative staff of a parent organization to carry them out, or it may need to contract some of them to an external organization.

Development and training of regulatory staff

6.21. "In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts" (Ref. [1], para. 4.7).

6.22. The training programme should include:

(a) The familiarization of each new employee with the regulatory process, including regulations, policies, procedures and guidance for assessment, inspection and emergency response.
(b) A plan for each employee that is tailored to the employee's needs and expected tasks within the regulatory body. The plan should specify the type of training, where it is to be obtained, and its timing and sequence. Career progression should be considered in devising individual training plans.
(c) The means for employees to protect themselves against any hazards that may be encountered during an inspection.
(d) Plans for regular refresher training to ensure that specialists are familiar with technological developments and developments in radiation protection.
(e) Procedures for the evaluation of the training programme in which account is taken of the long term need for specialists and managers and the changing needs of the regulatory body. Such procedures should also provide for adjustments in individual training plans to take into account the need for career progression and the changing circumstances of regulatory staff.

6.23. The regulatory body's training programme should consist of some combination of the following:

(a) Self study,
(b) Formal university level instruction and occupational or technical training courses,
(c) Workshops and seminars,
(d) Participation in scientific and technical events,
(e) On the job training (at home or abroad).

6.24. Training requires substantial human and financial resources. The regulatory body should therefore carefully specify and justify its training programme, include the training costs in its budget, and ensure that the programme is adequately put into effect. There is often pressure to reduce or delay training because of other, short term need of funds or personnel. Although such circumstances cannot be avoided entirely, the regulatory body's management should ensure that they do not unduly disrupt the training programme.

6.25. Further guidance on the development of training programmes for regulatory staff is provided in Ref. [12]. An example of the design, development and implementation of a training programme for the staff of a regulatory body is provided in Ref. [13].

7. DOCUMENTATION OF THE FUNCTIONS AND ACTIVITIES OF THE REGULATORY BODY

7.1. The term documentation means a written, retrievable record covering all aspects of the regulatory programme, including records of events, the recommendations of consultants and committees, decisions reached, determinations made, lessons learned, authorizations issued, inspection findings and enforcement actions. Up to date and adequate documentation of the functions and activities of the regulatory body should be prepared and maintained for the following reasons or to meet the following objectives:

(a) A regulatory body is an institution whose regulatory requirements and guides, organizational structures, management, staff and operating procedures will change over time. Its institutional memory should reside in its documentation and should not depend on the memories or the availability of individuals who were employed by the regulatory body at any particular time. Orderly institutional evolution and the ability to adjust to changing circumstances depend to a large extent on being able to reconstruct the rationale for actions taken in the past and on the effectiveness of the results.
(b) To enable the regulatory body to deal with legal challenges, particularly in respect of its regulatory requirements and enforcement actions, and also to respond to political or public concerns relating to the regulatory system.

(c) To enable the regulatory body to reconstruct and to understand what occurred in, or contributed to, an accident or a degradation of radiation safety, particularly in respect of regulatory requirements, safety assessments and findings from inspections.
(d) To establish appropriate quality control within the regulatory system.
(e) For the orderly day to day conduct of business with the community regulated and others that may be affected or interested, such as those in government and members of the public.

7.2. The principal types of document that should be maintained by the regulatory body include:

(a) Regulations and guides and guidance to the community regulated on how to implement the regulations. Regulations and guides often reflect complex technical, legal and policy considerations. The background to the regulations and guides should also be documented and maintained.
(b) Internal procedures of the regulatory body, including procedures for: developing regulations and guides; issuing, amending, suspending, revoking and terminating authorizations; review and assessment; inspection; enforcement; and issuing public information.
(c) Relevant performance standards.
(d) All authorizations and notifications, which should include details of the radiation sources.
(e) All communications between the regulatory staff and operators, starting with the submission of a notification or an application for authorization, issuing an authorization, and continuing through inspection findings, enforcement actions and, finally, the communications associated with the termination of an authorization.
(f) The regulatory body's review of any safety assessment submitted by the applicant or any other basis for granting an authorization.
(g) Reports of inspections and investigations.
(h) Operational data required to be submitted to the regulatory body by operators.
(i) The priorities assigned for the regulatory body's workload and the basis for the priorities.
(j) Meeting reports and consultants' advice.
(k) Administrative records (e.g. budgets, funding, training).

7.3. There are other kinds of records that should be maintained as part of the regulatory infrastructure but which may not be held in the possession of the regulatory body. Such records should be made available to the regulatory body

upon request. Records of occupational exposure may be maintained by a national dosimetry service, for example.

7.4. Records that operators are required to maintain should be specified in the regulations (see Ref. [2] for the types of record). The regulatory body should determine through inspection that the required records are being maintained and, on the basis of the information they contain, should determine whether or not operations are safe and in compliance with regulatory requirements. When an authorization is terminated, some of the operational documents should be maintained (e.g. records relating to the transfer of radioactive waste to another organization or the disposal of radioactive waste, records of workers' exposures, records of a termination of authorization survey to determine whether remaining facilities and equipment are free from radioactive contamination). The regulatory body should specify in its regulations which types of documentation (e.g. records of a survey showing a site to be free from contamination prior to the termination of a licence) are to be maintained after the termination of an authorization and should ensure the availability of a depository for such documents, since an operator may be a corporation, an institute, or other body that may no longer exist after the termination of an authorization.

