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Organization and implementation of a national regulatory infrastructure governing protection against ionizing radiation and the safety of radiation sources

Interim report for comment

Jointly sponsored by FAO, IAEA, OECD/NEA, PAHO, WHO

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ORGANIZATION AND IMPLEMENTATION OF A
NATIONAL REGULATORY INFRASTRUCTURE
GOVERNING PROTECTION AGAINST IONIZING RADIATION
AND THE SAFETY OF RADIATION SOURCES
INTERIM REPORT FOR COMMENT

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FOREWORD

A number of IAEA Member States are undertaking to strengthen their radiation protection and safety infrastructures in order to facilitate the adoption of the requirements established in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Standards) jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO) (the Sponsoring Organizations). In this connection, the IAEA has developed a technical co-operation programme (Model Project on Upgrading Radiation Protection Infrastructure) to improve radiation protection and safety infrastructures in 51 Member States, taking into account national profiles and needs of the individual participating countries.

The present report deals with the elements of a regulatory infrastructure for radiation protection and safety and intends to facilitate the implementation of the Basic Safety Standards in practice. It takes into account the proposals in an earlier report, IAEA-TECDOC-663, but it has been expanded to include enabling legislation and modified to be more attuned to infrastructure issues related to implementation of the Standards. The orientation is toward infrastructures concerned with protection and safety for radiation sources used in medicine, agriculture, research, industry and education rather than infrastructures for protection and safety for complex nuclear facilities. It also discusses options for enhancing the effectiveness and efficiency of the infrastructure in accordance with the size and scope of radiation practices and available regulatory resources within a country.

Moreover, with a view to ensuring adequate harmonization between different international guidance documents in this area, the present report takes fully into account the draft requirements (May, 1998) in the IAEA Safety Standards Series for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety and the work carried out by the ARCAL (Arreglos Regionales Cooperativos para la Promocion de la Ciencia y la Tecnologia Nucleares en America Latina) Programme in Latin America and, particularly, the document ARCAL XVII 'Proyecto de Reglamento Generico de Proteccion Radiologica (Abril 1997)'.

The advice provided in the report is expected to serve for a future Safety Standards Guide. The report is jointly sponsored by the FAO, IAEA, OECD/NEA, PAHO and WHO. In addition, the ILO has also actively participated in meetings and made a significant contribution, especially on the issues related to the protection of workers.

EDITORIAL NOTE

In preparing this publication for press, staff of the IAEA have made up the pages from the original manuscript(s). The views expressed do not necessarily reflect those of the IAEA, the governments of the nominating Member States or the nominating organizations.

Throughout the text names of Member States are retained as they were when the text was compiled.

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1. INTRODUCTION

BACKGROUND

1.1. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the 'Standards' or the 'BSS') were published as IAEA Safety Series No. 115 in 1996 [1]. This publication marks the culmination of efforts that have continued over the past decades towards harmonization of radiation protection and safety standards internationally, and is jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO).

1.2. The purpose of the Standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure (hereinafter called 'radiation safety'). The requirements are based on the principles set out in the Safety Fundamentals, published as IAEA Safety Series Nos 110 and 120 [2, 3], and on the basic requirements for legal and governmental infrastructure for the safety of sources of ionizing radiation, the safe management of radioactive waste and the safe transport of radioactive material[1]. They indicate the different aspects that should be covered by an effective radiation safety programme, and are not intended to be applied as they stand in all countries and regions, but should be adapted to take account of local situations. The ways in which States interpret and apply the Standards will vary depending on legal systems, technical resources, the scale of installations and related factors.

1.3. The term 'infrastructure' refers to the underlying structure of systems and organizations. As radiation technologies have advanced and as radiation safety correspondingly has become more complex over the years, the Standards can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and services, and a 'safety culture' shared by all those with responsibilities for protection, including both management and workers. The infrastructure requires clear lines of authority and responsibility, and adequate resources to operate the system at all levels. While general advice on the organization of radiation safety infrastructures is contained in the preamble to the Standards, there is a need for more detailed advice. This is because of variations between countries, and because some Member States have no any infrastructure for radiation safety, or the infrastructure is either not appropriate or ineffective for the types of practices involved.

OBJECTIVE

1.4. This report is mainly intended to assist those Member States which need to establish or improve their national radiation safety infrastructure in order to implement the requirements of the Standards. Member States receiving assistance in applications of nuclear energy or radiation technology from FAO, IAEA, ILO, PAHO or WHO are expected, as a condition of such Agreements, to implement the Standards or equivalent radiation protection and safety

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[1] IAEA Safety Standards Series *in preparation*; Safety Requirements: Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety (May 1998 draft).

standards as may be appropriate for their situations. This can only be ensured by having an adequate radiation safety infrastructure.

1.5. In addition to providing advice on the essential elements of a radiation safety infrastructure at the governmental level, a further objective is to provide advice on the optimization of resource utilization within the infrastructure.

SCOPE

1.6. This report covers the elements of a radiation safety infrastructure at the national level needed to apply the Standards to radiation sources such as those used in medicine, agriculture, research, industry and education. It also provides advice on approaches to the organization and operation of the infrastructure aimed at achieving its maximum efficiency.

1.7. The advice given in this publication is not sufficient for complex nuclear fuel cycle, reactor and waste management operations which require a more elaborate and technically advanced infrastructure. Also, this report does not cover the safety infrastructures at the user level. These are addressed in practice-specific safety documents. It does cover, however, the interface between the government and those subject to its control. While intended primarily to assist in establishing a national infrastructure appropriate for control of radiation practices and sources, the advice is also generally applicable for an infrastructure appropriate for intervention. However, the infrastructure for intervention is different in some respects than it is for the control of practices and sources. Those aspects of an infrastructure that are unique to intervention are covered in a separate section of this report.

STRUCTURE

1.8. This report starts with the legal framework for the infrastructure. It then moves on to the functions of a Regulatory Authority followed by the basic elements of a regulatory programme. These elements are discussed in detail, providing advice on how each element can be optimized and integrated with the other elements to enhance effectiveness and efficiency. The final part of the main text addresses quality assurance, analysis of programme data, and priorities related to operation of the regulatory infrastructure.

1.9. An important part of the report is the Appendix which contains sample legislation and regulations. It is general in nature and should be adapted to each country's particular needs and administrative structure. Moreover, it contains a number of annexes indicating numerical criteria and reference levels to be applied to fulfill these Regulations, which cover administrative, radiation protection performance, management, safety of sources, radioactive waste management, transport and emergency intervention requirements, as well as for occupational, medical and public exposure protection. By their very nature, these numerical values may undergo changes with time due to policy or technical and scientific developments.

2. LEGAL FRAMEWORK FOR A RADIATION PROTECTION AND SAFETY INFRASTRUCTURE

2.1. Radiation protection and the safety of radiation sources are typically governed by legal systems consisting of statutes or laws enacted by national legislatures, and some combination of regulations, ordinances, and standards. In general, there is no sharp distinction between regulations and ordinances. Standards are criteria, frequently developed by professional organizations, which are often incorporated in regulations or ordinances. How these terms, or similar kinds of terminology, are employed and the level within government at which regulatory requirements can be issued depends upon national legal systems and preferences.

2.2. For purposes of discussing the legal framework for a radiation safety infrastructure in this report, two terms are employed: legislation which establishes the basic framework of the national infrastructure, and regulations containing more specific protection and safety requirements, which in many countries are issued at a level below the national legislature, e.g., by a local government or by the Regulatory Authority. Administrative procedures for issuing regulations vary among countries. For example, in some countries regulations are developed by the Regulatory Authority, issued by a legislative body, and then implemented by the Regulatory Authority. In some other countries, the Regulatory Authority issues and implements its regulations after a period of public review and comment on proposed regulations.

2.3. If it is determined that new or additional legislation is needed to establish an appropriate infrastructure to implement the Standards, a note of caution is necessary. Most countries will have some legislation and regulations in existence governing radiation safety. These should be carefully reviewed, and modified, incorporated or eliminated as may be appropriate when considering new or revised legislation. The objective is to minimize overlapping or conflicting requirements, and prevent gaps in coverage of protection and safety.

SCOPE OF BASIC LEGAL FRAMEWORK

2.4. A basic legal framework, i.e., a statute or law, should be established by the national legislative body, which allows the beneficial uses of ionizing radiation and provides for adequate radiation protection and safety (hereinafter called the 'legislation'). Exposures whose magnitude or likelihood are essentially unamenable to control should be excluded. Except for the excluded exposures, the legislation should be applicable to occupational, public and medical exposures, and to all sources of ionizing radiation regardless of intention to use the source. This means that it should not only apply to radioisotope sources which always emit radiation but also, for example, to radiation generating (e.g., X ray) machines even in storage since they have the potential for producing radiation. Exclusions from the legislation should be broadly characterized as covering those sources not amenable to regulatory control and identified either in the legislation or implementing regulations by the type of source or the type, quantity or quality of radiation from the source. Typically, such exclusions include ^{40}K in the body, cosmic radiation at the surface of the earth, low concentrations of natural radionuclides in raw materials and other sources of unenhanced background radiation with the exception of radon in buildings.

PRIME RESPONSIBILITY FOR SAFETY

2.5. A fundamental concept that should be made clear in the legislation is that prime responsibility for radiation protection and the safety of sources resides with registrants and licensees in control of such sources and with employers of occupationally exposed workers.

REGULATORY AUTHORITY

Functions and responsibilities

2.6. Full and proper implementation of the Standards requires that an independent Regulatory Authority be established by Government through legislation to regulate the introduction and conduct of any practice involving sources of radiation. It is essential that the responsibilities of the Regulatory Authority are kept completely distinct from those of any other party so that the regulators can preserve their independence of judgment and decision as safety authorities. For this purpose, there should be clear separation of functions and responsibilities of the Regulatory Authority from those of other government departments and agencies having responsibility for development and promotion of regulated practices. There should also be a clear separation or independence of the Regulatory Authority from those subject to regulation, e.g., registrants, licensees and manufacturers of radiation sources. In addition, the Regulatory Authority should avoid engaging in activities which could compromise or appear to compromise that separation, e.g. providing consultant services.

2.7. The term 'Regulatory Authority' is generic and is intended to mean in this report a single authority or a system of authorities competent to discharge functions and responsibilities identified in the legislation. Although it is desirable to have all regulatory responsibilities for radiation protection and safety concentrated in a single organization, they are sometimes divided. An example of such division of responsibilities would be a situation where the Ministry of Transport is responsible for regulating the safe transport of hazardous materials and a separate Regulatory Authority is responsible for radiation safety. Since radioisotopes are usually classified as hazardous materials, there is the potential for overlapping jurisdiction during transport of radioisotopes. In most countries there is almost certain to be some division of responsibilities for radiation protection and safety among governmental authorities, with a potential for overlapping jurisdictions and gaps in safety and protection coverage. Legislation to establish the governmental infrastructure should ensure that the regulation of all aspects of radiation safety are covered and responsibilities are clearly defined and allocated. Where regulatory responsibilities are divided, the legislation should establish clear lines of authority and responsibility so that gaps in protection and safety are prevented and overlapping of authority minimized, and those in possession of sources can understand which aspects of their activities are subject to the various governmental authorities. For these purposes, the legislation should require relevant regulatory authorities to establish a system of liaison and working procedures to ensure an appropriate degree of co-ordination and co-operation. Such liaison and working procedures are often established between government organizations through a 'memorandum of understanding' which sets out liaison procedures and defines those aspects of protection and safety for which their respective organizations will assume primary or lead responsibility in a way which prevents or brings attention to overlapping or conflicting regulatory requirements, and avoids gaps in control.

2.8. The legislation should empower and require the Regulatory Authority, or the appropriate government body in consultation with the Regulatory Authority, to issue:

- regulations governing radiation safety;
- regulations governing notification and authorization (registration or licensing);
- exclusions and exemptions from regulatory requirements; and
- supporting guides as may be appropriate to assist in implementing the regulations.

2.9. If the Regulatory Authority must go to a higher level in government, e.g. to parliament, to have its regulations issued or amended, more time and effort are usually required to accomplish change. Unwarranted delay can adversely affect radiation safety as well as the utilization of new radiation technologies. Therefore, it is desirable to empower the Regulatory Authority directly to issue radiation safety regulations and guides to the extent feasible. This would allow a more flexible and timely adaptation of requirements for safe practice with the advancement of knowledge and technology.

2.10. With respect to compliance with regulatory requirements, the legislation should specifically empower and require the Regulatory Authority to:

- assess applications for permission to conduct practices that entail exposure to radiation;
- grant authorizations of such practices and associated sources, subject to specified conditions;
- conduct inspections to assess radiation safety conditions and compliance with applicable regulations and other requirements specified in an authorization;
- have access to the premises of persons in possession of radiation sources which are subject to notification or authorization in order to discharge regulatory responsibilities;
- initiate enforcement actions to correct adverse radiation safety conditions and ensure compliance with regulatory requirements; and
- impose sanctions as may be appropriate consistent with national legal procedures governing such matters.

2.11. In order to ensure the effective discharge of its responsibilities and functions, the legislation should also empower the Regulatory Authority to:

- communicate directly with higher level governmental authorities in all cases in which this is considered to be necessary to exercise effectively the functions of the Regulatory Authority;
- co-operate with other governmental bodies having competence in such areas as health and safety, environmental protection and security;
- enter into agreements or arrangements with other governmental and non-governmental bodies, where such actions are necessary to meet regulatory responsibilities, (this includes matters such as arrangements for the availability of essential facilities and services which are beyond the capabilities required of persons authorized to conduct practices and which are not otherwise available, such as personnel dosimetry services or certification of private dosimetry services, operation of a national registry for occupational exposure, education and training of specialists in radiation protection and safety, calibration of radiation measuring equipment, waste disposal and management of emergencies);
- obtain such documents and solicit such opinions from public or private organizations or persons as may be both necessary and appropriate;
- maintain contact with regulatory bodies of other countries and relevant international organizations; and

- establish a public information system through which the public, its representatives and the information media can be informed about the radiation safety aspects of regulated practices and about the regulatory process.

Funding

2.12. Provision should be made either through the implementing legislation or the national fiscal process to budget for staffing and staff training, facilities, equipment, use of consultants, etc., adequate for the Regulatory Authority to discharge its responsibilities and maintain its independence. If costs are to be recovered by authorization and inspection fees, authority to levy charges should be granted by the legislation. To the extent that the Regulatory Authority levies charges for authorizations, inspections and fines related to enforcement, a direct link between the generated funds and the Regulatory Authority budget should be avoided to prevent abuses, or the appearance of abuses, by the Regulatory Authority. For example, fees and fines might be channelled directly to the national treasury. This helps to minimize challenges to the bases for charges or fines levied, as well as challenges to the Regulatory Authority's independence.

ADDITIONAL LEGISLATIVE CONSIDERATIONS

2.13. Inadvertent transfer of radiation sources to persons not authorized to possess them (e.g., a ^{60}Co industrial gauge to a scrap metal recycle plant) or illegal trafficking in such sources is a growing problem. In the past it has caused deaths and serious injuries and necessitated costly decontamination. There are many reasons why the problem exists and seems to be growing, but basically it stems from two fundamental deficiencies: lack of an effective regulatory control through notification or authorization and inspection, and lack of regulatory requirements for, or enforcement of, security and accountability of sources. The problem appears to be particularly acute in countries where the regulatory infrastructure is weak or essentially non-existent. Therefore, when preparing new legislation, particular consideration should be given to how the system of regulatory authorities will be integrated and how each authority will co-operate in this area so that a strong system of control works, and timely and effective enforcement and corrective actions are taken when violations occur.

2.14. All countries import some sources and some countries import most of their sources. To the extent warranted, the legislation should establish a direct link between Customs Authorities and the Regulatory Authority to ensure that there is adequate control over sources entering the country, and that the persons importing or receiving the sources are identified and authorized.

3. BASIC ELEMENTS OF A REGULATORY PROGRAMME

3.1. Radiation safety of sources should be established and maintained through a regulatory programme consisting of:

- regulations which set forth requirements and standards for protection and safety, and related administrative requirements;
- a system of notification and authorization (registration or licensing) for control over possession and use of radiation sources;
- provisions for establishing exclusions and granting exemptions from regulatory requirements;
- compliance monitoring, including inspection, to assess the status of safety and compliance with regulatory requirements;
- enforcement to compel compliance with regulatory requirements;
- investigation of accidents and management of emergencies; and
- dissemination of information on protection and safety.

3.2. The size, complexity and structure of the regulatory programme should be compatible with the magnitude and safety implications of the regulated practices and sources, as well as with the resources available to regulate them.

REGULATIONS

3.3. The principal purpose in establishing a system of regulations is to codify radiation safety requirements of general applicability. The regulations should define the administrative requirements for notification and for authorization by registration or licensing, as well as the requirements that are considered essential from the standpoint of ensuring the protection and safety of workers and members of the public and, when appropriate, of patients. By providing orderly procedures and clear statements of requirements, regulations serve to stabilize the regulatory process.

3.4. Regulations should be written in a language which is clear and easily understood. They should be unambiguous and precise so as to be readily enforceable. The Regulatory Authority should follow uniform and orderly procedures for establishing, revising and revoking regulations. These procedures should be efficient and flexible enough to permit revisions to keep pace with changing conditions, including the evolution of technology.

Performance regulations versus prescriptive regulations

3.5. The development of any particular radiation safety regulation will involve a balance between two opposing requirements: the need for flexibility to permit easy adaptation of the regulations to evolving circumstances and technology (frequently called 'performance regulations') versus the need to include detailed requirements for ease in determining when the requirements are being met (frequently called 'prescriptive regulations'). A performance orientated regulation is more general, and simply specifies the overall radiation safety requirement and basic operational parameters. A prescriptive orientated regulation is more specific and states how to achieve radiation safety. In practice, most regulations contain both performance and prescriptive requirements, but can often be characterized as being either predominantly performance orientated or prescriptive orientated. An example of a

performance orientated regulation would be one which requires the user to plan and organize operations so that exposures are maintained as low as reasonably achievable and demonstrate this by using 'adequate' workplace monitoring and 'appropriate' instruments. It might also require the maintenance of adequate records to demonstrate compliance. The equivalent prescriptive regulation would be practice specific and it would define exactly how to achieve adequate restriction of exposure and when and where to conduct workplace monitoring, what type of instrument should be used and how and what records should be maintained.

3.6. Performance orientated regulations have an advantage in that they can be relatively easy to develop, and are focused on objectives, namely what is to be achieved in terms of protection and safety. They can be made applicable to a range of practices involving ionizing radiation and, if carefully drafted, do not need to be changed frequently to keep up to date with changing technology. However, a principal disadvantage is that they need to be interpreted in relation to each different practice. This places a significant burden on the time and skills of both the regulatory staff and the users.

3.7. Prescriptive regulations are largely practice-specific and so have the advantage of providing, both, the regulatory staff and the user with clearly defined requirements for a particular practice. They prescribe what to do to comply with the requirements and how to do it in order to achieve an adequate level of protection and safety. Prescriptive regulations reduce the time and skills necessary to perform a licensing review or conduct an inspection. They enable the authorization and inspection process to focus on simple verification of compliance. However, a highly prescriptive approach can have an undesirable side effect in that it can drive a 'compliance culture' rather than a 'safety culture' if positive steps are not taken to prevent it. Prescriptive regulations also have other disadvantages. They are more difficult to prepare, requiring more detailed and expert knowledge of the specific practice in question and considerable experience in operational radiation safety. They are narrowly applicable to a specific practice and may need to be regularly amended to keep pace with technology changes. They are best suited to widespread practices where the equipment and procedures do not vary significantly among different users.

3.8. As a practical matter, regulatory authorities will need a basic foundation of performance orientated regulations governing the general principles of radiation protection and the safety of sources. These can be based on the Standards. More prescriptive regulations directed at those practices which are most widespread or which have the greatest potential for exposure of workers would be a useful supplement to the performance regulations. The aim should be to enable the Regulatory Authority to use its more scarce, highly skilled personnel for the preparation of regulations, to conduct the licensing and inspection of those practices for which only performance regulations are available, and to undertake inspections in non-routine situations. Less professional judgment and discretion are required to apply the more precise prescriptive regulations to the more routine situations.

Exclusion

3.9. According to the Standards, "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". This concept essentially applies to some exposures to radiation which are part of the natural environment, such as cosmic rays or exposures from natural radioactivity in the body. These exposures are regarded as unavoidable and, most importantly, it is usually not practicable to control them through a regulatory system. The regulations

should include provisions and criteria for establishing which exposures are excluded from the regulatory control. It is important to note that the concept of exclusion applies to exposures and not to the sources or practices giving rise to the exposures.

NOTIFICATION AND AUTHORIZATION BY REGISTRATION OR LICENSING

3.10. The Standards apply the terms "notification, and authorization by registration or licensing" to broadly indicate an appropriate type of control based upon the level of risk or complexity associated with practices; notification being applied to the lowest order of risk or complexity, and licensing to the highest. However, some countries have these terms already embedded in their legislation and regulations, and they are often employed somewhat differently than in the Standards. For example, some countries may apply the term 'registration' to the system to authorize the use of radiation generators and radioisotope sources, and reserve 'licensing' for nuclear fuel cycle facilities and nuclear power plants, essentially in line with the meaning attributed to these terms in the Standards. Other countries may use the term 'licence' for the authorization of all radiation sources that are not otherwise excluded or exempt from the system of control. This does not necessarily imply that there is a significant difference in the scope and depth of the safety evaluations for practices which are subject to registration in one country and licensing in another. Of fundamental importance, regardless of the terminology employed, is that the Regulatory Authority determine adequacy of protection and safety, and likelihood of compliance with regulatory requirements prior to granting authorizations within its system of control.

3.11. In order to illustrate methods for achieving effectiveness and efficiency in the system of control, this report explains the terms notification, registration and licensing in more detail than do the Standards.

Notification

3.12. Notification as defined in the Standards is by way of a document submitted to the Regulatory Authority by a legal person to notify the possession of a source or the intention to carry out a practice. It is the basic mechanism which provides information to the Regulatory Authority about a proposed action. For sources or practices for which registration or licensing is required, the application for either serves also as notification. For those practices or sources for which normal exposures are expected to be very small and the likelihood and magnitude of potential exposures are negligible, notification may be the only requirement if the Regulatory Authority decides that they are of sufficient low risk as not to require licensing or registration, but they are not suitable for exemption for some reason, e.g. to prevent uncontrolled waste disposal. Notification can provide useful information, for example:

- in situations where a Regulatory Authority is in an organizational phase and does not know who is in possession of sources, the first step would be to identify users and what they possess prior to initiating an authorization programme;
- to obtain data about distribution, volume and patterns of use and disposal prior to making a decision about granting an exemption for certain types of sources; and
- to obtain information from those who own but do not take physical possession of sources, e.g. an importer or broker.

Registration

3.13. Registration can be a relatively simple and efficient authorization mechanism if certain criteria for its use can be met. General criteria which can be used to assess the suitability of a practice as a candidate for registration are:

- radiation safety can largely be ensured by the design of facilities and equipment;
- operating procedures are simple to follow;
- radiation safety training requirements are minimal;
- operations within a practice do not vary significantly among users;
- there is a history of few safety problems with operations; and
- the number of users within the practice is large.

3.14. There are two approaches to the organization and operation of a registration system. The first is for the Regulatory Authority to establish in its regulations and advice the safety requirements concerning design of facilities and equipment, operating procedures, quality assurance, etc. which must be met as a precondition for registration, and the safety requirements to be imposed on each registrant. The second approach is for the Regulatory Authority to conduct a pre-registration, one-time, 'generic' safety assessment of a particular design of facilities and equipment as well as the related operating procedures, maintenance requirements, training requirements, etc., as provided by a manufacturer or supplier. These two approaches to the operation of a registration system are not mutually exclusive. Depending on the nature of the practice, one or the other or a combination of both may be most effective.

3.15. Once the safety requirements are established by regulation or 'generic' safety assessments, a person applying for registration needs to submit only the minimum necessary information to the Regulatory Authority. The information submitted by a registration applicant typically should include:

- clear identification of the source and associated facilities and equipment to be utilized in the practice;
- the location of use;
- identification of the individual responsible for source safety; and
- agreement to follow all applicable operating, maintenance and disposal requirements.

3.16. Approval of an application for registration then becomes mainly an administrative task with little technical judgment required. Information contained in the applications should be recorded in the Regulatory Authority document control system for inspection and other purposes.

Licensing

3.17. Licensing is required for all practices not otherwise designated by the Regulatory Authority as suitable for the simpler processes of notification or registration. In particular, licensing should be required for the higher risk or more complex practices, including those in which the protection depends largely on human performance as, for example, medical applications and industrial radiography. The licensing process requires each person proposing to use sources within a practice to submit an application containing detailed information related to the proposed use of the source and the radiation protection and source safety

provisions, as well as an assessment of the nature, magnitude and likelihood of the exposures attributed to the source. The Regulatory Authority then evaluates the application to determine that the applicant, and the manner in which the sources are to be used, are likely to comply with applicable regulations and requirements. When issued, the licence grants authority to use sources for specific purposes within boundary conditions and other requirements specified in the licence.

3.18. In general, licensing is a more resource intensive process than is registration, because it requires a case by case evaluation of each proposed use within a practice. In some instances, the process may include pre-licensing and pre-operational inspections by the Regulatory Authority to ensure that all relevant protection and safety precautions are taken into account and are satisfactory. Both the level of skills and the effort required to conduct such evaluations depends somewhat on the mix of performance and prescriptive regulations against which the evaluations are conducted.

Authorized legal persons

3.19. The legal persons holding a registration (registrants) or a licence (licensees) bear the primary responsibility for setting up and implementing the technical and organizational measures that are needed for ensuring protection and safety for the sources for which they are authorized. They may appoint other people to carry out actions and tasks related to this authorization, but they must retain the responsibility for the actions and tasks themselves.

3.20. One of the important specifications in an authorization is the clear identification of personnel who have key responsibilities for protection and safety and those who could substantially affect protection and safety by virtue of tasks involving operation or manipulations of sources. The objective is to ensure that only appropriately qualified personnel fill such positions. The simplest way to accomplish this is to specify on the authorization the names of persons who are qualified to fill such positions. If staff turnover is high, as is often the case for industrial radiography and medical practices, for example, the authorization can specify the qualification credentials, i.e. training, experience, professional certifications, etc., required of any person who fills a certain position. When a new staff member is added in accordance with the qualification requirements, the Regulatory Authority often requires notification of the change of personnel.

Classification of practices and sources

3.21. The decision of whether a practice or source warrants a licence or a registration or a simple notification is to be based on the consideration of such elements as the following:

- the risk associated with the practice and sources within the practice;
- the degree of control required by the complexity of the equipment and installations associated with the practice and sources within the practice;
- the size of the workforce directly or indirectly submitted to occupational exposure; and
- the potential health and environmental consequences of accidental events involving the sources within the practice.

On the basis of these criteria, then:

(a) *notification* would be adequate for such practices and sources as:

- educational use of small sealed sources in schools;

(b) a *registration* would be required for such practices and sources as:
- radio-immunoanalysis;
- low activity industrial gauges;
- diffractometry apparatus;
- dental diagnostic X rays;
- consumer products distribution;

(c) a *licence* would be needed for such practices and sources as:
- industrial irradiators;
- high activity industrial gauges;
- industrial radiography;
- radiotherapy;
- medical X ray diagnostics;
- nuclear medicine;
- use of non sealed sources;
- radionuclide production;
- use of sources in research institutions;
- storage of radioactive materials;
- radioactive waste storage or disposal facilities.

Revalidation of licences and registration

3.22. The advantages of requiring revalidation after a set time interval are that licensing and registration details are kept more up to date. If a registration or licence is issued without an expiry date, revalidation may involve a periodic review of their status and documentation of the review results. However, an expiration date forces a review. In such instances, the review and documentation of results would normally take place as a part of the renewal process and forms the basis for the Regulatory Authority making indicated adjustments in the registration or licence after checking against:

- current regulatory requirements;
- changes in the user's own requirements or provisions for radiation safety; and
- the findings of the Regulatory Authority's inspection programme.

3.23. Revalidation of both licences and registrations also is a beneficial reminder to users that they have regulatory obligations to meet. This is particularly important in cases where on site inspections are infrequent because of limitations on the resources of the Regulatory Authority.

3.24. The frequency of revalidation is influenced by many factors, including:

- the frequency of inspection by the Regulatory Authority;
- the safety record within a practice;
- the stability of the user's operation; and
- the frequency of regulatory changes affecting the practice.

EXEMPTIONS FROM REGULATORY REQUIREMENTS

3.25. Exemptions can be divided into two broad categories: exemption of practices and sources within practices from regulatory control requirements, including those of notification and authorization by registration or licensing; and exemptions from procedural requirements of regulations to accommodate specific situations provided that an equivalent degree of protection and safety can be achieved by alternative methods.

3.26. The Standards specify the general principles and dose criteria for exemption that are applicable to sources whose activity or concentration exceed the values in Table I-I of Schedule I. Safety Series No. 89 [4] and provides advice on the regulatory process for such exemptions. A case of exemption needing particular attention involves the transfer of consumer products which are manufactured or supplied under regulatory control to persons who are exempt from regulatory requirements with respect to possession, use and disposal of these sources. Prior to granting this kind of exemption, a determination must be made that the dose criteria are likely to be met taking into account the anticipated volume and patterns of distribution, exposure during normal use and misuse or accidents, and likely methods of disposal. Examination of product design, prototype testing and quality assurance is part of the evaluation process. Manufacturers or suppliers that distribute products expected to be subsequently exempt from further regulatory control should be required by regulation or license conditions to meet all product specifications that form part of the exemption conditions. Once an exemption is granted, periodic retrospective analysis of distribution data and other relevant information should be performed to confirm that the initial basis for the exemption remains valid. It is important to bear in mind that once sources are distributed under an exemption it is not practical, if not impossible, to recover the sources and bring them under regulatory control. Therefore, conservative assumptions in performing the safety assessment are indicated.

3.27. With respect to exemption of sources, Schedule I of the Standards provides data by total activity, activity concentration or dose rate on sources which may be exempted without further analysis or other considerations. Conservative assumptions were employed in deriving these exemption levels. Because of modelling uncertainties and the demanding technical process in directly applying the performance criteria in Schedule I of the Standards for exemptions, it is desirable first to determine that the proposed candidate for exemption cannot reasonably meet the exemption values contained in Schedule I, Table I.I.

3.28. To the extent that regulations are prescriptive, they may contain requirements that cannot be reasonably accomplished during the use of sources in special situations. Regulations should provide for the granting of alternatives to certain procedural regulatory requirements upon justification of the need and provided that the use of alternative procedures meets the broad health and safety objectives embodied in the regulations. Request for deviation from any particular aspect of the regulations should be uncommon. If there are frequent requests for such deviation to the regulations, the basis and need for the requirement should be re-examined.

3.29. An example of an alternative to a specific procedural regulatory requirement might be one where the collection and storage, in hospitals, for decay of radioisotope contaminated excreta may not be practical, and may involve other kinds of significant risk. In such instances, using performance-based dose criteria as the primary criteria, early disposal of such

waste may be justified even though the activity concentrations may exceed the generic levels specified in regulations established by the Regulatory Authority.

Clearance from regulatory requirements

3.30. Sources, including substances, materials and objects, within authorized practices can be cleared, that is, exempted from further regulatory requirements and control, provided that they comply with exemption levels established as specified in Schedule I of the Standards or approved by the Regulatory Authority. The BSS refers to it as clearance of sources within authorized practices from regulatory requirements. The criteria for clearance are essentially the same as for exemption and therefore there are not practical implications.

COMPLIANCE MONITORING

3.31. Compliance monitoring is conducted by the Regulatory Authority to determine whether practices are carried out and sources are used in accordance with the requirements of relevant regulations and with any licence or registration conditions. Key elements of compliance monitoring include on-site inspection, radiation safety appraisals, accident notification and investigation, as well as periodic feedback from users about key operational safety parameters.

3.32. Compliance monitoring provides either the assurance that radiation safety requirements are being met, or the opportunity to require corrective action if they are not. It can take the form of on-site inspections or regulatory mechanisms which require the user to notify the regulatory authority in specified situations, e.g., equipment malfunctions and actual or suspected overexposure. The principal component of compliance monitoring is on-site inspection, which is often the principal means for direct personal contact between the users and staff from the Regulatory Authority. Because it is the component of the regulatory regime closest to actual operations, it is normally where the greatest proportion of regulatory resources should be allocated.

3.33. Many Regulatory Authorities are resource limited in terms of an insufficient number of staff, or insufficient staff experience. Insufficient skills can be particularly troublesome for Regulatory Authorities with regulatory programmes in the organizational phase. In such situations the quality of inspection can be greatly affected by the proportion of performance and prescriptive oriented regulations incorporated into the regulatory structure. For many types of practices, an adequate inspection programme can be based on the use of personnel with basic training in radiation safety and a knowledge of practices using ionizing radiation, inspecting against the requirements of prescriptive regulations. The use of outside experts can supplement and enhance the skill level available to the Regulatory Authority.

3.34. The priority and frequency of inspections will be influenced by the risk and complexity associated with the practice and whether the operation is conducted under a notification, registration or license. In general, a pre-operational safety review for authorization can somewhat reduce the priority and frequency of follow on compliance inspections. The greatest influence on inspection priority and frequency, however, will depend on potential accident consequences and the type and frequency of violations found during inspections. In order to establish a priority system, it is necessary to compile and analyze data on performance within practices.

USE OF PERFORMANCE INDICATORS

3.35. In addition to determining compliance with all applicable regulatory requirements, an inspection should provide a general sense of the 'safety' of operations. Perspectives on safety in general can be aided by the use of 'performance indicators', which is a term employed to denote specific sets of circumstances that aid in identifying the potential for degraded safety performance. The kinds of information available as performance indicators for practices using radiation sources are usually early subjective warnings of degraded performance. In this sense they are negative performance indicators and are usually management related. Based on experience, the more common indicators of degraded performance include poor housekeeping, poor financial stability, insufficient staffing, high staff turnover and poor record retrieval systems. Although performance indicators are not in themselves regulatory infractions, they are often found in conjunction with them. Performance indicators can be used as a basis to inform source users of the need to improve, and also as a basis for establishing the frequency of inspection of any particular source user.

ENFORCEMENT

3.36. Enforcement is the action taken by the Regulatory Authority to correct non-compliance with regulatory requirements. A strong and effective enforcement programme is a key component of the regulatory infrastructure for assuring success in meeting regulatory objectives.

3.37. Enforcement actions fall in three broad categories:

- Both informal and formal instructions to correct a regulatory infraction or adverse safety condition that could lead to an infraction, but where there is not an immediate threat to health and safety. In such situations, operations can continue while corrective actions are being taken.
- Suspension of operations in whole or in part until a regulatory infraction or safety condition, which has the potential for an immediate threat to health and safety, is corrected.
- Suspension of operations in whole or in part, or restriction of operations because of a record of poor performance or adverse safety conditions such that the Regulatory Authority can no longer conclude that operations are likely to be safe and in compliance with applicable regulations.

3.38. When informal instructions are given, e.g. orally by an inspector on site, the instruction should be followed in writing, and a written reply required of the user confirming that corrective action has been accomplished, unless it involves a very minor infraction or can be corrected in the inspector's presence. In all of the above categories, communications between the Regulatory Authority and the user should be clear, timely, unambiguous and well documented.

3.39. The Regulatory Authority should be sufficiently empowered to impose sanctions that will deter deliberate or careless deviations from regulatory requirements. Voluntary compliance with safety standards should normally be quite high but pressures of time, economic competition or worker dissatisfaction can result in serious violations of regulatory requirements and harm or risk of harm to workers, members of the public or patients. Personnel training and high qualification are unfortunately no guarantee against actions to

bypass safety systems. Serious accidents have occurred because of such actions by well trained and highly experienced scientists and managers. Consequently, the deterrence provided by a credible enforcement policy is a necessary component of the regulatory programme.

3.40. Enforcement is an activity which warrants a high priority and demands a dedicated effort. It can only be accomplished by instilling the enforcement ethic within the staff of the Regulatory Authority. The establishment of a published enforcement policy will put users of sources on notice about the possible sanctions and penalties for failure to comply with regulatory requirements. A published policy also benefits the Regulatory Authority's staff by providing advice and justification for enforcing the requirements and causing prompt and effective corrective actions. It is particularly helpful when regulations have been violated but there has been no apparent or immediate harm to workers. A lack of enforcement action because no harm was done might indicate to the user that ignoring the requirements is acceptable, and this might lead to a gradual erosion of the margin of safety provided by the regulations.

INVESTIGATION OF ACCIDENTS

3.41. Should an accident occur, an investigation to determine why it occurred and how to prevent similar accidents is necessary. Most, but not all, accidents involving radiation sources are minor and confined to the workplace. Such accidents are usually investigated by the user and the investigation results, along with corrective actions, reported to the Regulatory Authority. For more serious accidents or potentially serious accidents, an independent investigation should be conducted by the Regulatory Authority and sometimes by other governmental authorities as well, in addition to the investigation conducted by the user. Although not completely separable, there are usually two main objectives to an investigation of a serious accident by authorities: determining why it happened and establishing responsibility and liability for its consequences. From a radiation protection standpoint, the former objective, determining why it happened, is of central interest. This aspect of the investigation should include:

- determination of the root causes and contributing factors;
- assessment of the consequences in terms of exposure and the likelihood of exposure;
- identification of corrective actions;
- deriving of lessons to be learned from the accident's causes and consequences, and the significance of these findings for other sources within a practice and for other practices;
- recommendations for prevention of similar accidents in the future, including adjustments in the regulatory programme as well as any adjustments in protection and safety programmes for those in possession of sources; and
- feedback of all findings and recommendations to relevant registrants, licensees, manufacturers, suppliers, etc.

3.42. One problem encountered in investigations by authorities of accidents involving actual or potential serious harm is that some legal systems prohibit public disclosure of accident details to protect the legal rights of both those charged with liability for the accident, as well as those that might have been injured as a consequence. Thus, the goal of rapid dissemination of information to prevent further accidents often conflicts with protection of legal rights. To the extent practicable, the technical aspects of an accident investigation should be separated from the legal aspects so that both goals, providing relevant information and

protecting legal rights, can be achieved. A separate investigative report which deals only with the technical aspects of the accident and avoids naming, or easy identification, of individuals can help to resolve this problem.

DISSEMINATION OF INFORMATION

3.43. An important supplement to the regulatory system is a mechanism for the periodic dissemination of information to relevant users, manufacturers, suppliers, etc. about protection, safety and related findings. This keeps those who might be affected alert to problems they may encounter and to the consequences if not properly addressed. Information can be exchanged in meetings or by periodic mailing of notices. However, these methods are not a substitute for more rapid actions that might need to be taken in the wake of a real or potential accident or incident which might have significant and immediate safety implications for others.

4. ROLE OF THE REGULATORY AUTHORITY IN EMERGENCY INTERVENTION

4.1. All sources shall be managed so that the risk of accidental exposure of workers, members of the public and patients (undergoing diagnosis or treatment) is acceptably low. However, the possibility of accidents or incidents must be recognized and plans put in place to deal with such events.

4.2. As part of establishing the basic framework for the national infrastructure, the government should clearly identify the organizations which will need to be involved in emergency intervention and specify their responsibilities. National practices in Member States differ considerably in the ways in which responsibilities for responding to non-radiological emergencies (such as fires, floods and earthquakes) are distributed among regulatory bodies, public authorities and others. As the basic organization for responding to radiological emergencies should be an integral part of the government's overall plans for dealing with emergencies in general, it is not possible to give definitive advice for assigning responsibilities for interventions in radiological accidents and incidents. The allocation of responsibilities for responding to accidents or incidents with radiation sources, and the emergencies they may entail, can be complex because it may involve combinations of registrants or licensees, employers, governmental organizations and other intervening organizations depending on the nature of the emergency. However, the Standards in Appendix V do specify the functions that government authorities need to ensure are discharged in emergency preparedness and intervention; the IAEA also has issued detailed advice on emergency planning and preparedness for accidents involving radiation sources in Safety Series No. 91 [5] and on medical handling of overexposed individuals in Safety Series No. 88 [6].

RESPONSIBILITY OF THE REGULATORY AUTHORITY IN EMERGENCIES

4.3. As a national authority for protection from radiation sources, the Regulatory Authority, if necessary in conjunction with other government bodies, should ensure that adequate emergency plans exist and that they are capable of being operated in emergency situations involving radiation sources. The primary responsibility for on-site emergency response should lie with the registrant or licensee. However, the Regulatory Authority, besides its general supervision responsibilities, will have a specific direct role in off-site emergency response. Accordingly, the Regulatory Authority, together with the other appropriate national, regional and local intervening organizations, should have a general plan or plans to coordinate and implement support to the protective actions foreseen by the emergency plans of registrants and licensees.

- In addition, the government should have emergency intervention plans to deal with situations which cannot be immediately or directly traced to a given registrant or licensee, such as in the following cases:
- lost, stolen or abandoned sources;
- sources brought illegally into the country;
- falling satellites equipped with radioactive sources; and
- radioactive contamination from unidentified sources or from accidental releases generated in accidents beyond national borders.

4.4. In some countries, the Regulatory Authority may be the only government authority with competence in radiation protection. Therefore, it may well be appropriate for the Regulatory Authority to have a role at an early stage of an emergency, particularly if the accident is severe or its duration appears likely to be prolonged. The Regulatory Authority constitutes a significant resource for radiation protection advice, and it is expected to be familiar with the practices and types of material involved in an accident. In many countries, the main role of the Regulatory Authority is to provide expert advice to the government and to those responsible for decision making, both during the acute phase of an emergency and in the post-emergency follow-up phase. Groups seeking advice may include licensees or registrants, police, civil defence and fire fighting services, medical authorities, public water suppliers, food and agricultural organizations and regional governments.

4.5. Where the Regulatory Authority has such a role, it is essential that specific channels of communication be established, particularly telephone, fax and e-mail numbers for use in emergency. It is highly desirable to have emergency procedures well documented and to ensure that any changes are made formally. Periodic emergency drills using realistic scenarios are an essential part of maintaining an effective emergency response capability within the Regulatory Authority.

4.6. Regarding cases of accidental exposure of people and depending upon local capabilities, the Regulatory Authority or a national emergency response authority should establish arrangements with recognized, specialized medical centres for decontamination, treatment of overexposed persons and follow-up of patients.

5. ROLE OF THE REGULATORY AUTHORITY IN RELATION TO INTERVENTION IN CHRONIC EXPOSURE SITUATIONS

5.1. Chronic exposure situations that might require remedial action include:

- exposure to radiation from natural sources, such as exposure to radon in houses and workplaces; and
- exposure to radioactive residues from past activities, such as those involving practices and the use of sources which were not covered by the system of notification or authorization, as well as from the long term radioactive contamination caused by accidents, after the circumstances requiring protective action have been dealt with.

5.2. Remedial actions to avert or reduce chronic exposure should be justified in that they do more good than harm. Assessing the balance between good and harm is never simple as it needs to include, in a broad sense, the prevailing health, social and economic factors involved. The Regulatory Authority for radiation protection might not be the organization charged with responsibility to make these decisions because of factors in addition to radiation protection that need to be taken into account. For example, it would be natural for that part of government concerned with safety codes for housing to take the national lead on setting the policy on chronic exposure situations in dwellings, with the Regulatory Authority acting as a source of expert advice on matters such as the establishment of action levels to implement the policy. Although the Regulatory Authority might not have responsibility, it should encourage the responsible governmental body to analyse the need for taking the action.

5.3. It is up to the government to allocate responsibilities for the management of interventions in chronic exposure situations between the Regulatory Authority and other relevant authorities and organizations. In any event, generic or site-and situation-specific remedial action plans should be jointly prepared by the concerned authorities and organizations. These plans should specify remedial actions and action levels that are justified and optimised, taking into account:

- the individual and collective radiation exposures;
- the radiological and non-radiological risks; and
- the financial and social costs, the benefits and the financial liability for the remedial actions.

6. ASSESSMENT OF THE EFFECTIVENESS OF THE REGULATORY PROGRAMME

6.1. The Regulatory Authority should establish procedures, including those for quality assurance and analysis of programme data, to ensure that it maintains an effective regulatory programme for radiation protection and the safety of radiation sources.

QUALITY ASSURANCE

6.2. A determination that a regulatory programme is effective should include assuring that:

- the Regulatory Authority has adequate resources which include staff, facilities and contracted services, e.g. expert consultants;
- the staff is adequately trained and suitably experienced;
- there is adequate supervisory overview of the quality of the authorization and inspection systems;
- there is appropriate and timely enforcement action; and
- the staff adheres to its regulations, policies and operating procedures.

ANALYSIS OF PROGRAMME DATA

6.3. Statistical data about the type and frequency of non-compliance found during inspections should be compiled and analysed. A good database supported by an efficient analysis programme might indicate, for example, the need to consider:

- clearer or more prescriptive regulations or advice;
- more in-depth authorization procedures;
- additional regulatory requirements to achieve adequate protection and safety; and
- a reassessment of inspection priorities.

6.4. It is also essential to require users to notify the Regulatory Authority of accidents or incidents that exceed certain specified parameters. An accident database can greatly facilitate the collation and evaluation of data. The Regulatory Authority should analyse such events, particularly with a view to determining whether there are generic implications for other users. Analysis can address equipment design, operating procedures and quality assurance programmes, and the results can have implications for either the user, the equipment manufacturer or both. When a generic problem is identified, follow-up action may involve:

- notifying the details to other users who are potentially at a similar risk;
- mandatory withdrawal from service of the device at fault;
- the placing of positive requirements on the manufacturer to assure corrective action; and
- modification of authorization requirements, or possible alterations to regulations.

7. ENSURING COST EFFECTIVENESS OF THE REGULATORY FRAMEWORK

GENERAL

7.1. Before making decisions about the optimum combination of regulations, licensing and registration and compliance monitoring techniques within a regulatory programme, attention should be paid to efficiency aiding and cost saving techniques that might be employed to supplement the programme. These can be divided into three broad categories:

- advice for users and the Regulatory Authority;
- use of consultants and advisory committees; and
- generic safety assessments.

7.2. Throughout the process of implementing a regulatory framework and programme, a Regulatory Authority should be aware of published protection, safety and regulatory information. If some of this can be adopted to meet national needs, it can have a significant effect on the costs of implementation and may usefully influence decisions about the chosen framework.

ADVICE FOR USERS AND FOR THE REGULATORY AUTHORITY

Guides for applicants and users

7.3. Guides can assist applicants and users in identifying the details which should be submitted in an application for authorization to use a radiation source and provide 'good practice' advice or recommendations for operations. A guide should be practice specific, enabling the applicant to provide appropriate and complete information. This improves the efficiency of the authorization process by reducing the communications necessary between the Regulatory Authority and the applicant. Such guides might also provide examples of at least one way to meet the requirements of the regulations for a specific practice, and model procedures to accomplish specific tasks appropriate to the practice, e.g., calibration of survey instruments, leak testing of sealed sources, clean up of spills and record keeping. The applicant can adopt such model procedures, or propose alternatives which would require more detailed review during the authorization process. Guides, specific to a practice, provide an important supplement to performance oriented regulations which have general applicability to more than a single practice. Guides should not be considered as regulations, but as advice or recommendations to assist users in meeting the requirements of regulations. They should be flexible and can be periodically revised without the need to go through the more elaborate and time consuming formal administrative process to promulgate regulations.

Standard review plans

7.4. Standard review plans are for use by the Regulatory Authority staff and identify the items which need to be evaluated and addressed in reviewing applications to register or license specific practices. Simple review plans may consist of a checklist of items to be reviewed, whilst more elaborate plans give the regulatory staff advice on what is acceptable and what is unacceptable on each item reviewed. Standard review plans not only add to the efficiency of the review by focusing attention on the important issues, but also enhance quality assurance for the Regulatory Authority by confirming that each element important to safety

has been considered. Additionally, they can provide a mechanism by which less skilled staff can review applications.

Inspection manuals

7.5. Inspection manuals are for use by the Regulatory Authority inspectors. They should identify items to be checked during inspection for each type of practice. The manual can consist of simple checklists or it can give the inspector advice on acceptable and unacceptable performance criteria. Inspection manuals aid inspection efficiency, provide a measure of quality assurance for the Regulatory Authority and enable less skilled staff to conduct inspections.

USE OF CONSULTANTS AND ADVISORY COMMITTEES

Consultants

7.6. Radiation sources are used in a wide range of practices, each of which has its unique characteristics. The staffing of the Regulatory Authority depends primarily on the volume of work rather than the complete range of skills necessary to address all issues which need to be resolved. The range of skills available within the Regulatory Authority will be centered on radiation safety and supplemented by persons with other engineering and scientific disciplines to the extent that these persons can be used efficiently as full time members of staff. It is unlikely that the staff of any Regulatory Authority, however large, will be able to embody the full range of skills and expertise necessary to resolve all the problems unique to each and every practice. The use of consultants with specialized expertise in particular subjects, (e.g., mechanical engineering, medical physics, geohydrology) is a cost efficient and effective way to enhance the technical depth and breadth of the Regulatory Authority's staff. Consultants who are expert in a particular practice can often be very helpful in drafting prescriptive regulations or advice covering that practice, and might also be used to supplement staff in its authorization and inspection functions. To the extent practicable, it is desirable to identify, well in advance of a specific need, a pool of consultants with specific skills and to make appropriate arrangements so that they are readily available on demand.

7.7. There are, however, several points of caution to be noted concerning the use of consultants:

- the Regulatory Authority's staff must have sufficient technical knowledge to enable them to identify problems, to determine when it would be cost effective to seek assistance from a consultant and to understand and correctly interpret the specialist's advice;
- as a general principle, consultants can only advise. It is still the Regulatory Authority's responsibility to evaluate such advice and to determine how it is to be applied; and
- ideally, consultants should be free of conflicts of interest so that they are able to provide impartial advice. There is a danger that a consultant's other activities as a specialist could create a bias which may be reflected in any advice given, and the potential for any such conflict of interest should be recognized and minimized.