8. SUPPORT SERVICES

8.1. For the regulatory body to function effectively, the regulatory body itself and the operators should have available certain services, as appropriate, through arrangements made within the State or else from abroad. Services such as the following may be required, depending on the types of practice that are authorized:

(a) Dosimetry services for the assessment and recording of individual external and internal doses for the types of practice authorized;
(b) Laboratory services with the capability to provide qualitative and quantitative analyses of radiation measurements;
(c) Calibration services with traceability to a standard of a standards dosimetry laboratory;
(d) Facilities for radioactive waste management for processing, long term storage and disposal of radioactive waste deriving from practices of the types authorized;

(e) Appropriate transport services for radioactive sources and radioactive waste;
(f) Training services commensurate with the scope of the regulatory system;
(g) Expert assistance to supplement the capabilities of the regulatory staff.

8.2. The list in para. 8.1 comprises the principal types of service needed in most States. Depending on the types of practice authorized and the technical capabilities of the operators, other services may also be required.

8.3. The regulatory body should ensure that support services are appropriately qualified (i.e. accredited, approved, certified or authorized by recognized and specialized institutions at the national or international level). For example, the regulatory body may require testing and calibration service providers to be accredited to ISO/IEC 17025 [14]. The requirements to be met by service providers should be specified in regulations or regulatory guides.

8.4. In some States, the regulatory body provides some of these services. "When such functions are undertaken, care shall be taken by the regulatory body to ensure that any conflict with its main regulatory functions is avoided and that the prime responsibility of the operator for safety is not diminished" (Ref. [1], para. 3.5). The managements of the regulatory functions and of the technical support services should be in separate organizational entities.

9. QUALITY MANAGEMENT FOR THE REGULATORY SYSTEM

9.1. The regulatory body should establish procedures, including those for fostering an appropriate safety culture, for quality management and for the analysis of programme data, to ensure that it maintains an effective regulatory system.

Safety culture

9.2. The Basic Safety Standards [2] state that the regulatory body should require that all parties develop a safety culture, which establishes that, as an overriding priority, radiation safety issues receive the attention warranted by their significance. This requirement for fostering a safety culture also applies to the regulatory body, since the regulatory body and its staff are essential

components of an effective regulatory system. The regulatory body should develop procedures and adopt management practices that foster and maintain an appropriate radiation safety culture among its staff.

Quality management

9.3. "The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and activities undertaken" (Ref. [1], para. 4.5).

9.4. The management system should be such as to ensure that:

(a) The regulatory body has adequate resources, including staff, facilities, services and logistical support (e.g. support for functional operation, training, vehicles, equipment and consultants).
(b) The staff is adequately trained and suitably experienced.
(c) The regulations are suitably complete and up to date.
(d) There is adequate supervisory overview of the quality of the authorization and inspection systems.
(e) Enforcement actions are proportionate, consistent, transparent and timely.
(f) The staff adheres to regulations, policies and operating procedures.
(g) Appropriate records are maintained and kept up to date.
(h) Operating policies and procedures are documented.
(i) Obsolete documents are removed and any unintentional use precluded.
(j) Self-assessments by the regulatory body and independent assessments of the regulatory body are carried out to assess its effectiveness; independent assessments may be carried out by appropriate national organizations or international organizations such as the IAEA [15].

Analysis of programme data and events

9.5. Statistical data about the type and frequency of non-compliances found in the course of performing regulatory functions should be compiled and analysed to assess the need for:

(a) Clearer or more prescriptive regulations or guides,
(b) Authorization procedures explained in greater depth,
(c) Additional regulatory requirements to achieve adequate radiation safety,
(d) The reassessment of inspection priorities,

(e) The reassessment of the enforcement policy,
(f) The reassessment of training requirements.

9.6. The regulatory body should review events having actual or potential radiological consequences, particularly with a view to determining whether there are general implications for other operators, and as the basis for actions such as:

(a) Reporting the details of the events to other operators who may be at risk from the occurrence of similar events and requiring those operators to take appropriate actions,
(b) Mandatory withdrawal from service of a device at fault,
(c) The placing of requirements on a manufacturer to ensure that corrective actions are taken,
(d) The modification of authorization requirements or the possible alteration of regulations.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1, IAEA, Vienna (2000).

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

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Standards Series No. GS-G-1.1, IAEA, Vienna (2002).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Standards Series No. GS-G-1.2, IAEA, Vienna (2002).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Standards Series No. GS-G-1.3, IAEA, Vienna (2002).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Documentation for Use in Regulating Nuclear Facilities, Safety Standards Series No. GS-G-1.4, IAEA, Vienna (2002).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA-TECDOC-1344, Vienna (2003).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Medical, Industrial and Research Facilities, Safety Standards Series No. WS-G-2.2, IAEA, Vienna (1999).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accidents, IAEA-TECDOC-953, Vienna (1997).

[10] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS OFFICE FOR THE CO-ORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Standards Series No. GS-R-2, IAEA, Vienna (2002).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), Safety Series No. TS-R-1 (ST-1, Revised), IAEA, Vienna (2000).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Standards Series No. RS-G-1.4, IAEA, Vienna (2001).
[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Training in Radiation Protection and the Safe Use of Radiation Sources, Safety Reports Series No. 20, IAEA, Vienna (2001).
[14] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, INTERNATIONAL ELECTROTECHNICAL COMMISSION, General Requirements for the Competence of Testing and Calibration Laboratories, ISO/IEC 17025, Geneva (1990).
[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Assessment by Peer Review of the Effectiveness of a Regulatory Programme for Radiation Safety, IAEA-TECDOC-1217, Vienna (2001).

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