Advisory committees

7.8. Advisory committees can support the Regulatory Authority in a variety of ways. Broadly based committees with membership drawn from other government departments,

scientific organizations and the regulated industry can bring broad perspectives to bear on the formulation of regulatory policy and regulations. A well founded committee can provide valuable service to the Regulatory Authority by helping to assure that policies and regulations are clear, practical and complete. This should result in regulations which represent a good compromise between the needs of the regulated industry and the requirement for strict regulatory control.

7.9. Another type of committee is the technical committee composed of members with a range of technical skills needed to bear on complex technical issues. These are often ad hoc committees. They perform a function similar to consultants but where a number of different skills are needed to address complex issues.

7.10. The cautions applicable to the use of consultants apply also to the selection and use of advisory committees, but with one additional factor. If committees are not properly organized and managed, they can be time consuming and cause delays in Regulatory Authority actions and their advice could be unfocused, not relevant or otherwise unhelpful. To avoid these situations, it is necessary to prepare clearly defined terms of reference and specific criteria for selection of its membership well before a committee is established. This should reduce the chance of later controversy about the role of the committee and who should serve on it. After the committee is formed, it is necessary to have well focused agendas for committee meetings and to place time deadlines on the need for decisions in order to avoid delays in Regulatory Authority decisions.

GENERIC SAFETY ASSESSMENTS

7.11. Co-operation between the Regulatory Authority and manufacturers or suppliers can lead to generic safety assessments of specific components or complete items of equipment. Highly skilled experts can be used for a single, pre-marketing generic safety assessment. Not only is it more cost effective, but it should achieve a much better standard of safety than the alternative approach of case-by-case evaluations, by different reviewers with varying levels of skill, on each occasion that a potential user applies for a license or for registration. The generic assessment should be documented along with a summary of the conditions of use of the device and any appropriate limitations on the use. If properly catalogued, the assessment will be readily available on each occasion that a licensing or registration application is considered, and can also be of benefit to inspection staff conducting subsequent appraisals in the workplace.

7.12. Generic assessments are particularly suited to relatively standard devices which are in fairly widespread use. Some variations in the conditions of use can be accommodated in the operational parameters specified in the assessment report.

8. PRIORITY ACTIONS

8.1. The information presented in this report can assist in establishing a basic set of priorities within a national regulatory infrastructure for a country which is in the process of establishing or consolidating a regulatory programme for the control of ionizing radiation.

8.2. Clearly, the ideal course of action will be determined by the prevailing circumstances, but it should be stressed that the introduction of a programme to achieve adequate control over radiation sources must inevitably be staged. Not all necessary features can be implemented at once. Establishing an appropriate infrastructure is an evolutionary process. Therefore, it is beneficial to identify priorities. The following provides advice on a priority sequence:

- enact legislation which provides for, among other things, the establishment of a national radiation safety infrastructure;
- establish a Regulatory Authority provided with necessary inspection and enforcement power;
- provide adequate staff resources for the Regulatory Authority and ensure their proper training;
- prepare basic regulations, almost certainly performance orientated, which provide a regulatory structure for radiation protection and safety required of users;
- initiate arrangements for the establishment of technical services (i.e., dosimetric, etc.) and emergency provisions;
- require notification to identify all users and to make them aware of the need to comply with the regulations;
- move firstly towards the licensing and inspection of hazardous practices, possibly employing consultants to provide expert advice;
- develop prescriptive orientated regulations/guides for the more common and widespread practices, again looking to consultants for assistance as necessary (this should enable authorization, inspection and compliance to be achieved with less discretion and the professional judgment needed on individual cases);
- establish a priority system for the authorization and inspection of less hazardous practices; and
- develop general criteria for registration of suitable practices.

8.3. At each stage, due regard should be paid to the need for quality assurance provisions covering development and implementation of the regulatory programme.

8.4. In addition to these more formal stages of infrastructure development, if the government does not know who is in possession of radiation sources and the Regulatory Authority is not fully organized, informal checks with likely source users should be made to determine possession. Likely candidates for source users include, for example, hospitals for medical diagnosis and therapy sources, pipeline construction companies for radiography sources, oil exploration companies for well logging sources and industries likely to use radiation gauging devices. Furthermore, early checks should be made to ensure that the more hazardous sources do not present an immediate threat to health and safety. Such sources include those used for radiation therapy, industrial radiography and product irradiation.

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Appendix

SAMPLE LEGISLATION AND REGULATIONS

INTRODUCTION

The purpose of this appendix is to provide advice on how to establish and maintain control over radiation sources through legislation and regulations.

The approach adopted for the sample legislation provided in this appendix is to set up a template comprising a straightforward legislative text and covering all the essential components of a legislative package as stipulated in the draft requirements (May 1998) of the IAEA Safety Standards Series on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. The example will clearly need adaptation and development to fit into national organizational and legal structures, and to accommodate particular national situations. Also, some countries may wish to incorporate some of the regulatory requirements into their basic law or legislation rather than in regulations issued by a Regulatory Authority.

The sample regulations illustrate a way to incorporate the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Standards, or BSS) into the national infrastructure as regulatory requirements in accordance with the draft requirements (May 1998) of the IAEA Safety Standards Series on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. This is not the only way to adopt the BSS as regulatory requirements, but it was chosen to be as clear and simple as possible in view of the particular needs of the countries to which the sample regulations are addressed. The types of practices generally utilized within those countries are, in fact, the more common, well developed uses of radiation sources involving equipment and procedures for which there is long operational experience, with the exclusion of complex nuclear facilities. The sample regulations are designed to focus on three main objectives, namely:

(1) establishing regulatory control over possession and use of radiation sources,
(2) maintaining doses from normal operations within limits and as low as reasonably achievable, and
(3) avoiding accidents or incidents.

That which follows illustrates conversion of the entire Principal Requirements of the BSS into regulations. The reason for including the entire Principal Requirements in the sample regulations is that, regardless of the national and local situations, all points in this portion of the BSS should be covered in order to establish a broad foundation for the regulatory programme.

Requirements for worker, medical, public and potential exposure protection are based on the Detailed Requirements of the BSS. Practice specific advice published by IAEA, WHO and PAHO can supplement the regulations as advice or as a third tier of prescriptive requirements. They would prescribe practice specific ways to satisfy relevant aspects of the more generally applicable performance requirements. This third tier is mainly where the Regulatory Authority would narrow the scope of its regulations to fit the type and size of its radiation source programme.

Conversion of the BSS and international practice specific advice into national regulations would, therefore, have a three-tiered structure as outlined in Fig. A.1.

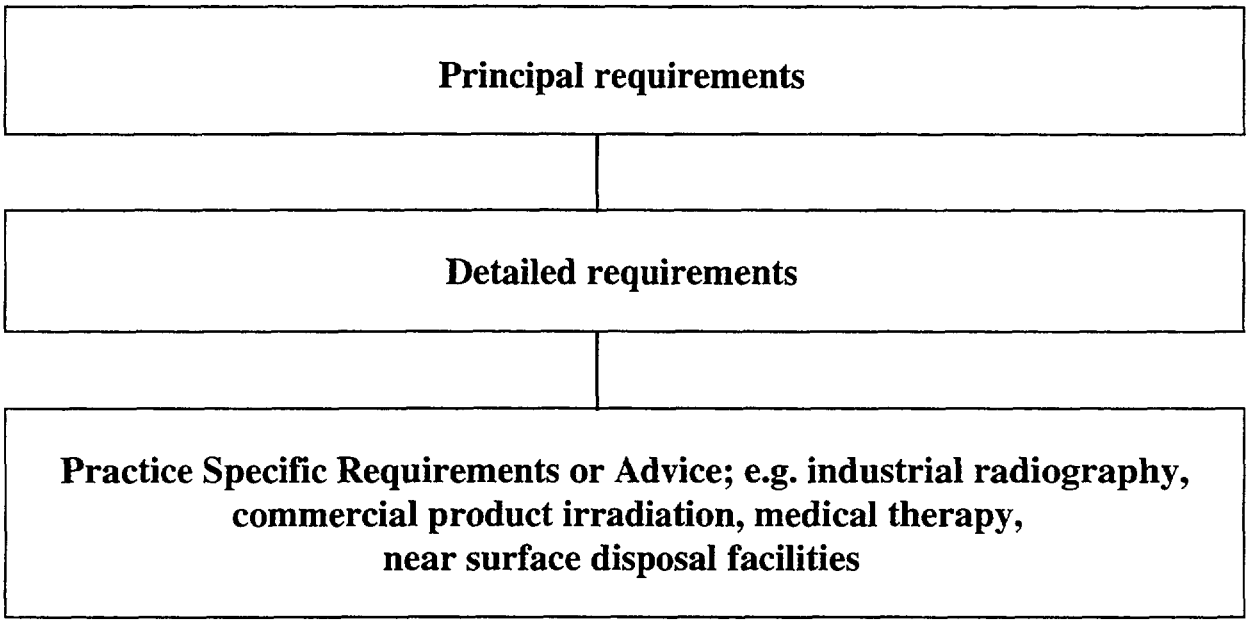

FIG. A.1. Three tiered structure of regulations based on the BSS including supporting prescriptive requirements advice.

The sample regulations apply to practices and the use of sources within practices. Except to the extent that they cover emergency intervention by authorized users for accidents with their sources, the sample regulations do not cover intervention guidelines and criteria as provided by the BSS. Because of the many and varied nature of interventions and their social and economic complexities, intervention is not very amenable to a set of strict regulations implemented by a Regulatory Authority. While the Regulatory Authority may have an important role in intervention, other government agencies might have the lead role depending upon the particular situation. Because of the social and economic implications of major decisions involving chronic exposure and the post-acute phase of accidents, intervention decisions are often made at governmental policy levels higher than the Regulatory Authority and other equivalent level agencies. It should be emphasized, however, that, regardless of who makes intervention decisions and who implements such decisions, intervention advice and criteria contained in the BSS should be taken into account.

The notes in italics which are contained in the sample legislation and under the relevant section or article in the sample regulations are explanatory and not part of the sample legislation or regulations.

SAMPLE LEGISLATION

Introduction

This legislation recognizes and takes into account that:

- uses of ionizing radiation introduce important benefits in medicine, industry and research;
- radiation exposure carries with it the potential to produce harmful effects in people; and
- it is necessary to establish legislation and regulations on the use of radiation sources and to designate a national organization as the Regulatory Authority to protect the health and safety of people while permitting the beneficial uses of ionizing radiation.

Objectives

The main purposes of the legislation are:

- to allow beneficial (*justified*) uses of ionizing radiation;
- to provide for adequate protection of people in current and future generations against the harmful effects of ionizing radiation and for the safety of radiation sources; and
- to provide a mechanism whereby these objectives are achieved through the establishment of a Regulatory Authority entrusted with an appropriate range of functions and responsibilities and provided with adequate resources.

Establishment of Regulatory Control

Article 1

This law shall apply to all situations involving exposure or the potential for exposure to ionizing radiation, except those which are excluded.

Article 2

The competent authority to apply this law is the *(State Office for Nuclear Safety, Ministry of Labour, etc.)*, hereinafter referred to as the Regulatory Authority.

Article 3

The (*Director/Chairman/Board*) of the Regulatory Authority shall be appointed by the (*President/Prime Minister/Parliament, etc.*).

Article 4

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

Article 5

The Regulatory Authority is empowered and required to undertake the following functions:

(a) to issue regulations (*or to prepare regulations for legislative adoption*) governing notification, authorization and exemption of practices and radiation sources and establishing radiation protection and safety requirements;
(b) to define the exposures that are excluded from regulatory requirements on the basis of their being unamenable to regulatory control;
(c) to issue authorizations and grant exemptions concerning the possession and use of radiation sources;
(d) to define in the regulations and authorizations the detailed obligations, including financial conditions, to be placed on those who possess radiation sources;
(e) to conduct inspections to assess radiation safety conditions and compliance with applicable regulations and other requirements specified in an authorization;
(f) to take such action as is necessary to enforce the requirements in any regulations and authorizations and to protect the health and safety of workers and the public and to impose sanctions for non-compliance with its requirements subject to any maximum specified by the (*Parliament or Minister*);
(g) to levy fees for authorizations and inspections. (*All such fees as well as funds obtained from fines levied for non-compliance with the regulatory requirements shall be deposited with the Treasury.*);
(h) to assist in emergency response;
(i) to initiate, recommend, or provide support on intervention, as appropriate;
(j) to advice other governmental authorities and organizations on matters within the competence of the Regulatory Authority;
(k) to promote or carry out research on radiation safety issues of regulatory concern;
(l) to maintain contact for information exchange and cooperation with regulatory bodies of other countries and relevant international organizations; and
(m) to establish appropriate mechanisms to inform the public about the regulatory process and the radiation safety aspects of regulated practices.

Article 6

Duly authorized representatives of the Regulatory Authority are permitted access to premises and facilities in which radiation sources are located or expected to be located in order to obtain information about the status of radiation safety and verify compliance with regulatory requirements.

Article 7

Resources for staffing and staff training, headquarters and equipment acquisition and maintenance, and inspection operational costs necessary for the Regulatory Authority to discharge its responsibilities shall be provided through the national fiscal process and reviewed annually.

Article 8

The Regulatory Authority is entitled to engage consultants to serve as individual expert advisers or as members of advisory committees as may be useful and appropriate for the Regulatory Authority to discharge its responsibilities.

Article 9

The Regulatory Authority is authorized to communicate directly with higher governmental authorities in all cases in which this is considered necessary to exercise effectively the functions of the Regulatory Authority.

Article 10

In case that other laws governing occupational, public, medical or environmental protection and safety under the control of other regulatory bodies also address the use of ionizing radiation, the Regulatory Authority and such other regulatory bodies are encouraged to enter into agreements for co-operation and co-ordination to avoid gaps or overlaps in regulatory control while discharging respective responsibilities. If appropriate agreements can not be developed to the mutual satisfaction of the agencies involved, the issues will be directed to (*Parliament, Congress, etc.*) for resolution.

Article 11

A permanent mechanism for exchange of information and cooperation shall be established between the Regulatory Authority and the Customs Authorities to ensure adequate control over sources entering the country and proper identification and authorization of the persons importing or receiving the sources.

Article 12

This law shall come into force on (*date*).

Notes:

1. *The enabling legislation is the basic legal document enacted by the national legislative body to allow for the beneficial uses of ionizing radiation and provide the framework for adequate protection of workers and the public from any radiation associated hazards.*

2. *The enabling legislation should be as simple as feasible, consistent with the national situation, so that the need for subsequent amendments is minimized. In contrast, regulations, which contain administrative and technical requirements, can be expected to be amended from time to time as knowledge is gained through operating experience and scientific developments, and as technology advances. Therefore, details, particularly administrative procedures and radiation safety requirements, are more appropriately determined by the Regulatory Authority once the enabling legislation has established that authority.*

3. *In many countries pressing social needs place severe demands on the limited resources available and it must be recognized that it may not be feasible to expect an 'ideal system' of radiation safety to be established, at least not on a short time-scale.*

   For example, a complete formal independence of the Regulatory Authority from promotional and regulated activities might not be always feasible; however, it is always desirable that -at least- an effective independence exists between the organs charged with regulation and promotional responsibilities, even if they are in the same governmental structure. The enabling legislation should reflect realistic expectations and the need for the efficient use of resources, rather than trying to follow the lines established in countries having different social and economic levels. It should not include requirements that might be counterproductive to the fulfilment of the Regulatory Authority's primary mission of protection and safety.

4. *To be effective, the Regulatory Authority will need to be adequately resourced financially and in terms of staff effort. It is, therefore, desirable to include in the enabling legislation the means for funding the Regulatory Authority, e.g. directly by fiscal legislation as a component of a larger organization. If the cost of operating a Regulatory Authority is to be recovered from fees imposed on those who possess radiation sources, the enabling legislation will need to make provision for the levy of such fees.*

5. *Deciding who has the authority and responsibility to regulate protection and safety of radiation sources can be an issue in certain situations. In those situations where the Regulatory Authority and responsibility is split between two or more government agencies, the enabling legislation should establish clear lines of authority and responsibility. This should, in principle, be relatively straightforward and easy to address in legislation. However, to the extent practicable, particularly where skill requirements are similar, responsibility should be vested in a single organization. Another kind of situation is not so straightforward. There are often separate pieces of legislation enacted at different times and having somewhat different objectives, which cloud the issue as to who should be responsible for what. The consequence can be that there may be some overlap and gaps. A typical example is one statute which establishes a Regulatory Authority responsible for radiation safety and another which establishes a Transportation Authority with responsibilities for the safe transport of hazardous substances, including radioactive material. If such is the case, the enabling legislation should contemplate such situations and provide for the co-ordination and co-operation of the various authorities involved to ensure that there are no gaps or overlaps with the statutory arrangements. In cases in which the share of responsibilities between two or more authorities is unclear, it can be useful to establish a national co-ordination committee, reporting to a level in government higher than the directors of the affected authorities, to resolve conflicts of competence between them.*

6. *In many countries, radiation sources are imported. Therefore, it would be appropriate for the enabling legislation to establish a direct link between the Customs Authorities and the Regulatory Authority so that the Regulatory Authority is apprised of any sources entering the country and the person importing them. Alternatively, such a link could be established through the regulations produced by the Regulatory Authority, although this approach might not be so effective because it would be more dependent on the good will of the two organizations for effective co-operation. It is also noted that there is considerable concern over the illicit traffic in radioactive substances and a good link between the Regulatory Authority and that responsible for import control would help to deal with this issue.*

7. *Certain services and facilities are essential for radiation safety. These might be beyond the capability of legal persons authorized to conduct practices to provide them for their own needs and they might not be available in the commercial sector. Such services and facilities could include training, personal dosimetry, environmental monitoring, central registries for occupational exposure records, and radioactive waste storage and disposal facilities. To the extent that such services and facilities are needed for adequate radiation safety but are not otherwise available, government may chose to provide for them through legislation. Such provisions could be included in the legislation which establishes a Regulatory Authority or in other comparable legislation. If such government services or facilities, e.g. waste disposal facilities, involve taking*

possession of radiation sources, the functions of the government organization responsible for such operations should be clearly separated in the legislation from the functions of the Regulatory Authority. It should be noted that provision of any such services and facilities does not detract from the ultimate responsibility for radiation safety borne by the legal persons authorized to conduct the practices.

SAMPLE REGULATIONS

The Regulatory Authority (*name, address, telephone/facsimile*).

Note: If useful, provide similar information about departments within the Regulatory Authority, e.g. Licensing, Inspection, Administration.

General Provisions

Note: The General Provisions are probably the most important part of the regulation because it provides the broad powers for the Regulatory Authority to do its job and, in particular, to deal with situations which might not be contemplated by the more detailed regulatory requirements which follow.

Article 1. **Entry into Force**

These Regulations shall come into force on __(*date*)_____. The Regulatory Authority may grant a delay in complying with specific articles in specific cases on receipt of a request in writing which justifies such a delay. In particular, if a modification to an existing practice or source is required by the Regulatory Authority in order to comply with some requirement of these Regulations, such a requirement shall take effect within the period required for the modification or any other period as approved by the Regulatory Authority.

Article 2. **Purpose**

These Regulations specify the minimum requirements for protection of the people against exposure to ionizing radiation and for the safety of radiation sources, hereinafter termed 'radiation safety' or 'protection and safety'. They do not relieve an authorized legal person from the duty to take any additional actions as may be appropriate and necessary to protect the health and safety of people.

Article 3. **Scope**

1. These Regulations apply to the adoption, introduction, conduct, discontinuance, or cessation of a practice and to the design, manufacture, construction or assembly, acquisition, import or export, distribution, selling, loaning or hiring, locating, commissioning, processing, possession, use and operation, maintenance or repair, transfer or decommissioning, disassembly, transport, storage or disposal of a source within a practice unless exposure from the source is excluded as specified in Article 6 of these Regulations or is exempted in accordance with Article 16 of these Regulations.

2. The sources within any practice to which the requirements for practices of these Regulations shall apply include:

Note: Text to be adjusted to local circumstances

(a) radioactive substances and devices that contain radioactive substances or produce radiation, including consumer products, sealed sources, unsealed sources, and radiation generators, including mobile radiography equipment;

(b) installations and facilities containing radioactive substances or devices which are used for industrial, medical, agricultural, research and education purposes; and
(c) any other source specified by the Regulatory Authority.

3. These Regulations shall apply to intervention by legal persons authorized to possess sources in the event of radiological emergencies involving their sources.

Article 4. **Definitions**

Terms shall be interpreted as defined in the Glossary.

Note: The glossary provided here contains a number of key terms that are defined in the BSS Glossary plus a few others.

Article 5. **Exposures**

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

Article 6. **Exclusions**

The following exposures are excluded from the requirements of these Regulations: exposures from natural radioactivity in the body, from cosmic radiation and from unmodified concentrations of natural radionuclides in raw materials, and any other sources that are essentially unamenable to control as may be determined by the Regulatory Authority.

Article 7. **Responsible Parties**

Note: Text to be adapted to local circumstances

1. The Regulatory Authority shall be responsible for the enforcement of these Regulations.
2. The principal parties having the main responsibilities for the application of these Regulations shall be:
   (a) those authorized by registration or license; and
   (b) employers.
3. Other parties shall have subsidiary responsibilities for the application of these Regulations. These parties may include, as appropriate:
   (a) suppliers;
   (b) workers;
   (c) radiation protection officers;
   (d) medical practitioners;
   (e) health professionals;
   (f) qualified experts;
   (g) ethical review committees; and
   (h) any other party to whom the principal party has delegated specific tasks.

4. The general responsibilities of the principal parties include the following:

(a) to establish radiation safety objectives in conformity with the relevant requirements of these Regulations; and

(b) to develop, implement and document a radiation safety programme commensurate with the nature and extent of the risks associated with the practices and interventions under their responsibility and sufficient to ensure compliance with the requirements of these Regulations. In particular, this programme shall include the following actions:

- to determine and keep continually under review the measures needed to achieve the radiation safety objectives, to ensure that the resources needed for their implementation are provided and regularly to verify that the radiation safety objectives are being achieved;
- to identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures;
- to facilitate consultation and co-operation between all relevant parties with respect to radiation safety; and
- to keep appropriate records regarding the discharge of their responsibilities.

Article 8. **Access to Premises and Information**

Legal persons responsible for authorized practices or sources within practices shall permit representatives of the Regulatory Authority access to premises and facilities in which such practices are conducted or sources located in order to obtain information about the status of radiation safety and verify compliance with regulatory requirements. Each legal person authorized to engage in a practice covered by these Regulations shall make available to the Regulatory Authority, upon reasonable notice, information and records regarding radiation safety.

Article 9. **Non-Compliance, Incidents and Accidents**

1. In the event of a breach of any applicable requirement of these Regulations, principal parties shall, as appropriate:

(a) investigate the breach and its causes, circumstances and consequences;

(b) take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;

(c) communicate to the Regulatory Authority on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken; and

(d) take whatever other actions are necessary as required by these Regulations.

2. The communication of a breach to the Regulatory Authority shall be timely and it shall be immediate whenever an emergency exposure situation has developed or is developing.

3. Failure to take corrective or preventive actions within a reasonable time in accordance with these Regulations shall be grounds for modifying, suspending or withdrawing any authorization that has been granted by the Regulatory Authority.

Article 10. **Enforcement**

The Regulatory Authority may revoke, suspend or modify an authorization to use a radiation source, or prohibit the possession of a radiation source, upon finding an undue threat to health and safety or non-compliance with applicable regulatory requirements. The Regulatory Authority may levy fines for non-compliance with applicable regulations and regulatory requirements commensurate with the nature of the infraction. The Regulatory Authority upon finding willful violations or attempted violations of its regulations or requirements may recommend to (*National Justice Authority*) for prosecution under national criminal statutes and codes.

Note: Fines should be included in Article 10 if provided for in the legislation.

Article 11. **Applicability of Other Regulations and Requirements and Resolution of Conflicts**

1. The requirements of these Regulations are in addition to, and not in place of, other applicable national and local laws and regulations. Nothing in these Regulations shall be construed as relieving employers from complying with applicable national and local laws and regulations governing workplace hazards, including radiation hazards from natural sources which are unconnected with the work. If a conflict exists between requirements contained herein and other laws or regulations, the Regulatory Authority shall be notified of such conflict in order to initiate steps towards resolution.

2. Nothing in these Regulations shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

Article 12. **Additional Requirements**

The Regulatory Authority may impose requirements by regulation, order, or conditions of an authorization, in addition to those established in these Regulations, as it deems appropriate or necessary to protect health or to minimize risk from radiation hazards.

Article 13. **Interpretation**

Except as specifically authorized, no official interpretation of these Regulations binding on the Regulatory Authority can be made by any officer or employee of the Regulatory Authority other than a written interpretation by (*identify who in the Regulatory Authority is authorized to make the official interpretation that will be binding*).

Administrative Requirements

Article 14. **General Obligations**

No person shall engage in activities which involve practices or sources within practices as specified in Article 3 of these Regulations unless the requirements of these Regulations, including the requirements for notification and authorization, are met.

Article 15. **Requirements for Notification**

1. Except as provided for in Article 16, any legal person who, on the effective date of these Regulations specified in Article 1, is responsible for a practice or in possession of a radiation source referred to in Article 3, shall submit a notification to the Regulatory Authority within 90 days of the effective date specified in Article 1. Annex 1 of these Regulations specifies the information to be provided in the notification.

2. Except as provided for in Article 16, any legal person intending to initiate a practice or to possess a radiation source referred to in Article 3, shall submit a prior notification to the Regulatory Authority of such an intention. Annex 1 of these Regulations specifies the information to be provided in the notification.

3. Sources and practices requiring notification only (*list to be established by the Regulatory Authority*).

4. After notification as specified in 1. or 2. above and for any practices or sources not included in the list given in 3. above, each legal person who applies to the Regulatory Authority for an authorization according to Article 17 is permitted to continue existing activities specified in the notification, following the requirements of these Regulations, until such time as the Regulatory Authority revokes such permission or grants an authorization.

Note: The Regulatory Authority may specify sources or practices for which notification is the only requirement. For other sources or practices, an application for authorization is deemed to include a notification.

Article 16. **Exemption of Practices and Sources**

1. Practices and sources within a practice may be exempted from the requirements of these Regulations provided that they comply with:

   (a) the exemption levels specified in Annex 2, or
   (b) any exemption levels defined by the Regulatory Authority on the basis of the exemption levels specified in Annex 2.

2. Exemptions shall not be granted for practices deemed not to be justified as specified in Article 20 paragraph 2.

3. The following practices and sources within a practice are automatically exempted from the requirements of these Regulations, including the requirement for notification, registration or licensing:

   (a) radioactive substances for which the total activity of a given nuclide present on the premises at any one time or its activity concentration contained in a mass of 1000 kg or less of material does not exceed the exemption levels specified in Annex 2;

   (b) apparatus containing radioactive substances exceeding the quantities or concentrations specified above, provided that:

- it is of a type approved by the Regulatory Authority; and
- it is constructed in the form of a sealed source, and it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus nor a dose to any member of the public exceeding 10 μSv in a year; or

(c) the operation of any electrical apparatus to which these Regulations apply, other than that referred in (d) to below, provided that:

- it is of a type approved by the Regulatory Authority; and
- it does not cause in normal operating conditions a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus; or

(d) the operation of any cathode ray tube intended for the display of visual images or other electrical apparatus operating at a potential difference not exceeding 30 kV, provided that it does not cause in normal operating conditions a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface of the apparatus.

Article 17. **Requirements for Authorization by Registration or Licence**

1. Except as provided in Article 15 paragraph 4, and Article 16 of these Regulations, any legal person intending to engage in a practice or possess a radiation source referred to in Article 3 shall apply to the Regulatory Authority for an authorization which shall take the form of either a registration or a licence. In the case of existing practices or sources which are notified according to Article 15 paragraph 1, the above mentioned application shall be submitted within 90 days of the effective date specified in Article 1. If the application refers to an industrial irradiation installation, an installation processing radioactive substances, a medical or industrial radiography facility, or for any use of source which the Regulatory Authority has not designated as suitable for registration, the authorization shall take the form of a licence.

2. Any legal person applying for an authorization shall:

(a) submit to the Regulatory Authority relevant information necessary to support the application, including:

- an evaluation of the nature, magnitude and likelihood of the exposures attributed to the practice and sources within the practice;
- a safety assessment in cases where this is prescribed by the Regulatory Authority, to be submitted as part of the application; and
- a determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group.

(b) take all necessary steps for the protection and safety of workers, of members of the public and, when applicable, of patients.

3. Any legal person responsible for a source to be used for medical exposure shall include in the application for a licence the qualifications in radiation protection of the medical practitioners who are to be so designated by name or by qualification credentials in the licence as the only individuals permitted to prescribe medical exposure by means of the authorized source.

Notes:

1. For some practices, particularly those which involve construction of facilities which are later difficult to modify, such as commercial product irradiators and radiotherapy facilities, a two stage licensing process is desirable. The Regulatory Authority should issue an authorization to construct before construction begins. This reduces the chance of large financial investments in designs or practices that for other reasons cannot be licensed to operate. A good way to implement a two stage process is for the Regulatory Authority to get an almost complete picture in the initial application; facility design, equipment description, general operating procedures and qualifications of personnel, etc. The Regulatory Authority may also wish to prohibit procurement of radiation sources (including import) until a particular stage of construction has been completed, and safe storage of the sources can be ensured. The licence can be granted for the entire operation with a licence condition which requires the licensee to notify the Regulatory Authority when construction is completed and relevant acceptance tests made, but before operations begin. The licence condition should prohibit operation by the licensee until notified by the Regulatory Authority that it is satisfied with the facility as constructed. The Regulatory Authority will normally conduct a preoperational inspection at this stage. Also, because of elapsed time and modifications during construction, there may be adjustments to the operating procedures and qualifications or identification of key personnel before permission is granted to operate.

2. The Regulatory Authority should, as part of its assessment of applications for authorization, also consider the financial capability of the applicant to comply with these regulations, particularly with respect to the decommissioning of facilities and the disposal of radioactive waste.

3. With the possible exception of gauging devices used on process or manufacturing lines, the Member States to which this example of Regulations is tailored are not likely to have many sources and practices that meet the criteria to be good candidates for registrations. For this reason, this example regulation has been simplified to include explicitly only authorization by licensing. If a Member State has candidates for registration with the characteristics indicated in the main text of this document it may wish to use a more general procedure as illustrated in Fig. A.2 and in Note 4.

4. FIG. A.2 illustrates how the procedure should be applied, i.e.:

- *(a) The applicant submits a notification to the Regulatory Authority of such intention, except for sources which are* excluded *or* exempt *from the requirements of these Regulations.*
- *(b) The applicant submits an application for registration or licensing for all sources except those which are* exempt *and those for which* notification *only is required (The Regulatory Authority will have specified those sources for which notification only is required). An application for registration or licensing fulfils the obligation of notification.*
- *(c) The Regulatory Authority, issues a registration or licence as appropriate.*

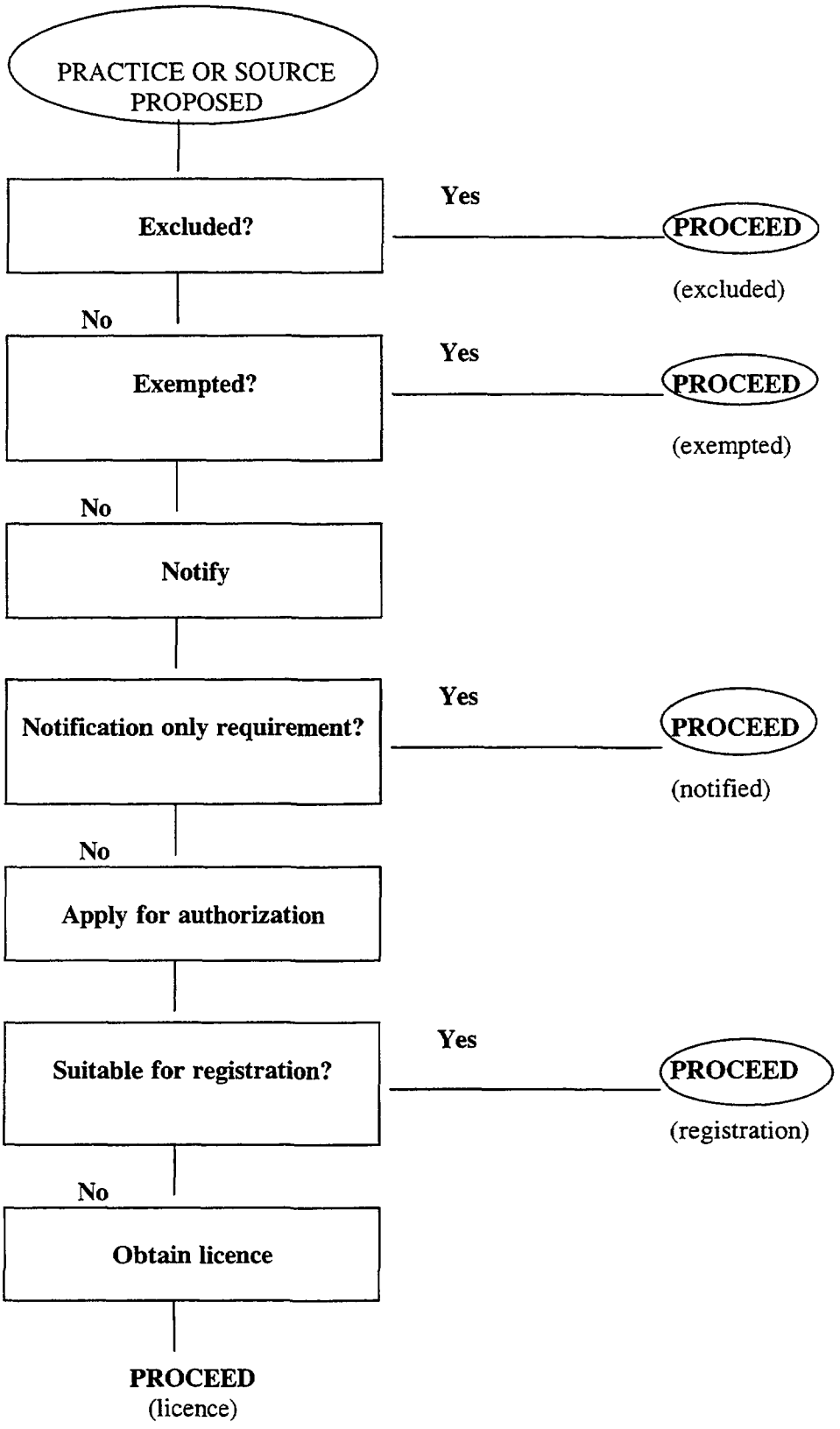

FIG. A.2. General procedure for notification and authorization (by registration or licensing).

5. *The sample regulations from this point forward refer to licensees only; however, if registration is to be included, the requirements placed on licensees in the statements that follow also apply to registrants, except in those specified instances in which they are applicable to licensees only.*

Article 18. **Responsibilities of Licensees**

1. Licensees shall bear the responsibility for establishing and implementing the technical and organizational measures that are needed for ensuring protection and safety for the practices and sources for which they are authorized and for compliance with all applicable requirements of these Regulations. They may appoint and shall specifically identify other people to carry out actions and tasks related to these responsibilities, but they shall retain the responsibility for the actions and tasks themselves.

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

3. Licensees shall ensure that only workers who are designated in the application by name and/or qualification credentials and authorized by reference in the licence, as having key assignments related to protection and safety, and other workers assigned tasks involving operation or handling of radiation sources which could substantially affect protection and safety shall be permitted to fulfil such required assignments and tasks.

Note: The Regulatory Authority should decide whether the licences will have a defined period of validity and, if so, establish appropriate licence renewal procedures.

Article 19. **Clearance**

Sources, including substances, materials and objects within authorized practices can be cleared from further compliance with the requirements of these Regulations provided that they comply with exemption levels established as specified in Annex 2 or approved by the Regulatory Authority.

Radiation Protection Performance Requirements

Note: The Radiation Protection Requirements as well as Management Requirements and Technical Requirements in that which follows are stated in very broad terms, very similar to the way they are in the BSS. Determination of compliance with many of these requirements would need then to be supplemented with prescriptive requirements and with additional actions taken by the Regulatory Authority as may be appropriate for ensuring adequate protection and safety. These prescriptive requirements and additional regulatory actions must be tailored to the specific conditions and needs of each individual country.

Article 20. **Justification of Practices**

1. No practice shall be authorized unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause, taking into account social, economic and other relevant factors. For this decision, the applicant for an authorization shall provide sufficient information and evidence on the benefits and the harm to support the justification of the practice.

2. The following practices are deemed to be not justified whenever they would result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products:

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

Article 21. **Dose Limitation**

The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, exceeds any relevant dose limit specified in Annex 3, except in the special circumstances considered in Article 42. Dose limits shall not apply to medical exposures from authorized practices.

Article 22. **Optimization of Protection and Safety**

In relation to exposures from any particular source within a practice, radiation safety shall be optimized in order that the magnitude of individual doses, except for therapeutic medical exposures, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the dose to individuals delivered by the source be subject to dose constraints, as it is specified in Article 23. The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation safety principles to achieve this objective.

Article 23. **Dose Constraints**

1. Except for medical exposure, the optimisation of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses to the individuals of the critical group do not exceed dose constraints which are equal to the dose limits specified in Annex 3 or any lower values established by the Regulatory Authority.

2. In case of any source that can release radioactive substances to the environment, the dose constraints shall be established so that the prospective annual doses to members

of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in Annex 4 or any lower values established by the Regulatory Authority.

Article 24. **Guidance Levels for Medical Exposure**

1. Guidance levels for medical exposure shall be used by medical practitioners in the conduct of diagnostic and therapeutic procedures involving exposure to radiation as well as in the optimisation of protection of patients.

2. The guidance levels shall be so established by relevant professional bodies, in consultation with the Regulatory Authority, as to provide an indication on what doses are achievable with current good practice for average sized patients.

3. The guidance levels shall be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgements and shall be revised as required by technological and scientific developments.

Management Requirements

Article 25. **Safety Culture**

Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:

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

Article 26. **Quality Assurance**

Licensees shall establish quality assurance programmes that provide, as appropriate:

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

Article 27. **Human Factors**

1. Licensees shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their responsibilities and

perform their duties with appropriate judgement and according to defined procedures, and are periodically retrained or re-qualified as may be appropriate.

2. Licensees, in co-operation with suppliers as appropriate, shall follow sound ergonomic principles in designing equipment and preparing operating procedures, in order to facilitate the safe use of equipment and minimize the contribution of human errors to accidents or incidents.

3. Licensees shall provide appropriate equipment, safety systems and procedures which:

   (a) reduce, as far as practicable, the possibility of human errors leading to unplanned exposure of any person;
   (b) provide means to detect human errors and correct or compensate for them; and
   (c) facilitate intervention in the event of an accident.

Article 28. **Qualified Radiation Safety Experts**

1. Licensees shall arrange for qualified radiation safety experts to be identified and made available for providing advice on the observance of these Regulations.

2. The qualifications of the radiation safety experts shall include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the authorized practices or sources within a practice.

3. Licensees shall keep the Regulatory Authority informed of the arrangements made with respect to paragraphs 1. and 2. above.

Verification of Protection and Safety

Article 29. **Safety Assessments**

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

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

Article 30. **Monitoring and Verification of Compliance**

1. Monitoring and measurements shall be conducted by licensees of the parameters necessary for verification of compliance with the requirements of these Regulations and the licence.

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

Article 31. **Records**

Records shall be maintained by licensees of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with requirements of these Regulations.

Occupational Exposure Protection

Article 32. **General Responsibilities**

1. Licensees and employers of workers who are engaged in activities that involve or could involve occupational exposure shall be responsible for the protection of these workers against any occupational exposure which is not excluded from these Regulations.

2. Licensees and employers shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that:

   (a) occupational exposures are limited as specified in Annex 3;
   (b) radiation safety is optimised in accordance with Articles 22 and 23;
   (c) policies, procedures and organisational arrangements for occupational protection and safety are established to implement the relevant requirements of these Regulations, and the resulting decisions on measures to be adopted for this purpose are recorded and made available to relevant parties, including workers, through their representatives where appropriate;
   (d) suitable and adequate facilities for radiation safety are provided, including personal protective devices and monitoring equipment, and arrangements are made for their proper use;
   (e) radiation safety and health surveillance services are provided through qualified experts;
   (f) arrangements are made to facilitate consultation and co-operation with workers, through their representatives where appropriate, about measures which are needed to achieve adequate radiation safety by an effective implementation of these Regulations; and
   (g) necessary conditions are provided and arrangements are made to promote a safety culture in the work force and achieve adequate training of workers on radiation safety matters.

3. If workers are to be engaged in work that involves or could involve a source which is not under the control of their employer, the licensee responsible for the source shall:

   (a) obtain from the employer, as a pre-condition for engagement of such workers, information on their previous occupational exposure history and other information as may be necessary to provide protection and safety in compliance with these Regulations;

(b) provide such workers with protective measures and safety provisions which are at least as good as those provided for employees of the licensee; and
(c) make dosimetric and other appropriate information available to the employer for the purpose of demonstrating that the level of protection provided to such workers is compatible with the requirements of these Regulations.

4. Licensees and employers shall ensure that workers under their responsibility who are exposed to radiation from sources, other than natural sources, that are not directly related to or required by their work receive the same level of protection as if they were members of the public.

5. Licensees and employers shall ensure that workers are informed of their obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources. In particular, licensees and employers shall ensure that workers:

(a) follow any applicable rules and procedures for protection and safety;
(b) properly use the monitoring devices and the protective equipment and clothing provided;
(c) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of these Regulations; and
(d) promptly report to the licensee and employer any circumstances that could adversely affect safety conditions or the requirements of these Regulations.

6. Licensees and employers shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of these Regulations, and shall take appropriate remedial actions.

Article 33. **Conditions of Service**

1. The conditions of service of workers shall be independent of the existence or the possibility of occupational exposure. Special compensatory arrangements or preferential treatment with respect to salary or special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits shall neither be granted nor be used as substitutes for the provision of proper protection and safety measures to ensure compliance with the requirements of these Regulations.

2. Female workers shall be advised by the licensee or employer that it is desirable to notify the employer of pregnancy. Once a female worker has notified the employer that she is pregnant, the employer shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection which is required for members of the public, as it is specified in Annex 3. The notification of pregnancy shall not be considered a reason to exclude a female worker from work.

3. Employers shall make every reasonable effort to provide workers with suitable alternative workplace or employment in circumstances where it has been determined, either by the Regulatory Authority or in the framework of the health surveillance programme required by these Regulations, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

4. No person under the age of 16 years shall be subjected to occupational exposure. No person under the age of 18 years shall be allowed to work in a controlled area unless supervised and then only for the purpose of the training.

Article 34. **Classification of Areas**

1. Controlled Areas:

   (a) Licensees shall designate as a controlled area any area in which specific protective measures or safety provisions are or could be required for:

      (i) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
      (ii) preventing or limiting the extent of potential exposures.

   (b) Licensees shall:

      (i) determine the boundaries of any controlled area on the basis of the magnitude and likelihood of expected exposures and the nature and extent of the required protection and safety provisions;
      (ii) delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means;
      (iii) where a source is brought into operation or energised only intermittently or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;
      (iv) display a warning symbol, recommended by the International Organization for Standardization (ISO) [7], and appropriate instructions at access points and other appropriate locations within controlled areas;
      (v) establish occupational protection and safety measures, including local rules and procedures that are appropriate for controlled areas;
      (vi) restrict access to controlled areas by means of administrative procedures, such as the use of work permits, and by physical barriers, which could include locks or interlocks; the degree of restriction being commensurate with the magnitude and likelihood of the expected exposures; and
      (vii) provide at entrances and exits of controlled areas appropriate means for change of clothing, contamination monitoring and personal decontamination.

2. Supervised Areas:

   (a) Licensees shall designate as a supervised area any area not already designated as a controlled area, but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.
   (b) Licensees shall delineate and identify the supervised areas by appropriate means, taking into account the nature and extent of radiation hazards in those areas.

3. Licensees shall periodically review conditions to determine the possible need to revise the protection measures or safety provisions, including the boundaries of controlled and supervised areas.

Article 35. **Local Rules and Supervision**

1. Licensees and employers shall, in consultation with workers, through their representatives if appropriate:

   (a) establish in writing, in a language comprehensible to the workers and others, such rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;
   (b) include in the local rules and procedures the values of any relevant authorized level, investigation level or other reference level and the procedure to be followed in the event that any such level is exceeded;
   (c) ensure that any work involving occupational exposure is adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions are observed; and
   (d) when required by the Regulatory Authority, designate a qualified radiation safety expert as Radiation Protection Officer.

Note: In some cases it will be appropriate to have the local rules and procedures in both the official language and in a local dialect.

2. Employers and licensees shall:

   (a) provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety, including information on general and local rules and procedures and on available protection and safety provisions, as well as adequate information on the significance for protection and safety of their actions;
   (b) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on:
      (i) the risk to the embryo or foetus due to exposure of a pregnant woman;
      (ii) the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant; and
      (iii) the risk to an infant ingesting radioactive substances by breast feeding;
   (c) provide to those workers who could be affected by an emergency plan appropriate information, instruction and training; and
   (d) keep records of the training provided to individual workers.

Article 36. **Personal Protective Equipment**

Licensees and employers shall:

(a) minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate well engineered controls and satisfactory working conditions;

(b) if necessary, ensure that workers are provided with suitable and adequate personal protective equipment, including as appropriate:
   (i) protective clothing;
   (ii) protective respiratory equipment with information on its protection characteristics and instructions on its proper use; and
   (iii) protective aprons and gloves and organ shields;

(c) arrange for regular testing and maintenance to be carried out on all personal protective equipment, including, as required, special equipment for use in the event of accidents and interventions; and

(d) take into account the following factors when assigning personal protective equipment for a given task:
   (i) medical fitness to sustain possible extra physical effort while using the protective equipment; and
   (ii) additional work time or inconvenience or additional non-radiological risks associated with the use of the protective equipment.

Article 37. **Exposure Assessment**

1. Licensees and employers shall arrange for the assessment of the occupational exposure of workers and shall ensure that adequate arrangements are made with appropriate dosimetry services under an adequate quality assurance programme.

2. For any worker who is normally employed in a controlled area, individual monitoring shall be undertaken where this is feasible. In cases where individual monitoring is not feasible, the occupational exposure of the workers shall be assessed on the basis of the results of monitoring of the workplace and of information on the locations and duration of exposure of the workers.

3. For any worker who is normally employed in a supervised area or who enters a controlled area only occasionally, the occupational exposure of the worker shall be assessed, but the assessment may be on the basis of the results of monitoring of the workplace or of individual monitoring.

4. The nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

5. Licensees and employers shall ensure that workers who may be exposed to radioactive contamination, including workers who use protective respiratory equipment, are identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed doses, as appropriate.

Article 38. **Monitoring of Workplace**

1. Licensees, in co-operation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of and the risks associated with the source.

2. The nature and frequency of monitoring of workplaces shall:

(a) be sufficient to enable:
  (i) evaluation of the radiological conditions in all workplaces;
  (ii) assessment of the exposure of workers in controlled areas and supervised areas; and
  (iii) review of the classification of controlled and supervised areas; and
(b) depend on the levels of ambient dose equivalent and airborne and surface activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

3. The programmes for monitoring of the workplace shall specify:

  (a) the quantities to be measured;
  (b) where and when the measurements are to be made and at what frequency;
  (c) the most appropriate measurement methods and procedures; and
  (d) reference levels and the actions to be taken if they are exceeded.

4. Licensees shall keep appropriate records of the findings of the workplace monitoring programme, which shall be made available to workers, where appropriate through their representatives.

Article 39. **Health Surveillance**

Employers and licensees, in accordance with the rules established by the Regulatory Authority, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks.

Article 40. **Records of Worker Exposure**

1. Employers and licensees shall maintain records of exposure for each worker for whom assessment of occupational exposure is required under Article 37. Such worker exposure records shall include information on:

  (a) the general nature of the work resulting in exposure, the doses and intakes at or above the relevant recording levels and the data upon which the dose assessments are based;
  (b) the periods of employment with different employers, if any, and the corresponding doses and intakes in each period of employment; and
  (c) the doses or intakes due to emergency interventions or accidents, which shall be distinguished from doses and intakes received during work in normal conditions.

2. Employers and licensees shall:

  (a) provide for access by workers to information in their own exposure records and workplace monitoring where appropriate; and
  (b) upon request of the Regulatory Authority or other persons or organizations with a demonstrated need for such records, including relevant employers and supervisors of the health surveillance programme, provide access to worker exposure records with due care and attention to the maintenance of appropriate confidentiality.

3. Exposure records for each worker shall be retained by the licensees and employers, or by the Regulatory Authority (*or other designated organisation*) in case the licensees and employers cease their activities. These records shall be preserved at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure.

Article 41. **Special Circumstances**

1. If a practice which is justified and for which radiation safety is optimised presents special circumstances which require a temporary change in some dose limitation requirements of these Regulations, the licensee shall not make any such temporary change without approval of the Regulatory Authority.

2. The application submitted by the licensee to obtain this approval shall include evidence to demonstrate that:
   (i) all reasonable efforts have been made to reduce exposures and optimise radiation safety provisions in accordance with the requirements of these Regulations; and
   (ii) the relevant employers and workers, through their representatives where appropriate, have been consulted on the need for and the conditions of the temporary change in dose limitation requirements.

3. Any temporary change in a dose limitation requirement of these Regulations shall be limited to specified work areas and shall be in accordance with the time and dose limitations for special circumstances specified in Annex 3.

Medical Exposure Protection

Note: The principles and objectives for medical exposure protection are similar to those for worker and public exposure protection. However, they are applied somewhat differently, because medical exposures are deliberate exposures of patients in diagnostic and therapeutic practices whereas normal exposures of workers and the public are an undesirable consequence of beneficial practices. Because medical exposure is only linked to medical radiation practices, the BSS contain prescriptive operational requirements only for patient protection. The provision of similar prescriptive requirements in the BSS for worker and public protection is not practical in view of the large and diversified range of practices involving worker and public exposure.

In order to maintain parallelism in the performance requirements for worker, medical and public exposure, in these Regulations, and to facilitate additions to prescriptive requirements as technology advances in medical radiation practices, the sample regulations includes the operational prescriptive requirements specified in II. 16, II.17 and II.18 of the BSS in Annex 4 and links them as requirements in the main body of the regulation. In addition, IAEA, WHO and PAHO publications contain advice which amplifies the performance requirements that should also be taken into account in the section of these sample regulations covering use of international protection and safety guides.

Article 42. **General Responsibilities**

1. 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;
   (c) medical and paramedical personnel are available as needed, and either are health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedures that the medical practitioner prescribes;
   (d) for therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of these Regulations are conducted by or under the supervision of a qualified expert in radiotherapy physics;
   (e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients be constrained as specified in Annex 3; and
   (f) training of personnel is carried out according to criteria approved by the Regulatory Authority.

2. Licensees shall to the extent practicable ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of these Regulations are fulfilled with the advice of a qualified expert in radiodiagnostic physics, nuclear medicine physics and radiopharmacy in the compounding of radiopharmaceuticals, as appropriate.

3. Medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with these Regulations with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

Article 43. **Justification of Medical Exposure**

1. Medical practitioners shall consider the justification of medical exposures that they prescribe by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

Note: In justifying each type of diagnostic examination by radiography, fluoroscopy or nuclear medicine, relevant guidelines should be taken into account, such as those established by the WHO [8-10].

2. Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

3. Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

4. The exposure of humans for medical research is deemed to be not justified unless it is:

   (a) in accordance with the provisions of the Helsinki Declaration [11] and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences (CIOMS) [12] and WHO [13]; and
   (b) subject to the advice of the licensee's Ethical Review Committee and to any other applicable laws and regulations.

Article 44. **Optimisation of Protection for Medical Exposures**

1. In addition to satisfying the general requirements for optimisation of radiation safety specified in other parts of these Regulations, licensees, in co-operation with suppliers where appropriate, shall satisfy the prescriptive design and operational requirements specified in Annex 4.

Article 45. **Calibration, Clinical Dosimetry and Quality Assurance for Medical Exposures**

1. Licensees shall ensure that:

   (a) the calibration of sources used for medical exposure is traceable to a Standards dosimetry laboratory;
   (b) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;
   (c) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered; and
   (d) calibrations of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may affect the calibration, as well as at regular intervals established or approved by the Regulatory Authority.

2. Licensees shall ensure that representative values of clinical dosimetry parameters are determined and documented.

3. Quality assurance programmes for medical exposures [14-17] shall include:

   (a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
   (b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
   (c) written records of relevant procedures and results;
   (d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
   (e) as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

Article 46. **Dose Constraints**

1. The optimisation of protection of persons exposed for medical research purposes, if such medical exposure does not produce direct benefit to the exposed individuals, shall be subjected to individual dose constrains established on a case-by-case basis by the Ethical Review Committee or other institutional body assigned a similar function.

2. Licensees shall constrain any dose to individuals incurred while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Annex 3.

Article 47. **Guidance Levels**

1. Licensees shall ensure that guidance levels for medical exposure, determined as specified in Article 24, are revised as technology improves and are used as guidance by medical practitioners, in order that:

   (a) corrective actions are taken as necessary if doses or activities fall substantially below the guidance levels, resulting in a decrease of medical benefit to patients by ineffective diagnostic information or insufficient therapeutic dosage; and
   (b) reviews are considered if doses or activities exceed the guidance levels, as an input to ensuring optimised protection of patients and maintaining appropriate levels of good practice.

2. In the transition period while guidance levels for medical exposure are being determined as specified in Article 24, licensees shall ensure that the performance of diagnostic radiology and nuclear medicine equipment is assessed on the basis of comparison with the guidance levels provided in Annex 5.

Article 48. **Maximum Activity for Patients in Therapy on Discharge from Hospital**

In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Annex 5 unless otherwise justified and the justification is documented. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

Article 49. **Investigation of Accidental Medical Exposures**

1. Licensees shall promptly investigate any of the following incidents:

   (a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner;

(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and

(c) any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

2. Licensees shall, with respect to any investigation required above:

(a) calculate or estimate the doses received and their distribution within the patient;

(b) indicate the corrective measures required to prevent recurrence of such an incident;

(c) implement all the corrective measures that are under their own responsibility;

(d) notify the Regulatory Authority by telephone or facsimile as soon as practicable, but not later than 24 hours after discovery, of any incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient;

(e) submit to the Regulatory Authority, within 30 days after discovery of the incident, a written report which states the cause of the incident and includes information on the doses, corrective measures and any other relevant information; and

(f) inform the patient and his or her doctor about the incident.

Article 50. **Records**

Licensees shall keep and make available, as appropriate, records of equipment calibration, clinical dosimetry and quality assurance, as well as any other necessary information to allow retrospective assessments of the doses received by patients.

Public Exposure Protection

Article 51. **General Responsibilities**

1. Licensees shall apply the requirements of these Regulations to any public exposure delivered by a practice or source for which they are responsible, unless the exposure is excluded from the Regulations or the practice or source delivering the exposure is exempted from the requirements of the Regulations.

2. Licensees shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:

(a) radiation safety policies, procedures and organizational arrangements for control of public exposure;

(b) measures for ensuring:

(i) the optimisation of the protection, subject to constraints as may be appropriate, of members of the public whose exposure is attributable to such sources; and

(ii) the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is

not higher than the dose limits for members of the public as specified in Annex 3;

(c) measures for ensuring the safety of such sources, in order that the likelihood of public exposures is controlled in accordance with the requirements of these Regulations;

(d) suitable and adequate facilities, equipment and services for the protection of the public, the nature and extent of which are commensurate with the magnitude and likelihood of the exposure;

(e) appropriate radiation safety training, and periodic retraining, to the personnel having functions relevant to the protection of the public;

(f) appropriate monitoring equipment and surveillance programmes to assess public exposure; and

(g) adequate records of the surveillance and monitoring.

Article 52. **Control of Visitors**

Licensees shall:

(a) ensure that visitors be accompanied in any controlled area by a person knowledgeable about the radiation safety measures for that area;

(b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions; and

(c) ensure that adequate control over entry of visitors to a supervised area be maintained and that appropriate signs be posted in such areas.

Article 53. **Sources of External Irradiation**

Licensees shall ensure that, if a source of external irradiation can cause exposure to the public:

(a) prior to commissioning, the floor plans and equipment arrangement for all new installations and all significant modifications to existing installations utilizing such sources of external irradiation are subject to review and approval by the Regulatory Authority;

(b) specific dose constraints for the operation of such a source are established to the satisfaction of the Regulatory Authority; and

(c) shielding and other protective measures that are optimised in accordance with the requirements of these Regulations are provided as appropriate for restricting public exposure to the satisfaction of the Regulatory Authority.

Article 54. **Radioactive Contamination in Enclosed Spaces**

Licensees shall ensure that:

(a) for sources for which they are responsible, measures that are optimised in accordance with the requirements of these Regulations are taken as appropriate for restricting public exposure in areas accessible to the public; and

(b) specific containment provisions are established for the construction and operation of those sources in order to avoid or minimise spread of contamination in areas accessible to the public.

Article 55. **Monitoring of Public Exposure**

Licensees shall, as appropriate:

(a) establish and carry out a monitoring programme, of magnitude and complexity commensurate with the type of and risks associated with the sources under their responsibility, which is sufficient to ensure that the requirements of these Regulations are satisfied and to assess the exposure of members of the public from sources of external irradiation and/or discharges of radioactive substances into the environment, as appropriate;
(b) keep appropriate records of the results of the monitoring programmes; and
(c) report a summary of the monitoring results to the Regulatory Authority at approved intervals and promptly inform the Regulatory Authority of any abnormal results which lead or could lead to an increase of public exposure.

Article 56. **Consumer Products**

1. Consumer products capable of causing exposure to radiation shall not be supplied to members of the public unless:

   (a) such exposure is excluded from these Regulations under Article 6; or
   (b) such products meet the exemption requirements specified in Article 16 or have otherwise been exempted by the Regulatory Authority; or
   (c) such products are authorized by the Regulatory Authority for use by members of the public.

2. Legal persons who import consumer products, as exempt products, for subsequent sale and distribution shall include in the application to the Regulatory Authority for authorization to distribute, a copy of the license or authorization issued by the Regulatory Authority in the country of manufacture or origin which authorizes distribution to members of the public in that country.

3. Legal persons who import consumer products for sale and distribution as exempt products shall ensure that:

   (a) legible labels are visibly and firmly affixed to each consumer product and its package, stating, in the local language, that:
      (i) the product contains radioactive material; and
      (ii) the sale of the product to the public has been authorised by the relevant Regulatory Authority;
   (b) basic information and instructions on the precautions of use and disposal of the product, written in the local language, are made available with the product.

Requirements for the Safety of Sources

Note: The requirements concerning the provisions to ensure the safety of radiation sources are aimed at the protection of workers, patients and members of the public against potential exposures. Many aspects of protection against potential exposure are covered explicitly or implicitly in other parts of these Regulations and this section only adds some requirements which are specific to the safety of sources. However, performance requirements for potential

exposure protection call for detailed safety and design analyses of radiation generators, sources and equipment. Many countries using these model regulations will have limited resources to do analyses of these kinds independently. This problem can be overcome in large measure by adopting IEC and ISO standards coupled with prescriptive specifications for specific practices as provided in relevant IAEA, WHO and PAHO guides. This sample regulations, therefore, are limited to general performance requirements concerning responsibilities of the licensees for the safety of the sources for which they are authorised.

Article 57. **General Responsibilities**

1. Licensees shall ensure the safety of the sources under their responsibility, from the moment of their acquisition throughout their entire operational life and up to their final disposal.

2. For this purpose, licensees shall ensure that a multilayer system of provisions (*defence in depth*) for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved is applied to the sources under their responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of (a) preventing accidents that may cause exposure; (b) mitigating the consequences of any such accident should it occur; and (c) restoring sources to safe conditions after any such accident.

3. Licensees shall ensure that, as applicable and appropriate, the location, design, construction and assembly, commissioning, operation and maintenance, and decommissioning of sources are based on sound engineering practice which (a) takes into account approved codes and standards and technical and scientific developments; (b) is supported by reliable managerial and organisational features; and (c) includes adequate safety margins in the design, construction and operation of sources.

Article 58. **Design and Procurement of Sources**

Licensees, in specific co-operation with suppliers whenever appropriate, shall:

(a) ensure, on procurement of new equipment containing radiation generators or sources, that such equipment and sources conform to applicable standards of the International Electrotechnical Commission (IEC) and the International Standards Organisation (ISO) or equivalent standards as may be approved by the Regulatory Authority. Except for IEC and ISO standards, other standards applied in the country of origin of such equipment and sources must have the specific approval of the Regulatory Authority;

(b) ensure that sources and equipment are tested to demonstrate compliance with the appropriate specifications;

(c) conduct a safety assessment, either generic or specific, for the sources for which they are responsible, according to the requirements of Article 29;

(d) ensure that performance specifications and operating and maintenance instructions, including protection and safety instructions, are provided in a major world language as approved by the Regulatory Authority and in compliance with the relevant IEC and

ISO standards with regard to 'accompanying documents', and that this information is translated into the local language when appropriate; and

(e) ensure that, where practicable, the operating terminology and operating values are displayed on operating consoles or other control systems in an appropriate language as specified in paragraph (d) above.

Article 59. **Accountability and Security of Sources**

1. Licensees shall maintain an accountability system that includes records of:

   (a) the location and description of each source for which they are responsible; and
   (b) the activity and form of each radioactive substance for which they are responsible.

2. Licensees shall make arrangements for the sources under their responsibility to be kept secure by ensuring that:

   (a) control of a source is not relinquished without compliance with all relevant requirements specified in the license and without immediate communication to the Regulatory Authority of information regarding any decontrolled, lost, stolen or missing source;
   (b) a source is not transferred unless the receiver possesses a valid authorization;
   (c) records are maintained of source inventory, including records of receipt, transfer and disposal of sources; and
   (d) a periodic inventory of sources is conducted at intervals specified in the license to confirm that they are in their assigned locations and are secure.

Article 60. **Feedback of Operating Experience**

1. Licensees shall ensure that information on, both, normal operation performance and abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the Regulatory Authority and other relevant parties, including other users, as specified by the Regulatory Authority.

2. In addition, and where applicable, licensees shall make suitable arrangements with suppliers of sources to establish and maintain mechanisms for transfer from licensees to suppliers of any information on the use, maintenance, disposal and malfunctioning that can be relevant for future improvements in the design and construction of the sources they have supplied.

Radioactive Waste Management Requirements

Article 61. **Scope**

This section of the Regulations applies to all aspects of radioactive waste management, including collection, segregation, characterisation, classification, treatment, conditioning, storage and disposal where the waste arises from medical, agricultural, industrial, research and education applications.

Article 62. **Radioactive Waste Classification**

Radioactive waste shall be classified in accordance with the nationally agreed strategy options and according to the activity concentration and half-lives of the radionuclides, as indicated in Table 1 [18].

Table 1

Class	Description
Cleared material/waste	Materials containing levels of radionuclides at concentrations less than the clearance levels established by the Regulatory Authority
Low level (short lived)/ Decay waste	Low level radioactive waste containing short lived radionuclides only *(e.g. with-half lives less than 100 days)* that will decay to clearance levels within three years after the time of its generation
Low and intermediate level short lived waste (LILW-SL)	Waste which will not decay to clearance levels within *3 years* and contains beta/gamma emitting radionuclides with half-lives less than *30 years* and/or alpha emitting radionuclides with an activity less than *400 Bq/g* and a total activity less than *4000 Bq* in each waste package
Low and intermediate level long lived waste (LILW-LL)	Radioactive waste containing radionuclides with concentrations above those for LILW-SL, but which does not generate heat at above 2 kW/m^3 of waste.

Note 1: The national waste management strategy should be established at a governmental level, but the strategy options should be considered in discussions with operators, regulators, independent scientific advisors and the international expert community.

Note 2: In applying the classification of the radioactive waste, attention should be given to inventory of long lived radionuclides in a repository that emit beta or gamma radiation. For radionuclides such as I-129 or Tc-99, allowable quantities or average concentrations within a repository depend strongly on site specific conditions.

Note 3: Conditioned low and intermediate level short-lived waste may be suitable for disposal in an authorized near surface disposal facility.

Note 4: Conditioned low and intermediate level long lived waste shall be stored pending disposal in an authorized geological disposal facility.

Article 63. **General Responsibilities**

Licensees shall be responsible for the safe management of the radioactive waste generated by the practices or sources for which they are authorized and shall take all necessary steps to this aim, including:

(a) keep the generation of, both, the activity and volume of radioactive waste to the minimum practicable by suitable design, operation and decommissioning of its facilities;

(b) ensure that radioactive waste is managed by appropriate classification, segregation, treatment, conditioning, storage and disposal, and maintain records of such activities;
(c) ensure that disposal of radioactive waste is not unnecessarily delayed; and
(d) report to the Regulatory Authority required information at intervals as may be specified in the license.

Article 64. **Licence Applications**

No person or organization shall generate, keep or manage radioactive waste except in accordance with a licence issued by the Regulatory Authority under the terms of Article 17 of these Regulations.

Note: The Regulatory Authority will need to take care that it receives all relevant information. The extent and type of information needed will be different for wastes of different types (e.g. small sealed sources as compared to unsealed radioactive materials from nuclear medicine procedures).

Article 65. **Appointment of Radioactive Waste Management Officer**

1. Each licensee shall appoint, when required by the Regulatory Authority, a technically competent person with the appropriate independence and authority to be a Radioactive Waste Management Officer in order to assist the licensee in the safe and efficient on-site management of radioactive waste.

Note 1: In discharging his duties, the Radioactive Waste Management Officer will need to:

(a) make and maintain contact with all relevant persons involved with radioactive waste to provide an authoritative point of advice and guidance;
(b) liaise as needed with the Radiation Protection Officer and with other radioactive waste management organizations;
(c) establish and maintain a detailed record keeping system for all stages of radioactive waste management, including the inventory of radioactive waste;
(d) ensure proper radioactive waste conditioning;
(e) ensure that on-site transfer of radioactive waste is carried out in accordance with written safety procedures;
(f) ensure that waste packages for off-site transportation are prepared to be in compliance with Transport Regulations;
(g) obtain approval from the Regulatory Authority for the transport of radioactive waste;
(h) ensure appropriate shielding, labelling, physical security and integrity of waste packages;
(i) ensure that any discharge of effluents is made below the limits authorized by the Regulatory Authority;
(j) ensure that solid waste disposed of in a municipal landfill is in accordance with clearance levels established by the Regulatory Authority;
(k) report on accidents and inappropriate waste management practices to the Licensees management; and
(l) maintain an up-to-date knowledge of the characteristics of discharge and disposal options.

Note 2: The Radioactive Waste Management Officer and Radiation Protection Officer could be the same person depending on the size and complexity of the waste management organization.

Article 66. **Control of Radioactive Waste Generation**

Licensees shall ensure that steps are taken to keep generation of radioactive waste and its environmental impact and cost to the minimum practicable by:

- avoiding the use of unnecessarily hazardous/toxic materials;
- minimizing the activity of waste by using the minimum quantity of radioactive material needed;
- using short lived radionuclides where possible;
- minimizing the amount of waste by preventing unnecessary contamination of materials; and
- maintaining consistency with the management strategy and systems.

Article 67. **Segregation, Collection and Characterisation of Radioactive Waste**

Licensees shall ensure that waste is segregated at the point of origin in accordance with the national waste management strategy as may be directed by the Regulatory Authority.

Note 1: In some cases it may be necessary to include in the regulations appropriate details as in the notes below.

Note 2: Waste should be segregated on the basis of categories which are of assistance in using available options for treatment, conditioning, storage and disposal. Possible categories are:

(a) Non-radioactive and radioactive;
(b) Short-lived (for example half-lives less than 100 days) suitable for decay storage;
(c) Activity and radionuclide content;
(d) Physical and chemical form:
  - *Liquid*
    - *Aqueous and*
    - *Organic;*
  - *Non-homogeneous (e.g. containing sludges or suspended solids);*
  - *Solid*
    - *Combustible/non-combustible (if applicable) and*
    - *Compactable/non-compactable (if applicable);*

(e) Spent sealed sources; and
(f) Non-radiological hazardous waste (e.g. toxic, pathogenic, infectious, genotoxic, biological).

Note 3: After segregation, each waste stream should be kept separately, for example, in separate containers.

Note 4: Waste containers should be:

(a) Clearly identified;
(b) Bear a radiation trefoil when in use;

(c) Robust;
(d) Compatible with the waste contents; and
(e) Able to be filled and emptied safely.

Note 5: The following information should be recorded for each waste container:

(a) Identification number;
(b) Radionuclides;
(c) Activity (if measured or estimated)/date of measurement;
(d) Origin (room, laboratory, individual, etc. if applicable);
(e) Potential/actual hazards (chemical, infectious, etc.);
(f) Surface dose rate/date of measurement;
(g) Quantity (weight or volume); and
(h) Responsible person.

Note 6: Containers for solid wastes should be lined with a durable plastic bag which can be sealed (tied with plastic adhesive tape, heat-sealed with an RF welder).

Note 7: Sharps should be collected separately and stored in rigid, puncture-resistant containers (preferably metal) which have been clearly labelled 'sharps'.

Note 8: Damp solid waste should be collected in such a way as to avoid leakage of the contaminated liquids. Normally double packaging is used.

Note 9: Liquid waste should be collected in suitable containers according to the chemical and radiological characteristics and volume of the waste, and the handling and storage requirements.

Note 10: Spent sealed sources should be kept in their shielding.

Note 11: Containers should be checked for radioactive contamination, and loose contamination should be removed before reuse.

Note 12: Radioactive waste should be characterised to determine activity, radionuclide content, physical and chemical form (liquid, solid, etc.) and associated hazards. This can be achieved by a combination of quality assurance (records of radionuclide inventory, activity balance, composition of materials used, etc.) and direct measurement techniques. Waste of unknown origin and composition will require detailed characterization. This may be complex and expensive.

Article 68. **Treatment and Conditioning of Radioactive Waste**

Licensees shall ensure that the treatment and conditioning of radioactive wastes is carried out in accordance with the national waste management strategy, and , in particular, meet any waste acceptance criteria established by the Regulatory Authority.

Note: Treatment and conditioning shall be implemented if it is necessary to improve the characteristics of waste prior to discharge into the environment, interim storage and/or disposal.

Article 69. **Discharge or Release of Radioactive Substances to the Environment**

1. Licensees shall ensure that radioactive substances from authorized practices and sources are not discharged to the environment unless:

   (a) such discharge is within the limits specified in the licence and is carried out in a controlled fashion using authorized methods; or
   (b) the activity discharged is confirmed to be below clearance levels established by the Regulatory Authority as specified in Article 16 of these Regulations.

2. Licensees, during the operational stages of sources under their responsibility, shall:

   (a) keep all radioactive discharges as far below the authorized limits as is reasonably achievable;
   (b) monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of critical group of population;
   (c) report discharges to the Regulatory Authority at intervals as may be specified in the licence; and
   (d) report promptly to the Regulatory Authority any discharges exceeding the authorized limits.

3. Whether activity is released within the clearance levels established by the Regulatory Authority or radioactive waste is discharged under licence, licensees shall consider the non-radiological hazards of the released waste and shall comply with the requirements of any other regulations concerning those hazards.

Article 70. **Disposal of Radioactive Waste**

When the radioactive waste is not suitable for discharge or release to the environment or for clearance within a reasonable time, the holder of the waste shall submit to Regulatory Authority its proposals for disposal of the waste and ensure that the criteria set by the Regulatory Authority for acceptance of the waste at any repository or any national waste management organization are met.

Article 71. **Transport of Radioactive Waste**

Licensees shall ensure that radioactive waste is prepared for transport to a storage or disposal site, and is regarded as a radioactive source for transport in accordance with all relevant regulations (*specify*).

Article 72. **Waste Storage**

Radioactive waste shall be stored in such a way as to protect human health and the environment and in particular shall not be stored in the vicinity of corrosive, explosive or easily flammable materials.

Note 1: In some cases it may be necessary to include in the regulations appropriate details as in the notes below.

Note 2: A dedicated facility/area shall be provided for the storage of radioactive wastes. Storage facilities/areas must be clearly demarcated, with controlled access. Storage areas for untreated (raw) waste shall be separate from those for conditioned waste.

Storage facilities/area shall have the following characteristics:

(a) Sufficient capacity to buffer the waste arisings before discharge, treatment and transportation;
(b) Simple construction provided with non-combustible and easily decontaminated walls and floors;
(c) Impermeable floor covering with a containment edge and slight slope to central collection area;
(d) Adequate ventilation;
(e) Air sampling and radiation alarms (as required by the Regulatory Authority);
(f) Fire detection/protection (as required by the Regulatory Authority);
(g) Fire resistant door(s) that can be locked;
(h) Compartments in order to separate different kinds of waste (e.g. to facilitate the safe storage of special hazard materials - volatile, pathogenic and putrescible materials, chemically reactive);
(i) Be demarcated as radiologically controlled areas;
(j) Utilise a log book system, listing the number of containers, entry date, waste type, activity, etc. The log book should be kept outside, but near the storage room or area;
(k) Provide protection from the environment (weather) including temperature extremes;
(l) Provide protection from intrusion (by man, animals, etc.); and
(m) Utilise movable radiation shielding (as appropriate).

Article 73. **Recycle and Reuse of Radioactive Materials**

Licensees using radioactive material shall:

(a) not dismantle any sealed source;
(b) before declaring the radioactive material as waste, consider whether the licensee or any other organization can make use of the material; and
(c) if appropriate, transfer the material after confirming with the Regulatory Authority that the organization to which it is transferred has the necessary authorization to hold that material.

Note: It is always preferable to make further use of radioactive material (e.g. a sealed source) rather than to declare it as waste and for someone to purchase another similar source. However, this must be done with the knowledge of the Regulatory Authority if it includes transfer between organizations and the process must not be used as a method of avoiding management of the waste.

Article 74. **Return of Sealed Sources to the Manufacturer**

When purchasing sealed sources, licensees shall make contractual arrangements for the return of the spent sealed sources to the manufacturer.

Note 1: It is recommended that any person or organization that proposes to import a sealed source containing radioactive material which 10 years after receipt will have an activity greater than 100 MBq shall:

(a) require the supplier, as a condition of any contract for purchase or as acceptance of any gift, to receive the source back after its useful lifetime within one year of the recipient requesting such return, provided that the recipient seeks to return the source to the supplier not later than 15 years after purchase; and
(b) submit to the Regulatory Authority a copy of relevant parts of the contract or acceptance document and obtain its written agreement prior to entering the contract or accepting the source.

Note 2: It is recommended also to make contractual arrangements with the generators of radionuclides, to return the waste resulting from the use of radionuclides, if such waste cannot be cleared after decay storage.

Article 75. **Quality Assurance**

Licensees shall submit a Quality Assurance Programme to the Regulatory Authority for approval as part of the licence application covering all aspects of the radioactive waste management, especially those features important to safety.

Note 1: The Quality Assurance Programme shall cover facilities, activities and waste and be commensurate with the scale of operations.

Note 2: The effectiveness of the Quality Assurance Programme shall be verified by independent audits to ensure that radioactive waste management activities are carried out to meet the requirement to protect human health and the environment.

Note 3: Quality assurance documentation should include:

(a) an inventory of radioactive waste, including origin, location, physical and chemical characteristics, and, as appropriate, a record of radioactive waste removed or discharged from the facility;
(b) site plans, engineering drawings, specifications and process descriptions;
(c) data resulting from quality assurance and quality control procedures and from operating activities;
(d) safety and environmental assessment methods and computer codes;
(e) results of safety and environmental assessments;
(f) effluent and environmental impact monitoring results;
(g) radioactive waste package identification; and
(h) disposal facility closure data.

Article 76. **Physical Protection**

The licensee shall ensure that all necessary means are taken to prevent unauthorised persons gaining access to the waste.

Article 77. **Records and Reports**

1. Licensees shall report to the Regulatory Authority and up-to-date the inventory of radioactive waste in their possession. The inventory shall be in such form and contain such details as the Regulatory Authority may require.

Note: It is recommended that the inventory is based on the classification in Table 1, Art. 62 above, and includes information on the origin, quantity and the physical, chemical and radiological characteristics of the wastes.

2. Shortly after the end of each year *(specify more precisely)* licensees shall send to the Regulatory Authority a copy of their waste inventory and a report for the year giving types, quantities and destinations of:

   (a) cleared materials released to the environment;
   (b) waste discharged to the environment;
   (c) spent radiation sources returned to suppliers; and
   (d) such other details as the Regulatory Authority may require.

3. The Regulatory Authority has the right to inspect and review the records at any time.

4. If any radioactive waste has been lost, stolen or is missing, the licensee shall promptly inform the Regulatory Authority and within 30 days submit a written report on the matter and the actions which have been taken.

5. If radioactive material has been released to the environment above the clearance criteria established by the Regulatory Authority or if waste has been discharged above the limits of licence issued by the Regulatory Authority, the licensee shall promptly inform the Regulatory Authority and within 30 days submit a written report on the matter and the actions taken.

Transport Requirements

Article 78. **Scope**

The provisions of these regulations are focused on the elements of a national transport programme necessary to safely transport radioactive material such as radiation sources typically found in medicine, industry and research. These sample regulations address the proper characterization and *packaging* of these radioactive materials and the requirements for the transport of excepted, industrial, *Type A*, *Type B(M)* and *Type B(U) packages*. They also identify the need for acceptable quality assurance and compliance assurance programmes and emergency response provisions.

Note: The following materials are excluded from the scope of these sample regulations:

- *radioactive material that is an integral part of the means of transport;*

- *radioactive material moved within an establishment which is subject to appropriate safety regulations in force in the establishment and where the movement does not involve public roads or railways;*

- *radioactive material implanted or incorporated into a person or live animal for diagnosis or treatment;*

- *radioactive material in consumer products which have received regulatory approval, following their sale to the end user; and*

- *natural material and ores containing naturally occurring radionuclides which are not intended to be processed for use of these radionuclides provided the activity concentration of the material does not exceed 10 times the exempt values specified in Article 3 of these regulations.*

Article 79. **Application**

The provisions of these regulations govern the domestic and international transport of radioactive material, which for the purpose of these regulations means any material containing radionuclides where both the activity concentration and the total activity exceed the limits for exempt *consignments*, as defined in Article 80 of these regulations, unless specifically excluded from the scope of these regulations in Article 78.

Note: These regulations are focused on the elements of a national transport programme necessary to safely transport radioactive material such as radiation sources typically found in medicine, industry and research. Provisions covering all transport scenarios as well as additional information on the broad provisions of these regulations are given in the IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition, IAEA Safety Standards Series No. ST-1 [19].

Article 80. **Exempt Consignments**

Exempt from the requirements of these regulations are *consignments* where either the activity concentration of the material or the total activity of the *consignment* is below the exempt limits specified in Annex 7 (Table I) for individual radionuclides. For material containing mixtures of radionuclides the activity concentration for exempt material and the activity limit for an exempt *consignment* may be derived as follows:

$$X_m = \frac{1}{\sum_i \frac{f(i)}{X(i)}}$$

where,

f(i) is the fraction of activity or activity concentration of radionuclide i in the mixture;
X(i) is the appropriate value of the activity concentration for exempt material or the activity limit for an exempt *consignment* as appropriate for the radionuclide i; and
X_m is the derived value of the activity concentration for exempt material or the activity limit for an exempt *consignment* in the case of a mixture.

For unknown radionuclides or mixtures the more restrictive values of activity concentration for exempt material or activity limits for exempt *consignments* specified in Annex 7 (Table II) shall be used.

Article 81. **Material Characterization**

A_1 and A_2 values for individual radionuclides as provided in Annex 7 (Table I) are basic activity values which are used for characterizing material to be transported and for specifying activity limits in these regulations. For material containing mixtures of known radionuclides the A_1 or A_2 value for the material may be derived as follows:

$$A_m = \frac{1}{\sum_i \frac{g(i)}{A(i)}}$$

where,

g(i) is the fraction of the activity of radionuclide i in the mixture;
A(i) is the appropriate value of A_1 or A_2 for the radionuclide i; and
A_m is the derived value of A_1 or A_2 for the material containing a mixture of radionuclides.

For unknown radionuclides or mixtures the more restrictive A_1 or A_2 values as specified in Annex 7 (Table II) shall be used.

Radioactive material or items to be transported shall be classified, using A_1 or A_2 values, as one of the following:

- material or instruments or articles not exceeding the limits for an *excepted package* (activity limits are specified in Annex 7 (Table III); in addition, the *radiation level* at 10 cm from any point on the external surface of any unpackaged instrument or article shall not be greater than 0.1 mSv/h),
- *low specific activity material* (defined in these regulations as *LSA-I*, *LSA-II* or *LSA-III*),
- *surface contaminated objects* (defined in these regulations as *SCO-I* or *SCO-II*),
- *Type A package* quantity (provided the activity of the material does not exceed the A_1 or A_2 values in Annex 7 (Tables I or II) or the A_1 or A_2 values as derived for material containing a mixture of known radionuclides), or
- Type B *package* quantity (when the activity of the material exceeds the limits for a *Type A package* but not any limit specified in the *competent authority* certificate for the *Type B(U)* or *Type B(M) package* in which it is to be transported.

Note: The complete and proper shipping names to be used for the transport of radioactive material are provided in Annex 7 (Table VIII).

Article 82. **Unpackaged Shipments**

Some radioactive materials may be transported unpackaged under the following conditions:

LSA-I and *SCO-I* may be transported unpackaged under *exclusive use* provided that all unpackaged material other than ores containing only naturally occurring radionuclides shall be

transported in such a manner that under routine conditions of transport there will be no escape of the radioactive contents from the *conveyance* nor will there be any loss of shielding.

Exclusive use is not required for *SCO-I* shipments where contamination on the accessible and the inaccessible surfaces is not greater than ten times the levels specified in Article 85(a). For *SCO-I* shipments where it is suspected that non-fixed contamination exists on inaccessible surfaces in excess of ten times the levels specified in article 85(a), measures shall be taken to ensure that radioactive material is not released into the *conveyance*.

Article 83. **Packaging/Package**

Radioactive material or items which require *packaging* for transport shall be packaged only in any of the following *package*s (in order of increased protection):

- *excepted package*
- *industrial package* (*Type IP-1*, *IP-2* or *IP-3*)
- *Type A package*
- *Type B(M) package*
- *Type B(U) package*
- *Type C package.*

*Industrial package*s (*IP-1*, *IP-2* or *IP-3*) may be used for the transport of *low specific activity material* or *surface contaminated object*s as specified in Annex 7 (Table IV) provided that the external *radiation level* at 3 m from the unshielded material or object or objects does not exceed 10 mSv/h.

Radioactive material or items may be transported in *package*s which provide more protection than required for the material.

Empty *package*s, which previously contained radioactive material, may be shipped as *excepted package*s provided that:

- they are in a well maintained condition and securely closed,
- the outer surface of any uranium or thorium in its structure is covered with an inactive sheath made of metal or some other substantial material,
- the level of internal non-fixed contamination does not exceed one hundred times the levels specified in article 8(b) in these regulations,
- any labels required for its previous use are no longer visible and
- all other requirements for *excepted package*s in these regulations are met.

Article 84. **Mixed Contents**

A *package* shall not contain any other items except such articles and documents as are necessary for the use of the radioactive material.

Article 85. **Contamination**

(a) Contamination means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 for all other alpha emitters.

Non-fixed contamination means contamination that can be removed from a surface during routine conditions of transport.

Fixed contamination means contamination other than non-fixed contamination.

(b) Non-fixed contamination on the external surfaces of *package*s and on the internal and external surfaces of *overpacks*, *freight container*s, tanks and intermediate bulk containers shall be kept as low as practicable and shall not exceed the following limits:

(i) beta, gamma and low toxicity alpha emitters 4 Bq/cm^2

(ii) all other alpha emitters 0.4 Bq/cm^2

(c) Fixed contamination levels are limited by *radiation level* limits for *package*s and *conveyance*s and by requirements for decontamination as specified in Article 95.

Article 86. **Maximum Radiation Levels**

(a) *Radiation level* limits apply to the following items and materials to be packaged for transport:

The *radiation level* at 10 cm from any point on the external surface of any unpackaged instrument or article which has activity levels below the limits for an *excepted package*s, shall not be greater than 0.1 mSv/h.

The quantity of *LSA material* or SCO in a single *industrial package* (*Type IP-1*, *IP-2* or *IP-3*) shall be so restricted that the external *radiation level* at 3 m from the unshielded material or object or objects does not exceed 10 mSv/h.

(b) *Radiation level* limits apply to *package*s or *overpack*s as follows:

The *radiation level* limit for *excepted package*s is 5 μSv/h at the surface of an *excepted package*.

The *radiation level*s for all other *package*s and *overpack*s, except for *consignment*s under *exclusive use*, shall not exceed 2 mSv/h at any point on any external surface of the *package* or *overpack* and, in addition, shall not exceed 0.1 mSv/h at 1 m from the external surfaces of the *package* or *overpack*.

For *consignment*s to be transported by road or rail under *exclusive use* the radiation levels on the external surface of any *package* or *overpack* shall not exceed 10 mSv/h and may only exceed 2 mSv/h provided that specific *vehicle* and shipment conditions are met as specified in Article 91.

For *exclusive use* shipments by air or by vessel the *radiation level*s on the external surface of any *package* or *overpack* greater than 2 mSv/h may be allowed only under special arrangement conditions which are not covered in these regulations.

(c) *Radiation levels* for *conveyances* are limited as follows:

Loading of *freight containers* and the accumulation of *packages*, *overpacks* and *freight containers* aboard a single *conveyance* shall be such that the *radiation level* under routine conditions of transport shall not exceed 2 mSv/h at any point on, and 0.1 mSv/h at 2 m from, the external surface of the *conveyance*.

(d) Further control over radiation exposure during transport is provided with limits on the transport index as specified in Article 87.

Article 87. **Transport Index**

To provide control over radiation exposure during transport a transport index (TI), based on *radiation levels*, is assigned to *package*, *overpack* or *freight container* or to unpackaged *LSA-I* or *SCO-I* as follows:

(a) Determine the maximum *radiation level* in units of millisieverts per hour (mSv/h) at a distance of 1 m from the external surfaces of the *package*, *overpack*, *freight container*, or unpackaged *LSA-I* and *SCO-I*. The value determined shall be multiplied by 100 and the resulting number is the *transport index*. For uranium and thorium ores and their concentrates, the maximum *radiation level* at any point 1 m from the external surface of the load may be taken as:

0.4 mSv/h	for ores and physical concentrates of uranium and thorium;
0.3 mSv/h	for chemical concentrates of thorium;
0.02 mSv/h	for chemical concentrates of uranium, other than uranium hexafluoride.

(b) For *tanks*, *freight containers* and unpackaged *LSA-I* and *SCO-I*, the value determined in step (a) above shall be multiplied by the appropriate factor from Table VI.

(c) The value obtained in steps (a) and (b) above shall be rounded up to the first decimal place (e.g. 1.13 becomes 1.2), except that a value of 0.05 or less may be considered as zero.

The *transport index* for each *overpack*, *freight container* or *conveyance* shall be determined as either the sum of the *TIs* of all the *packages* contained, or by direct measurement of *radiation level*, except in the case of non-rigid *overpacks* for which the *transport index* shall be determined only as the sum of the *TIs* of all the *packages*.

Any *package* or *overpack* having a TI greater than 10 shall be transported only under *exclusive use*.

The TI limits for *freight containers* and *conveyances* not under *exclusive use* are provided in Annex 7 (Table IX).

There is no limit on the sum of transport indexes for *consignments* of *LSA-I* material.

Where a *consignment* is transported under *exclusive use*, there is no limit on the sum of the transport indexes aboard a single *conveyance*.

Article 88. **Marking**

Where unpackaged *LSA-I* or *SCO-I* material is contained in receptacles or packing material and shipped under conditions specified in Article 82, the outer surface of these receptacles or wrapping materials may bear the marking "RADIOACTIVE LSA-I" or "RADIOACTIVE SCO-I" as appropriate.

All *package*s shall be legibly and durably marked on the outside of the *packaging* with an identification of either the *consignor* or *consignee*, or both.

Each *package* of gross mass exceeding 50 kg shall have its permissible gross mass legibly and durably marked on the outside of the *packaging*.

All *package*s shall be legibly and durably marked on the outside of the *packaging* with the appropriate United Nations number from Annex 7 (Table VIII) preceded by the letters "UN". For each *package* other than *excepted package*s the proper shipping name as identified in Annex 7 (Table VIII) must also be included with this marking.

*Industrial package*s shall be legibly and durably marked on the outside of the *packaging* with "TYPE IP-1", "TYPE IP-2" or "TYPE IP-3" as appropriate.

*Type A package*s shall be legibly and durably marked on the outside of the *packaging* with "TYPE A".

Each *package* which conforms to an approved *Type B(U)*, *Type B(M)* or *Type C package* design shall be legibly and durably marked on the outside of the *packaging* with:

(a) The identification mark allocated by the *Regulatory Authority* to the design of that *package*;
(b) A serial number to uniquely identify each *packaging* which conforms to that design;
(c) In the case of a *Type B(U)* or *Type B(M) package* design, with "TYPE B(U)" or "TYPE B(M)".
(d) In the case of a *Type C package* design, with "TYPE C".

In addition, each *package* which conforms to a *Type B(U)*, *Type B(M)* or *Type C package* design shall have the outside of the outermost receptacle which is resistant to the effects of fire and water plainly marked by embossing, stamping or other means resistant to the effects of fire and water with the trefoil symbol for radioactive material shown in Annex 8 (Figure 1).

Article 89. **Labelling Requirements**

Labelling is required in accordance with the assigned category for *package*s and *overpack*s. *Packages* and *overpacks* shall be assigned to either category I-WHITE, II-YELLOW or III-YELLOW in accordance with the conditions specified in Annex 7 (Table VII) and with the following requirements:

(a) For a *package* or *overpack*, both the *transport index* and the surface *radiation level* conditions shall be taken into account in determining which is the appropriate category. Where the *transport index* satisfies the condition for one category but the surface *radiation level* satisfies the condition for a different category, the *package* or *overpack*

shall be assigned to the higher category. For this purpose, category I-WHITE shall be regarded as the lowest category.

(b) The *transport index* shall be determined following the procedures specified in Article 87.

The labels for these categories are shown in Annex 8 (Figures 2, 3 and 4).

For all *packages*, any labels which do not relate to the contents shall be removed or covered.

Excepted packages do not require any labelling. All other *packages*, *overpacks* and *freight containers* shall bear labels which conform to the models in Annex 8 (Figures 2, 3 or 4). These labels shall be affixed to two opposite sides of the outside of a *package* or *overpack* or on the outside of all four sides of a *freight container* or tank. On large *freight containers* and tanks enlarged labels maybe used, in accordance with dimensions specified in Annex 8 (Figure 6), in which case no placarding will be required.

Article 90. **Information Required on Labels**

Labels shall be completed with the following information:

(a) Contents:
  (i) Except for *LSA-I material*, the name(s) of the radionuclide(s) as taken from Annex 7 (Table I), using the symbols prescribed therein. For mixtures of radionuclides, the most restrictive nuclides must be listed to the extent the space on the line permits. The group of *LSA* or *SCO* shall be shown following the name(s) of the radionuclide(s). The terms "*LSA-II*","*LSA-III*", "*SCO-I*" and "*SCO-II*" shall be used for this purpose.
  (ii) For *LSA-I material*, the term "*LSA-I*" is all that is necessary; the name of the radionuclide is not necessary.

(b) Activity: The maximum activity of the *radioactive contents* during transport expressed in units of becquerels (Bq) with the appropriate SI prefix.

(c) For *overpacks* and *freight containers* the "contents" and "activity" entries on the label shall bear the information required in subparas (a) and (b), respectively, totalled together for the entire contents of the *overpack* or *freight container* except that on labels for *overpacks* or *freight containers* containing mixed loads of *packages* containing different radionuclides, such entries may read "See Transport Documents".

(d) *Transport index*: See Article 87. (No *transport index* entry is required for category I-WHITE.)

Article 91. **Loading and Segregation**

(a) The following conditions for loading and segregation apply to all *consignments*:

Consignments shall be segregated from other dangerous goods during transport in compliance with the relevant transport regulations

Radioactive material shall be segregated from undeveloped photographic film so that the radiation exposure of film due to the transport of radioactive material is limited to 0.1 mSv per *consignment* of such film.

(b) Where a *consignment* is to be transported, not under *exclusive use*, the following conditions apply:

The *consignment* shall not include any *package* or *overpack* having a transport index greater than 10.

Loading of *freight containers* and the accumulation of *packages*, *overpacks* and *freight containers* aboard a single *conveyance* shall be so limited that the total sum of the transport indexes aboard the *conveyance* does not exceed the values shown in Annex 7 (Table IX).

Loading of *freight containers* and the accumulation of *packages*, *overpacks* and *freight containers* aboard a single *conveyance* shall be such that the *radiation level* under routine conditions of transport shall not exceed 2 mSv/h at any point on, and 0.1 mSv/h at 2 m from, the external surface of the *conveyance*.

(c) Where a *consignment* is to be transported under *exclusive use* there is no limit on the sum of transport indexes but *radiation levels* are controlled as follows:

For road and rail *consignments* under exlusive use the *radiation level* shall not exceed:

- 10 mSv/h at any point on the external surface of any *package* or *overpack*, and may only exceed 2 mSv/h provided that:

  (i) the *vehicle* is equipped with an enclosure which, during routine conditions of transport, prevents the access of unauthorized persons to the interior of the enclosure, and
  (ii) provisions are made to secure the *package* or *overpack* so that its position within the *vehicle* remains fixed during routine conditions of transport, and
  (iii) there is no loading or unloading during the *shipment*;

- 2 mSv/h at any point on the outer surfaces of the *vehicle*, including the upper and lower surfaces, or, in the case of an open *vehicle*, at any point on the vertical planes projected from the outer edges of the *vehicle*, on the upper surface of the load, and on the lower external surface of the *vehicle*; and

- 0.1 mSv/h at any point 2 m from the vertical planes represented by the outer lateral surfaces of the *vehicle*, or, if the load is transported in an open *vehicle*, at any point 2 m from the vertical planes projected from the outer edges of the *vehicle*.

Article 92. **Placarding**

(a) *Consignments* consisting solely of *excepted packages* do not require placarding. Where other *packages* are involved the following requirements for placarding apply:

(b) Large *freight containers* carrying *packages* other than *excepted packages*, and *tanks* shall bear four placards which conform with the model given in Annex 8 (Figure 6). The placards shall be affixed in a vertical orientation to each side wall and each end wall of the large *freight container* or *tank*. Any placards which do not relate to the contents shall be removed. Instead of using both labels and placards, it is permitted as an alternative to

use enlarged labels only, as shown in Annex 8 (Figures 2, 3 and 4) where appropriate, with dimensions of the minimum size shown in Annex 8 (Figure 6).

(c) Where the *consignment* in the *freight container* or *tank* is unpackaged *LSA-I* or *SCO-I* or where an *exclusive use consignment* in a *freight container* is packaged *radioactive material* with a single United Nations number, the appropriate United Nations number for the *consignment* (see Table VIII in Annex 7) shall also be displayed, in black digits not less than 65 mm high, either:

(i) in the lower half of the placard shown in Annex 8 (Figure 6), preceded by the letters "UN" and against the white background, or
(ii) on the placard shown in Annex 8 (Figure 7).

When the alternative given in (ii) above is used, the subsidiary placard shall be affixed immediately adjacent to the main placard, on all four sides of the *freight container* or *tank.*

(d) Rail and road *vehicles* carrying *packages*, *overpacks* or *freight containers* labelled with any of the labels shown in Annex 8 (Figures 2, 3 or 4), or carrying *consignments* under *exclusive use*, shall display the placard shown in Annex 8 (Figure 6) on each of:

(i) The two external lateral walls in the case of a rail *vehicle*; and
(ii) The two external lateral walls and the external rear wall in the case of a road *vehicle.*

In the case of a *vehicle* without sides the placards may be affixed directly on the cargo-carrying unit provided that they are readily visible; in the case of physically large *tanks* or *freight containers*, the placards on the *tanks* or *freight containers* shall suffice. In the case of *vehicles* which have insufficient area to allow the fixing of larger placards, the dimensions of the placard as described in Figure 6 may be reduced to 100 mm. Any placards which do not relate to the contents shall be removed.

(e) Where the *consignment* in or on the *vehicle* is unpackaged *LSA-I material* or *SCO-I* or where an *exclusive use consignment* is packaged *radioactive material* with a single United Nations number, the appropriate United Nations number (see Table VIII) shall also be displayed, in black digits not less than 65 mm high, either:

(i) In the lower half of the placard shown in Annex 8 (Figure 6), preceded by the letters "UN" and against the white background, or
(ii) On the placard shown in Annex 8 (Figure 7).

When the alternative given in (ii) above is used, the subsidiary placard shall be affixed immediately adjacent to the main placard, either on the two external lateral walls in the case of a rail *vehicle* or the two external lateral walls and the external rear wall in the case of a road *vehicle.*

Article 93. **Transport Documents**

Transport documentation, to accompany the *consignment*, need to include particulars of the *consignment*, a *consignor*'s declaration and information for *carriers* as specified in the following:

Particulars of consignment

The *consignor* shall include in the transport documents with each *consignment* the following information, as applicable in the order given:

(a) The proper shipping name, as specified in Annex 7 (Table VIII);
(b) The United Nations Class number "7";
(c) The United Nations number assigned to the material as specified in Annex 7 (Table VIII), preceded by the letters "UN";
(d) The name or symbol of each radionuclide or, for mixtures of radionuclides, an appropriate general description or a list of the most restrictive nuclides;
(e) A description of the physical and chemical form of the material, or a notation that the material is *special form radioactive material.* A generic chemical description is acceptable for chemical form;
(f) The maximum activity of the *radioactive contents* during transport expressed in units of becquerels (Bq) with an appropriate SI prefix.
(g) The category of the *package*, i.e. I-WHITE, II-YELLOW, III-YELLOW;
(h) The *transport index* (categories II-YELLOW and III-YELLOW only);
(i) For *consignments* including fissile material other than excepted fissile material, the *criticality safety index*;
(j) The identification mark for each *competent authority* approval certificate (*special form radioactive material*, , *package design*, or *shipment*) applicable to the *consignment*;
(k) For *consignments* of *packages* in an *overpack* or *freight container*, a detailed statement of the contents of each *package* within the *overpack* or *freight container* and, where appropriate, of each *overpack* or *freight container* in the *consignment.* If *packages* are to be removed from the *overpack* or *freight container* at a point of intermediate unloading, appropriate transport documents shall be made available;
(l) Where a *consignment* is required to be shipped under *exclusive use*, the statement "EXCLUSIVE USE SHIPMENT"; and
(m) For *LSA-II*, *LSA-III*, *SCO-I* and *SCO-II*, the total activity of the *consignment* as a multiple of A_2.

Consignor's declaration

The *consignor* shall include in the transport documents a declaration in the following terms or in terms having an equivalent meaning:

"I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packed, marked and labelled, and are in all respects in proper condition for transport by (insert mode(s) of transport involved) according to the applicable international and national governmental regulations."

The declaration shall be signed and dated by the *consignor.* Facsimile signatures are acceptable where applicable laws and regulations recognize the legal validity of facsimile signatures.

The declaration shall be made on the same transport document which contains the particulars of *consignment* listed above.

Information for carriers

The *consignor* shall provide in the transport documents a statement regarding actions, if any, that are required to be taken by the *carrier*. The statement shall be in the languages deemed necessary by the *carrier* or the authorities concerned, and shall include at least the following points:

(a) Supplementary requirements for loading, stowage, carriage, handling and unloading of the *package*, *overpack* or *freight container* including any special stowage provisions for the safe dissipation of heat (see Article 94 (b)), or a statement that no such requirements are necessary;
(b) Restrictions on the mode of transport or *conveyance* and any necessary routing instructions;
(c) Emergency arrangements appropriate to the *consignment*.

The applicable *Regulatory Authority* certificates need not necessarily accompany the *consignment*. The *consignor* shall make them available to the *carrier(s)* before loading and unloading.

Article 94. **Storage and Dispatch**

*Consignment*s of radioactive material shall be stored and dispatched as follows:

(a) Segregation during storage in transit is required from other dangerous goods, and from persons and undeveloped photographic films and plates;
(b) Provided that its average surface heat flux does not exceed 15 W/m^2 and that the immediately surrounding cargo is not in sacks or bags, a *package* or *overpack* may be stored among packaged general cargo without any special stowage provisions except as may be specifically required by the *Regulatory Authority* in an applicable approval certificate; and
(c) Any provisions in the *Regulatory Authority* approval certificates and any relevant pre-use and pre-shipment requirements shall be observed.

Article 95. **Carriage**

Category II-YELLOW or III-YELLOW *package*s or *overpack*s shall not be carried in compartments occupied by passengers, except those exclusively reserved for couriers specially authorized to accompany such *package*s or *overpack*s.

For transport by road, no persons other than the driver and assistants shall be permitted in *vehicle*s carrying *package*s, *overpack*s or *freight container*s bearing category II-YELLOW or III-YELLOW labels.

Article 96. **Decontamination**

*Conveyance*s and equipment used regularly for the transport of radioactive material shall be periodically checked to determine the level of contamination. The frequency of such checks shall be related to the likelihood of contamination and the extent to which radioactive material is transported.

Conveyances and equipment which have, in the course of transport of radioactive material, become contaminated above the previously stated contamination limits or which show a *radiation level* in excess of 5 μSv/h at the surface, shall be decontaminated as soon as possible by a qualified person and shall not be reused unless the non-fixed contamination does not exceed the previously stated contamination limits. In addition, the *radiation level* resulting from the fixed contamination on surfaces after decontamination shall be less than 5 μSv/h.

Article 97. **Notification of Regulatory Authority**

Before the first *shipment* of any *package* requiring *Regulatory Authority* approval, the *consignor* shall ensure that copies of each applicable *Regulatory Authority* certificate applying to that *package design* have been submitted to the *Regulatory Authority* of each country through or into which the *consignment* is to be transported. The *consignor* is not required to await an acknowledgement from the *Regulatory Authority*, nor is the *Regulatory Authority* required to make such acknowledgement of receipt of the certificate.

For each *shipment* listed in (a), (b), (c) or (d) below, the *consignor* shall notify the *Regulatory Authority* of each country through or into which the *consignment* is to be transported. This notification shall be in the hands of each *Regulatory Authority* prior to the commencement of the *shipment*, and preferably at least 7 days in advance.

(a) *Type C packages* containing *radioactive material* with an activity greater than 3000 A_1 or 3000 A_2, as appropriate, or 1000 TBq, whichever is the lower;
(b) *Type B(U) packages* containing *radioactive material* with an activity greater than 3000 A_1 or 3000 A_2, as appropriate, or 1000 TBq, whichever is the lower;
(c) *Type B(M) packages*;
(d) *Shipment* under *special arrangement.*

The *consignment* notification shall include:

(a) Sufficient information to enable the identification of the *package* or *packages* including all applicable certificate numbers and identification marks;
(b) Information on the date of *shipment*, the expected date of arrival and proposed routeing;
(c) The names of the *radioactive materials* or nuclides;
(d) Descriptions of the physical and chemical forms of the *radioactive material*, or whether it is *special form radioactive material* or *low dispersible radioactive material*; and
(e) The maximum activity of the *radioactive contents* during transport expressed in units of becquerels (Bq) with an appropriate SI prefix. For *fissile material*, the mass of *fissile material* in units of grams (g), or multiples thereof, may be used in place of activity.

The *consignor* is not required to send a separate notification if the required information has been included in the application for *shipment* approval.

Article 98. **Other Provisions**

(a) For radioactive material having subsidiary risks and for transport of radioactive material with other dangerous goods, the relevant transport regulation for dangerous goods of each of the counties through or into which the material is to be transported shall apply in addition to these regulations.

(b) Emergency response provisions, including provisions for damaged and leaking *packages*, shall be established.
(c) Quality assurance programmes, which are acceptable to the *Regulatory Authority*, based on international, national or other standards shall be established.
(d) Compliance assurance programmes, which are acceptable to the *Regulatory Authority*, shall be established.
(e) Customs operations involving the inspection of the radioactive contents of a *package* should be carried out only in a place where adequate means of controlling radiation exposure are provided and in the presence of qualified persons. Any *package* opened on customs instructions shall, before being forwarded to the *consignee*, be restored to its original condition.
(f) Where a *consignment* is undeliverable, the *consignment* shall be placed in a safe location and the appropriate *Regulatory Authority* shall be informed as soon as possible and a request made for instructions on further action.

Requirements for Emergency Intervention

Article 99. **Responsibilities of Licensees**

1. If an authorised practice or source within a practice has a potential for accidents which may provoke unplanned exposure of any person, the licensee shall ensure that an emergency plan appropriate for the source and its associated risks is prepared and is kept operational.

2. If an authorized source is involved in an accident or incident, the licensee is responsible for taking such protective actions as may be required for protection of occupationally exposed workers undertaking intervention and for protection of the public from exposure as set forth in the licence application and emergency plans approved by the Regulatory Authority, or as might otherwise by required by the Regulatory Authority to protect against, mitigate or remediate a hazardous situation involving the licensed sources.

Article 100. **Licensee Emergency Response Planning Requirements**

Each licensee responsible for sources for which prompt intervention may be required shall ensure that the emergency plan defines on-site responsibilities and takes account of off-site responsibilities of other intervening organizations appropriate for implementation of the emergency plan. Such emergency plans shall, as appropriate:

(a) characterise the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;
(b) identify the various operating and other conditions of the source which could lead to the need for intervention;
(c) describe the methods and instruments for assessing the accident and its consequences on and off the site;
(d) provide for protection and mitigation actions, and assignment of responsibilities for initiating and discharging such actions;
(e) provide for rapid and continuous assessment of the accident as it proceeds and determining the need for protective actions.

(f) allocate responsibilities for notifying the relevant authorities and for initiating intervention;
(g) provide procedures, including communication arrangements, for contacting any relevant Intervening Organization and for obtaining assistance from fire-fighting, medical, police and other relevant organizations;
(h) provide for training personnel involved in implementing emergency plans and be rehearsed at suitable intervals in conjunction with designated authorities; and
(i) provide for periodic review and updating of the plan.

Article 101. **Implementation of Intervention**

1. The licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken when they are justified, taking into account health, social and economic factors.
2. The form, scale and duration of any justified intervention shall be optimised so as to produce the maximum net benefit under the prevailing social and economic circumstances.
3. Licensees shall promptly notify the Regulatory Authority when an accidental situation requiring intervention has arisen or is expected to arise and shall keep them informed of:
   - the current situation and its expected evolution;
   - the measures taken to terminate the accident and to protect workers and members of the public; and
   - the exposures that have been incurred and that are expected to be incurred.

Article 102. **Protection of Workers Undertaking an Intervention**

1. No worker undertaking an intervention shall be exposed in excess of the maximum single year dose limit for occupational exposure specified in Annex 4 except:

   (a) for the purpose of saving life or preventing serious injury; or
   (b) if undertaking actions to prevent the development of catastrophic conditions.

   When undertaking intervention under these circumstances, all reasonable efforts shall be made to keep doses to workers below twice the maximum single year dose limit, except for life saving actions, in which every effort shall be made to keep doses below ten times the maximum single year dose limit in order to avoid deterministic effects on health. In addition, workers undertaking actions in which their doses may approach or exceed ten times the maximum single year dose limit shall do so only when the benefits to others clearly outweigh their own risk.

2. Workers who undertake actions in which the dose may exceed the maximum single year dose limit shall be volunteers and shall be clearly and comprehensively informed in advance of the associated health risk, and shall, to the extent feasible, be trained in the actions that may be required.

3. Once the emergency phase of an intervention has ended, workers undertaking recovery operations, such as repairs to equipment and buildings, waste disposal or decontamination shall be subject to the full system of detailed requirements for occupational exposure specified in these Regulations.

4. All reasonable steps shall be taken to provide appropriate protection during the emergency intervention and to assess and record the doses received by workers involved in emergency intervention. When the intervention has ended, the doses received and the consequent health risk shall be communicated to the workers involved.

5. Workers shall not normally be precluded from incurring further occupational exposure because of doses received in an emergency exposure situation. However, qualified medical advice shall be obtained before any such further exposure if a worker who has undergone an emergency exposure receives a dose exceeding ten times the maximum single year dose limit, or at the worker's request.

Use of International Protection and Safety Guides

Article 103. Applicants for authorizations may propose to adopt prescriptive recommendations regarding facilities and equipment, procedures, qualifications and training of personnel, maintenance and quality assurance contained in safety and good practice publications issued by the IAEA, WHO, PAHO or other international bodies as methods by which performance requirements in these Regulations will be met. In such instances, the applicant shall:

(a) identify the document(*s*); and
(b) identify both the particular recommendation or part of the document being adopted and the performance requirement in these Regulations it is intended to implement.

Article 104. The Applicant for licence may adopt by reference any of the documents listed under References to the extent that they are relevant to the particular practice. Applicants may propose to use other relevant documents which are not listed under References provided that the documents are clearly identified and copies of the relevant parts of the documents are included with the application.

Article 105. The Regulatory Authority on its own initiative or upon request will revise and update the list under References from time to time.

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ANNEXES

Annex 1

QUESTIONNAIRE FOR NOTIFICATION OF PRACTICES AND SOURCES

(Name and address of the Regulatory Authority)
(Use one form for each source to be notified)

1. Name and address of the legal person.
2. Name and address of the organization.
3. Nature of the practice in which the source is used:
4. Identification of each source:

RADIONUCLIDE:

Activity (Bq):
Chemical form:
Sealed source: YES/NO If Yes = Manufacturer:
Model:

RADIATION GENERATING EQUIPMENT:

Manufacturer:
Model:
Operating potential:

Nature of the equipment in which the source is installed:
Model (if appropriate):
Date:

.....
Signature for legal person

Note: This is only a suggested form — It can be designed in any manner being more appropriate for the local situation.

Annex 2

EXEMPT CONCENTRATIONS AND QUANTITIES OF RADIONUCLIDES

(This annex reproduces Table I-1 of Schedule I of IAEA Safety Series No. 115 [1])

TABLE I-I. EXEMPTION LEVELS: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES (ROUNDED)*

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
H-3	1×10^6	1×10^9	Fe-52	1×10^1	1×10^6
Be-7	1×10^3	1×10^7	Fe-55	1×10^4	1×10^6
C-14	1×10^4	1×10^7	Fe-59	1×10^1	1×10^6
O-15	1×10^2	1×10^9	Co-55	1×10^1	1×10^6
F-18	1×10^1	1×10^6	Co-56	1×10^1	1×10^5
Na-22	1×10^1	1×10^6	Co-57	1×10^2	1×10^6
Na-24	1×10^1	1×10^5	Co-58	1×10^1	1×10^6
Si-31	1×10^3	1×10^6	Co-58m	1×10^4	1×10^7
P-32	1×10^3	1×10^5	Co-60	1×10^1	1×10^5
P-33	1×10^5	1×10^8	Co-60m	1×10^3	1×10^6
S-35	1×10^5	1×10^8	Co-61	1×10^2	1×10^6
Cl-36	1×10^4	1×10^6	Co-62m	1×10^1	1×10^5
Cl-38	1×10^1	1×10^5	Ni-59	1×10^4	1×10^8
Ar-37	1×10^6	1×10^8	Ni-63	1×10^5	1×10^8
Ar-41	1×10^2	1×10^9	Ni-65	1×10^1	1×10^6
K-40	1×10^2	1×10^6	Cu-64	1×10^2	1×10^6
K-42	1×10^2	1×10^6	Zn-65	1×10^1	1×10^6
K-43	1×10^1	1×10^6	Zn-69	1×10^4	1×10^6
Ca-45	1×10^4	1×10^7	Zn-69m	1×10^2	1×10^6
Ca-47	1×10^1	1×10^6	Ga-72	1×10^1	1×10^5
Sc-46	1×10^1	1×10^6	Ge-71	1×10^4	1×10^8
Sc-47	1×10^2	1×10^6	As-73	1×10^3	1×10^7
Sc-48	1×10^1	1×10^5	As-74	1×10^1	1×10^6
V-48	1×10^1	1×10^5	As-76	1×10^2	1×10^5
Cr-51	1×10^3	1×10^7	As-77	1×10^3	1×10^6
Mn-51	1×10^1	1×10^5	Se-75	1×10^2	1×10^6
Mn-52	1×10^1	1×10^5	Br-82	1×10^1	1×10^6
Mn-52m	1×10^1	1×10^5	Kr-74	1×10^2	1×10^9
Mn-53	1×10^4	1×10^9	Kr-76	1×10^2	1×10^9
Mn-54	1×10^1	1×10^6	Kr-77	1×10^2	1×10^9
Mn-56	1×10^1	1×10^5	Kr-79	1×10^3	1×10^5

TABLE I-I. (cont.)

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Kr-81	1×10^4	1×10^7	Tc-97	1×10^3	1×10^8
Kr-83m	1×10^5	1×10^{12}	Tc-97m	1×10^3	1×10^7
Kr-85	1×10^5	1×10^4	Tc-99	1×10^4	1×10^7
Kr-85m	1×10^3	1×10^{10}	Tc-99m	1×10^2	1×10^7
Kr-87	1×10^2	1×10^9	Ru-97	1×10^2	1×10^7
Kr-88	1×10^2	1×10^9	Ru-103	1×10^2	1×10^6
Rb-86	1×10^2	1×10^5	Ru-105	1×10^1	1×10^6
Sr-85	1×10^2	1×10^6	Ru-106[a]	1×10^2	1×10^5
Sr-85m	1×10^2	1×10^7	Rh-103m	1×10^4	1×10^8
Sr-87m	1×10^2	1×10^6	Rh-105	1×10^2	1×10^7
Sr-89	1×10^3	1×10^6	Pd-103	1×10^3	1×10^8
Sr-90[a]	1×10^2	1×10^4	Pd-109	1×10^3	1×10^6
Sr-91	1×10^1	1×10^5	Ag-105	1×10^2	1×10^6
Sr-92	1×10^1	1×10^6	Ag-110m	1×10^1	1×10^6
Y-90	1×10^3	1×10^5	Ag-111	1×10^3	1×10^6
Y-91	1×10^3	1×10^6	Cd-109	1×10^4	1×10^6
Y-91m	1×10^2	1×10^6	Cd-115	1×10^2	1×10^6
Y-92	1×10^2	1×10^5	Cd-115m	1×10^3	1×10^6
Y-93	1×10^2	1×10^5	In-111	1×10^2	1×10^6
Zr-93[a]	1×10^3	1×10^7	In-113m	1×10^2	1×10^6
Zr-95	1×10^1	1×10^6	In-114m	1×10^2	1×10^6
Zr-97[a]	1×10^1	1×10^5	In-115m	1×10^2	1×10^6
Nb-93m	1×10^4	1×10^7	Sn-113	1×10^3	1×10^7
Nb-94	1×10^1	1×10^6	Sn-125	1×10^2	1×10^5
Nb-95	1×10^1	1×10^6	Sb-122	1×10^2	1×10^4
Nb-97	1×10^1	1×10^6	Sb-124	1×10^1	1×10^6
Nb-98	1×10^1	1×10^5	Sb-125	1×10^2	1×10^6
Mo-90	1×10^1	1×10^6	Te-123m	1×10^2	1×10^7
Mo-93	1×10^3	1×10^8	Te-125m	1×10^3	1×10^7
Mo-99	1×10^2	1×10^6	Te-127	1×10^3	1×10^6
Mo-101	1×10^1	1×10^6	Te-127m	1×10^3	1×10^7
Tc-96	1×10^1	1×10^6	Te-129	1×10^2	1×10^6
Tc-96m	1×10^3	1×10^7	Te-129m	1×10^3	1×10^6

TABLE I-I. (cont.)

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Te-131	1×10^{2}	1×10^{5}	Ce-143	1×10^{2}	1×10^{6}
Te-131m	1×10^{1}	1×10^{6}	Ce-144[a]	1×10^{2}	1×10^{5}
Te-132	1×10^{2}	1×10^{7}	Pr-142	1×10^{2}	1×10^{5}
Te-133	1×10^{1}	1×10^{5}	Pr-143	1×10^{4}	1×10^{6}
Te-133m	1×10^{1}	1×10^{5}	Nd-147	1×10^{2}	1×10^{6}
Te-134	1×10^{1}	1×10^{6}	Nd-149	1×10^{2}	1×10^{6}
I-123	1×10^{2}	1×10^{7}	Pm-147	1×10^{4}	1×10^{7}
I-125	1×10^{3}	1×10^{6}	Pm-149	1×10^{3}	1×10^{6}
I-126	1×10^{2}	1×10^{6}	Sm-151	1×10^{4}	1×10^{8}
I-129	1×10^{2}	1×10^{5}	Sm-153	1×10^{2}	1×10^{6}
I-130	1×10^{1}	1×10^{6}	Eu-152	1×10^{1}	1×10^{6}
I-131	1×10^{2}	1×10^{6}	Eu-152m	1×10^{2}	1×10^{6}
I-132	1×10^{1}	1×10^{5}	Eu-154	1×10^{1}	1×10^{6}
I-133	1×10^{1}	1×10^{6}	Eu-155	1×10^{2}	1×10^{7}
I-134	1×10^{1}	1×10^{5}	Gd-153	1×10^{2}	1×10^{7}
I-135	1×10^{1}	1×10^{6}	Gd-159	1×10^{3}	1×10^{6}
Xe-131m	1×10^{4}	1×10^{4}	Tb-160	1×10^{1}	1×10^{6}
Xe-133	1×10^{3}	1×10^{4}	Dy-165	1×10^{3}	1×10^{6}
Xe-135	1×10^{3}	1×10^{10}	Dy-166	1×10^{3}	1×10^{6}
Cs-129	1×10^{2}	1×10^{5}	Ho-166	1×10^{3}	1×10^{5}
Cs-131	1×10^{3}	1×10^{6}	Er-169	1×10^{4}	1×10^{7}
Cs-132	1×10^{1}	1×10^{5}	Er-171	1×10^{2}	1×10^{6}
Cs-134m	1×10^{3}	1×10^{5}	Tm-170	1×10^{3}	1×10^{6}
Cs-134	1×10^{1}	1×10^{4}	Tm-171	1×10^{4}	1×10^{8}
Cs-135	1×10^{4}	1×10^{7}	Yb-175	1×10^{3}	1×10^{7}
Cs-136	1×10^{1}	1×10^{5}	Lu-177	1×10^{3}	1×10^{7}
Cs-137[a]	1×10^{1}	1×10^{4}	Hf-181	1×10^{1}	1×10^{6}
Cs-138	1×10^{1}	1×10^{4}	Ta-182	1×10^{1}	1×10^{4}
Ba-131	1×10^{2}	1×10^{6}	W-181	1×10^{3}	1×10^{7}
Ba-140[a]	1×10^{1}	1×10^{5}	W-185	1×10^{4}	1×10^{7}
La-140	1×10^{1}	1×10^{5}	W-187	1×10^{2}	1×10^{6}
Ce-139	1×10^{2}	1×10^{6}	Re-186	1×10^{3}	1×10^{6}
Ce-141	1×10^{2}	1×10^{7}	Re-188	1×10^{2}	1×10^{5}

TABLE I-I. (cont.)

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Os-185	1×10^{1}	1×10^{6}	Rn-222[a]	1×10^{1}	1×10^{8}
Os-191	1×10^{2}	1×10^{7}	Ra-223[a]	1×10^{2}	1×10^{5}
Os-191m	1×10^{3}	1×10^{7}	Ra-224[a]	1×10^{1}	1×10^{5}
Os-193	1×10^{2}	1×10^{6}	Ra-225	1×10^{2}	1×10^{5}
Ir-190	1×10^{1}	1×10^{6}	Ra-226[a]	1×10^{1}	1×10^{4}
Ir-192	1×10^{1}	1×10^{4}	Ra-227	1×10^{2}	1×10^{6}
Ir-194	1×10^{2}	1×10^{5}	Ra-228[a]	1×10^{1}	1×10^{5}
Pt-191	1×10^{2}	1×10^{6}	Ac-228	1×10^{1}	1×10^{6}
Pt-193m	1×10^{3}	1×10^{7}	Th-226[a]	1×10^{3}	1×10^{7}
Pt-197	1×10^{3}	1×10^{6}	Th-227	1×10^{1}	1×10^{4}
Pt-197m	1×10^{2}	1×10^{6}	Th-228[a]	1×10^{0}	1×10^{4}
Au-198	1×10^{2}	1×10^{6}	Th-229[a]	1×10^{0}	1×10^{3}
Au-199	1×10^{2}	1×10^{6}	Th-230	1×10^{0}	1×10^{4}
Hg-197	1×10^{2}	1×10^{7}	Th-231	1×10^{3}	1×10^{7}
Hg-197m	1×10^{2}	1×10^{6}	Th-nat	1×10^{0}	1×10^{3}
Hg-203	1×10^{2}	1×10^{5}	(incl. Th-232)		
Tl-200	1×10^{1}	1×10^{6}	Th-234[a]	1×10^{3}	1×10^{5}
Tl-201	1×10^{2}	1×10^{6}	Pa-230	1×10^{1}	1×10^{6}
Tl-202	1×10^{2}	1×10^{6}	Pa-231	1×10^{0}	1×10^{3}
Tl-204	1×10^{4}	1×10^{4}	Pa-233	1×10^{2}	1×10^{7}
Pb-203	1×10^{2}	1×10^{6}	U-230[a]	1×10^{1}	1×10^{5}
Pb-210[a]	1×10^{1}	1×10^{4}	U-231	1×10^{2}	1×10^{7}
Pb-212[a]	1×10^{1}	1×10^{5}	U-232[a]	1×10^{0}	1×10^{3}
Bi-206	1×10^{1}	1×10^{5}	U-233	1×10^{1}	1×10^{4}
Bi-207	1×10^{1}	1×10^{6}	U-234	1×10^{1}	1×10^{4}
Bi-210	1×10^{3}	1×10^{6}	U-235[a]	1×10^{1}	1×10^{4}
Bi-212[a]	1×10^{1}	1×10^{5}	U-236	1×10^{1}	1×10^{4}
Po-203	1×10^{1}	1×10^{6}	U-237	1×10^{2}	1×10^{6}
Po-205	1×10^{1}	1×10^{6}	U-238[a]	1×10^{1}	1×10^{4}
Po-207	1×10^{1}	1×10^{6}	U-nat	1×10^{0}	1×10^{3}
Po-210	1×10^{1}	1×10^{4}	U-239	1×10^{2}	1×10^{6}
At-211	1×10^{3}	1×10^{7}	U-240	1×10^{3}	1×10^{7}
Rn-220[a]	1×10^{4}	1×10^{7}	U-240[a]	1×10^{1}	1×10^{6}

TABLE I-I. (cont.)

Nuclide	Activity concentration (Bq/g)	Activity (Bq)	Nuclide	Activity concentration (Bq/g)	Activity (Bq)
Np-237[a]	1×10^0	1×10^3	Cm-244	1×10^1	1×10^4
Np-239	1×10^2	1×10^7	Cm-245	1×10^0	1×10^3
Np-240	1×10^1	1×10^6	Cm-246	1×10^0	1×10^3
Pu-234	1×10^2	1×10^7	Cm-247	1×10^0	1×10^4
Pu-235	1×10^2	1×10^7	Cm-248	1×10^0	1×10^3
Pu-236	1×10^1	1×10^4	Bk-249	1×10^3	1×10^6
Pu-237	1×10^3	1×10^7	Cf-246	1×10^3	1×10^6
Pu-238	1×10^0	1×10^4	Cf-248	1×10^1	1×10^4
Pu-239	1×10^0	1×10^4	Cf-249	1×10^0	1×10^3
Pu-240	1×10^0	1×10^3	Cf-250	1×10^1	1×10^4
Pu-241	1×10^2	1×10^5	Cf-251	1×10^0	1×10^3
Pu-242	1×10^0	1×10^4	Cf-252	1×10^1	1×10^4
Pu-243	1×10^3	1×10^7	Cf-253	1×10^2	1×10^5
Pu-244	1×10^0	1×10^4	Cf-254	1×10^0	1×10^3
Am-241	1×10^0	1×10^4	Es-253	1×10^2	1×10^5
Am-242	1×10^3	1×10^6	Es-254	1×10^1	1×10^4
Am-242m[a]	1×10^0	1×10^4	Es-254m	1×10^2	1×10^6
Am-243[a]	1×10^0	1×10^3	Fm-254	1×10^4	1×10^7
Cm-242	1×10^2	1×10^5	Fm-255	1×10^3	1×10^6
Cm-243	1×10^0	1×10^4			

[a] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214

Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

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* The guidance exemption levels set forth in Table I-I of Schedule I are subject to the following considerations: (a) They have been derived using a conservative model based on (i) the criteria of para. (I-3) and (ii) a series of limiting (bounding) use and disposal scenarios. The values of activity concentration and total activity represent the lowest values calculated in any scenario for a moderate quantity of material. (See COMMISSION OF THE EUROPEAN COMMUNITIES, Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) below Which Reporting Is Not Required in the European Directive, Radiation Protection 65, Doc. XI-028/93, CEC, Brussels (1993). (b) The application of exemption to natural radionuclides, where these are not excluded, is limited to the incorporation of naturally occurring radionuclides into consumer products or their use as a radioactive source (e.g. Ra-226, Po-210) or for their elemental properties (e.g. thorium, uranium). (c) In the case of more than one radionuclide, the appropriate sum of the ratios of the activity or activity concentration of each radionuclide and the corresponding exempt activity or activity concentration shall be taken into account. (d) Unless the exposure is excluded, exemption for bulk amounts of materials with activity concentrations lower than the guidance exemption levels of Table I-I may nevertheless require further consideration by the Regulatory Authority.

Annex 3

DOSE LIMITS FOR EXPOSURES INCURRED FROM PRACTICES

OCCUPATIONAL DOSE LIMITS

The occupational exposure of any worker shall be so controlled that the following limits are not exceeded:

(a) an effective dose of 20 mSv per year averaged over five consecutive years;[1]
(b) an effective dose of 50 mSv in any single year;
(c) an equivalent dose to the lens of the eye of 150 mSv in a year; and
(d) an equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded:

- an effective dose of 6 mSv in a year;
- an equivalent dose to the lens of the eye of 50 mSv in a year; and
- an equivalent dose to the extremities or the skin of 150 mSv in a year.

SPECIAL CIRCUMSTANCES

When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to Article 42:

(a) the dose averaging period mentioned in paragraph (a) above may exceptionally be up to 10 consecutive years as specified by the Regulatory Authority, and the effective dose for any worker shall not exceed 20 mSv per year averaged over this period and shall not exceed 50 mSv in any single year, and the circumstances shall be reviewed when the dose accumulated by any worker since the start of the extended averaging period reaches 100 mSv; or
(b) the temporary change in dose limitation shall be as specified by the Regulatory Authority, but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed 5 years.

DOSE LIMITS FOR THE PUBLIC

The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed the following limits:

(a) an effective dose of 1 mSv in a year;
(b) in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year;
(c) an equivalent dose to the lens of the eye of 15 mSv in a year; and
(d) an equivalent dose to the skin of 50 mSv in a year.

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[1]The start of the averaging period shall be coincident with the first day of the relevant annual period starting from the date of entry into force of the Regulations, with no retroactive averaging.

INTERNAL EXPOSURE

Internal exposure caused by inhalation or ingestion of radioactive substances shall be estimated in accordance with the methodologies, parameters and values contained in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115 [1], Schedule II.

Note: Most radiation sources in the Member States to which this sample Regulations is addressed will not involve significant internal exposure. Therefore, it seems unnecessary and overly complicating to include all the tables, equations, etc. related to this subject in the sample Regulations.

DOSE LIMITATION FOR COMFORTERS AND VISITORS OF PATIENTS

The dose limits set out in this part shall not apply to comforters or visitors of patients. However the dose of any such comforter or visitor shall be constrained so that it is unlikely that the dose will exceed 5 mSv during the period of the diagnostic examination or treatment. The dose to children visiting patients who have ingested or have been injected radioactive materials shall be similarly constrained to less than 1 mSv.

Annex 4

MEDICAL EXPOSURE — DESIGN AND OPERATIONAL REQUIREMENTS

Design of sources and equipment

1. The requirements for the safety of sources specified in Articles 58 to 61 of these Regulations shall apply to sources used in medical exposure where relevant and, in particular, equipment used in medical exposure shall be so designed that:

   (a) failure of equipment or components can be promptly detected so that any unplanned exposure of patients can be avoided or minimised; and
   (b) the risk of delivering unplanned exposure to patients by human error is minimised.

2. Licensees, in co-operation with suppliers where relevant or appropriate, shall:

   (a) ensure that radiation generators, sources and accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information or therapeutic results;
   (b) ensure that equipment containing sources for medical exposure is conform to applicable international (*e.g. IEC, ISO*) and national standards;
   (c) ensure that performance specifications and operating and maintenance instructions, including radiation safety aspects, are provided in a major world language understandable to the users as well as in the local language;
   (d) identify and take all reasonable measures to prevent failures and human errors that could result in unplanned medical exposures, including the establishment of adequate procedures for calibration, quality assurance and operation of diagnostic and therapeutic equipment as well as the selection, training and periodic retraining of suitably qualified personnel;
   (e) ensure that any radiation emitting equipment is provided with radiation beam control mechanisms, including safety interlocks and clear and fail-safe 'on-off' indicators;
   (f) ensure that devices are provided to limit the exposure to the area being examined or treated and keep exposure rates outside this area, due to radiation leakage or scattering, as low as reasonably achievable;
   (g) ensure that, when appropriate, monitoring equipment is installed or is available to give warning of an unusual situation or trend in the use of radiation emitting equipment for diagnostic or therapeutic applications.

Operational aspects

1. Diagnostic exposure

Licensees shall make sure that:

(a) the medical practitioners who prescribe or conduct radiological diagnostic examinations:

   (i) ensure that the appropriate equipment is used;
   (ii) ensure that the exposure of patients is the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image

quality established by appropriate professional bodies and relevant guidance levels for medical exposure;

(iii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;

(iv) avoid radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical reasons for such examinations;

(v) plan any diagnostic examination of the abdomen or pelvis of women of reproductive capacity so as to deliver the minimum dose to any embryo or foetus that might be present;

(vi) ensure that portable and mobile radiological equipment is used only for examinations where it is impractical or not medically acceptable to transfer patients to a stationary radiological installation and only after proper attention has been given to the radiation protection measures required in its use; and

(vii) ensure that, whenever feasible, shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid is provided as appropriate.

(b) the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology:

(i) the area to be examined, the number and size of views per examination (*e.g. number of films or computed tomography slices*) or the time per examination (*e.g. fluoroscopic time*);

(ii) the type of image receptor (*e.g. high versus low speed screens*);

(iii) the use of antiscatter grids;

(iv) proper collimation of the primary X ray beam to minimize the volume of patient tissue being irradiated and to improve image quality;

(v) appropriate values of operational parameters (*e.g. tube generating potential, current and time or their product*);

(vi) appropriate image storage techniques in dynamic imaging (*e.g. number of images per second*); and

(vii) adequate image processing factors (*e.g. developer temperature and image reconstruction algorithms*).

2. Nuclear medicine

Licensees shall make sure that:

(a) the medical practitioners who prescribe or conduct diagnostic applications of radionuclides:

(i) ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective taking into account relevant guidance levels for medical exposure;

(ii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;

(iii) avoid administration of radionuclides for diagnostic procedures to women pregnant or likely to be pregnant unless there are strong clinical indications;

(iv) for mothers in lactation, recommend discontinuation of nursing until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling; and

(v) ensure that administration of radionuclides to children for diagnostic procedures is carried out only if there is a strong clinical indication, and the activity of the radionuclides administered is reduced according to body weight, body surface area or other appropriate criteria.

(b) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:

(i) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;

(ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable; and

(iii) appropriate image acquisition and processing.

3. Therapeutic exposure

Licensees shall make sure that the medical practitioners who prescribe or conduct radiotherapy procedures with radiation sources or with radionuclides:

(a) ensure that the prescribed absorbed dose is delivered to the planning target volume or organ;

(b) ensure that exposure of normal tissue during radiotherapy is kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding is used when feasible and appropriate;

(c) avoid radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless there are strong clinical indications;

(d) avoid administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing, unless there are strong clinical indications;

(e) plan any therapeutic procedure for pregnant women so as to deliver the minimum dose to any embryo or foetus; and

(f) inform the patient of possible risks.

Annex 5

GUIDANCE LEVELS OF DOSE, DOSE RATE AND ACTIVITY FOR MEDICAL EXPOSURE

(This annex reproduces Tables III-I to III-VI from IAEA Safety Series No. 115 [1])

GUIDANCE LEVELS FOR DIAGNOSTIC RADIOLOGICAL PROCEDURES

TABLE III-I. GUIDANCE LEVELS OF DOSE FOR DIAGNOSTIC RADIOGRAPHY FOR A TYPICAL ADULT PATIENT

Examination		Entrance surface dose per radiograph[a] (mGy)
Lumbar spine	AP	10
	LAT	30
	LSJ	40
Abdomen, intravenous urography and cholecystography	AP	10
Pelvis	AP	10
Hip joint	AP	10
Chest	PA	0.4
	LAT	1.5
Thoracic spine	AP	7
	LAT	20
Dental	Periapical	7
	AP	5
Skull	PA	5
	LAT	3

Notes: PA: posterior-anterior projection; LAT: lateral projection; LSJ: lumbo-sacral-joint projection; AP: anterior-posterior projection.

[a] In air with backscatter. These values are for conventional film-screen combination in the relative speed of 200. For high speed film-screen combinations (400–600), the values should be reduced by a factor of 2 to 3.

TABLE III-II. DOSE GUIDANCE LEVELS FOR COMPUTED TOMOGRAPHY FOR A TYPICAL ADULT PATIENT

Examination	Multiple scan average dose[a] (mGy)
Head	50
Lumbar spine	35
Abdomen	25

[a] Derived from measurements on the axis of rotation in water equivalent phantoms, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and abdomen) in diameter.

TABLE III-III. DOSE GUIDANCE LEVELS FOR MAMMOGRAPHY FOR A TYPICAL ADULT PATIENT

Average glandular dose per cranio-caudal projection[a]
1 mGy (without grid)
3 mGy (with grid)

[a] Determined in a 4.5 cm compressed breast consisting of 50% glandular and 50% adipose tissue, for film–screen systems and dedicated Mo-target Mo-filter mammography units.

TABLE III-IV. DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT

Mode of operation	Entrance surface dose rate[a] (mGy/min)
Normal	25
High level[b]	100

[a] In air with backscatter.

[b] For fluoroscopes that have an optional 'high level' operational mode, such as those frequently used in interventional radiology.

TABLE III-V. GUIDANCE LEVELS OF ACTIVITY FOR PROCEDURES IN NUCLEAR MEDICINE FOR A TYPICAL ADULT PATIENT

Test	Radio-nuclide	Chemical form[a]	Maximum usual activity per test[b] (MBq)
Bone			
Bone imaging	$^{99}Tc^m$	Phosphonate and Phosphate compounds	600
Bone imaging by single photon emission computerized tomography (SPECT)	$^{99}Tc^m$	Phosponate and Phosphate compounds	800
Bone marrow imaging	$^{99}Tc^m$	Labelled colloid	400
Brain			
Brain imaging (static)	$^{99}Tc^m$	TcO_4^-	500
	$^{99}Tc^m$	Diethylenetriaminepenta-acetic acid (DTPA), gluconate and glucoheptonate	500
Brain imaging (SPECT)	$^{99}Tc^m$	TcO_4^-	800
	$^{99}Tc^m$	DTPA, gluconate and glucoheptonate	800
	$^{99}Tc^m$	Exametazime	500
Cerebral blood flow	^{133}Xe	In isotonic sodium chloride solution	400
	$^{99}Tc^m$	Hexamethyl propylene amine oxime (HM-PAO)	500
Cisternography	^{111}In	DTPA	40
Lacrimal			
Lacrimal drainage	$^{99}Tc^m$	TcO_4^-	4
	$^{99}Tc^m$	Labelled colloid	4
Thyroid			
Thyroid imaging	$^{99}Tc^m$	TcO_4^-	200
	^{123}I	I^-	20
Thyroid metastases (after ablation)	^{131}I	I^-	400
Parathyroid imaging	^{201}Tl	Tl^+, chloride	80

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form[a]	Maximum usual activity per test[b] (MBq)
Lung			
Lung ventilation imaging	$^{81}Kr^{m}$	Gas	6000
	$^{99}Tc^{m}$	DTPA-aerosol	80
Lung ventilation study	^{133}Xe	Gas	400
	^{127}Xe	Gas	200
Lung perfusion imaging	$^{81}Kr^{m}$	Aqueous solution	6000
	$^{99}Tc^{m}$	Human albumin (macroaggregates or microspheres)	100
Lung perfusion imaging (with venography)	$^{99}Tc^{m}$	Human albumin (macroaggregates or microspheres)	160
Lung perfusion studies	^{133}Xe	Isotonic solution	200
	^{127}Xe	Isotonic chloride solution	200
Lung imaging (SPECT)	^{99}Tc	Macroaggregated albumin (MAA)	200
Liver and spleen			
Liver and spleen imaging	$^{99}Tc^{m}$	Labelled colloid	80
Functional biliary system imaging	$^{99}Tc^{m}$	Iminodiacetates and equivalent agents	150
Spleen imaging	$^{99}Tc^{m}$	Labelled denaturated red blood cells	100
Liver imaging (SPECT)	$^{99}Tc^{m}$	Labelled colloid	200
Cardiovascular			
First pass blood flow studies	$^{99}Tc^{m}$	TcO_4^-	800
	$^{99}Tc^{m}$	DTPA	800
	$^{99}Tc^{m}$	Macroaggregated globulin 3	400
Blood pool imaging	$^{99}Tc^{m}$	Human albumin complex	40
Cardiac and vascular imaging/probe studies	$^{99}Tc^{m}$	Human albumin complex	800
Myocardial imaging/probe studies	$^{99}Tc^{m}$	Labelled normal red blood cells	800

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form[a]	Maximum usual activity per test[b] (MBq)
Myocardial imaging	$^{99}Tc^m$	Phosphonate and phosphate compounds	600
Myocardial imaging (SPECT)	$^{99}Tc^m$	Isonitriles	300
	^{201}Tl	Tl^+ chloride	100
	$^{99}Tc^m$	Phosphonate and phosphate compounds	800
	$^{99}Tc^m$	Isonitriles	600
Stomach, gastrointestinal tract			
Stomach/salivary gland imaging	$^{99}Tc^m$	TcO_4^-	40
Meckel's diverticulum imaging	$^{99}Tc^m$	TcO_4^-	400
Gastrointestinal bleeding	$^{99}Tc^m$	Labelled colloid	400
	$^{99}Tc^m$	Labelled normal red blood cells	400
Oesophageal transit and reflux	$^{99}Tc^m$	Labelled colloid	40
	$^{99}Tc^m$	Non-absorbable compounds	40
Gastric emptying	$^{99}Tc^m$	Non-absorbable compounds	12
	^{111}In	Non-absorbable compounds	12
	$^{113}In^m$	Non-absorbable compounds	12
Kidney, urinary system and adrenals			
Renal imaging	$^{99}Tc^m$	Dimercaptosuccinic acid	160
Renal imaging/renography	$^{99}Tc^m$	DTPA, gluconate and glucoheptonate	350
	$^{99}Tc^m$	Macroaggregated globulin 3	100
	^{123}I	O-iodohippurate	20
Adrenal imaging	^{75}Se	Selenorcholesterol	8

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form[a]	Maximum usual activity per test[b] (MBq)
Miscellaneous			
Tumour or abscess imaging	^{67}Ga	Citrate	300
	^{201}Tl	Chloride	100
Tumour imaging	$^{99}Tc^{m}$	Dimercaptosuccinic acid	400
Neuroectodermal tumour imaging	^{123}I	Meta-iodo-benzyl guanidine	400
	^{131}I	Meta-iodo-benzyl guanidine	20
Lymph node imaging	$^{99}Tc^{m}$	Labelled colloid	80
Abscess imaging	$^{99}Tc^{m}$	Exametazime labelled white cells	400
	^{111}In	Labelled white cells	20
Thrombus imaging	^{111}In	Labelled platelets	20

[a] In some countries some of the compounds are considered obsolete.

[b] In some countries the typical values are lower than those indicated in the table.

GUIDANCE LEVEL OF ACTIVITY FOR DISCHARGE FROM HOSPITAL

TABLE III-VI. GUIDANCE LEVEL FOR MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

Radionuclide	Activity (MBq)
Iodine-131	1100[a]

[a] In some countries a level of 400 MBq is used as an example of good practice.

Annex 6

ADVICE ON DEVELOPMENT OF NATIONAL POLICY AND STRATEGIES FOR RADIOACTIVE WASTE MANAGEMENT

INTRODUCTION

A particular problem arising from the beneficial uses of radioactive materials is the generation of radioactive waste. Radioactive waste often entails difficult technical and social issues, particularly if it is generated in the absence of a national policy and strategy on how it is to be managed. The purpose of this annex is to provide Member States with advice on policy and strategies for the management of radioactive waste from the application of radiation sources and radionuclides in medicine, agriculture, industry, research and education within the context of the general radiation safety policy and objectives [1, 3].

ESTABLISHING A NATIONAL POLICY

Member States in which radioactive waste exists or is likely to be produced need to establish a national policy for its management. This policy should be consistent with the internationally agreed waste management objective and principles defined in Refs [20] and [21] and should be established as described in Ref. [22].

The objective of waste management is to deal with radioactive waste and dispose of it in a manner that ensures protection of human health and the environment now and in the future without imposing undue burdens on future generations. More specifically, the principles of waste management must address the following issues:

- Protection of human health, both within and beyond national borders;
- Protection of the environment, both within and beyond national borders;
- Protection of future generations;
- Burdens on future generations;
- National legal and administrative framework;
- Control of radioactive waste generation;
- Safety of waste management facilities.

A strategy is also needed to implement this policy. Both, the policy and strategy should reflect national circumstances, structures and priorities and the range of radioactive wastes involved. The implementation of parts of the strategy may involve co-operation with other countries and international organizations.

DEVELOPMENT OF A NATIONAL STRATEGY

Analysis of present and likely future situations regarding radioactive waste

Before any strategy for radioactive waste management can be established, the State or an organisation appointed by it should undertake, as far as reasonable and practicable, a complete analysis of the present and likely future situation with respect to radioactive waste generation in the country.

In order to conduct this analysis, it is often necessary to establish a clear distinction between waste which requires regulatory control and most for which such a control is not warranted. To make this distinction, exemptions levels and levels of clearance from regulatory requirements need to be specified by the Regulatory Authority. Advice on the establishment of such levels is contained in Article 16 and Annex 2.

A national strategy is then required in order to define the scope, infrastructure and implementation of waste management. One of the elements of the strategy is the decision to either implement centralised waste management, or to manage waste entirely at the source (e.g. at the generator's premises). The decision to select either centralised or decentralised waste management will depend on the quantity and activity of waste arisings, and on the outcome of a cost-benefit analysis. In the case of a decision for a centralised facility, the biggest waste generator or the generator with better capability should be assigned as central radioactive waste management facility.

Options for managing radioactive waste

As a next step in establishing a waste management strategy, a range of options may need to be considered depending on the amount and the characteristics of the waste generated in medical, agricultural, industry and research practices.

Much solid waste that arises from the use of sources may be suitable for release from regulatory control either immediately or after a period of decay storage, which may extend to a few years. Such waste may be released within clearance levels established by the Regulatory Authority. The recycle or reuse of materials is also possible if the Regulatory Authority has approved such option.

If release is not viable, consideration should be given to the return of the waste to the producer/supplier of the source. This is of particular importance for large sealed sources and sources containing long-lived radionuclides.

For solid waste that cannot be released from regulatory control or returned to the producer/supplier, an acceptable destination will need to be identified. This could be either a disposal facility or a long-term storage facility, pending future disposal. In both cases prior treatment or conditioning of waste may be needed.

For waste which is produced in airborne or liquid form, various forms of management at the source are possible, but invariably a fraction of it must be discharged into the environment in controlled conditions in order to ensure its safe dilution.

Responsibility and funding

Waste strategy decisions have significant funding implications which must be addressed by those responsible through the establishment of a funding system on a national basis. The waste generators are responsible for the waste they generate. However, government may choose to assume the ultimate responsibility for operation of radioactive waste disposal facilities for a number of reasons which include the need to assure adequate long term care and institutional controls, and to avoid proliferation of disposal facilities. In such cases, the function of the Regulatory Authority should be clearly separate and independent from the

operating organisations and the government may recover the costs of waste management operations from the waste generators through an appropriate financial instrument.

Radioactive waste management system

Once a national waste management strategy has been established, its implementation requires the setting up of a comprehensive radioactive waste management system including, both, an operational capability for dealing with the radioactive waste and an independent regulatory capability for controlling the way in which it is dealt with. For the operational capability appropriate facilities and operators are required. A Member State is required to establish a legal framework and a Regulatory Authority to enforce compliance with legal requirements.

The use of the term 'system' does not necessarily imply a single centralized system for the Member State. Rather, it is the summation of all the individual components, for example set of laws, regulatory organizations, operators, facilities, etc. that are required for the management of radioactive waste.

The basic elements of a radioactive waste management system are:

- identification of the parties involved in the different steps of radioactive waste management, including waste generators and their responsibilities;
- a rational set of safety, radiological and environmental protection objectives from which standards and criteria may be derived within the regulatory system;
- identification of existing and anticipated radioactive wastes, including their location, radionuclide content and other physical and chemical characteristics;
- control of radioactive waste generation;
- identification of available methods and facilities to process, store and dispose of radioactive waste on an appropriate time-scale;
- taking appropriately into account interdependencies among all steps in radioactive waste on an appropriate time-scale;
- appropriate research and development to support the operational and regulatory needs; and
- a funding structure and allocation of resources that are essential for radioactive waste management, including decommissioning.

Legal framework

The general requirements for a legal framework for radiation safety are described in Chapter 2. In particular, the legal framework aimed at regulating and controlling radioactive waste should cover the following aspects:

- Classification;
- Exemption and clearance;
- Generation;
- Pretreatment, treatment, conditioning, interim storage and transport;
- Destination (recycle, reuse, return to supplier, interim storage; discharge/disposal); and
- Quality assurance (national inventories, documentation, waste acceptance criteria, etc.)

These aspects are discussed in some detail in the following:

Classification of radioactive waste

A fundamental stage of radioactive waste management is the classification of waste. This will enable the selection and application of the most appropriate waste management option. Radioactive waste should be classified according to its radionuclide content and its physical, chemical and biological properties.

Exemption and clearance

Some radioactive materials with radionuclide content below nationally established exemption levels can be exempted from regulatory control as they represent a negligible radiological hazard. Exempted materials will never enter into the regulatory system. Such materials include domestic smoke detectors. Levels for automatic exemption of materials containing different radionuclides are given in Annex 2.

Furthermore the waste arising from regulated activities can be cleared from the regulatory control if the radionuclide content is below nationally established clearance levels so that such waste represent a negligible radiological hazard (clearance waste). Such low radionuclide inventories may be obtained for short lived radionuclides, after an appropriate storage period (*decay waste, see Appendix, Article 63 of the sample Regulations*).

Establishment of exemption and clearance levels and any release from the regulatory control is responsibility of the Regulatory Authority.

Generation

An essential component of radioactive waste management is to ensure that the activity and amount and also the associated non-radiological hazard of radioactive waste are kept to the minimum practicable level. Complete prevention of waste generation is preferable but in most cases impossible. However, steps can be taken to reduce the overall environmental impact and cost by:

- avoiding the use of unnecessarily hazardous/toxic materials;
- minimizing the activity of waste by using the minimum quantity of radioactive material needed;
- using short lived radionuclides where possible;
- minimizing the amount of waste by preventing unnecessary contamination of materials; and
- maintaining consistency with the management strategy and systems.

Pretreatment

Pretreatment of waste may be the initial step in waste management that occurs after waste generation. It consists of, for example, collection, segregation, chemical adjustment and decontamination and may include a period of operational storage. This initial step provides the best opportunity to segregate waste streams at source. This may facilitate recycling within the process or disposal as non-radioactive waste when the quantities of radionuclides present in the waste are so low that they are below the exemption or clearance levels. It also provides the opportunity to segregate radioactive waste for different disposal routes.

Treatment

Treatment of radioactive waste includes those operations intended to improve safety or economy by changing the characteristics of the radioactive waste. The basic treatment concepts, applicable for small volumes of waste are:

- Volume reduction
  Solid Waste: shredding and compaction;
  Liquid Waste: evaporation under controlled conditions.
- Removal of radionuclides
  Solid waste: decontamination;
  Liquid waste: ion exchange.
- Change of composition
  Liquid waste:precipitation/filtration.

It is important to be aware that treatment processes may result in the production of secondary radioactive waste streams (contaminated filters, spent resins, sludges), which will also need to be appropriately managed.

Conditioning

Conditioning of radioactive waste involves those operations that convert it into a form which is more suitable for handling, transportation, storage and disposal. The operations may include immobilization of radioactive waste with cement, placing the waste into a container and providing additional packaging. In many instances, pretreatment, treatment and conditioning take place in close conjunction with one another.

Storage

Storage facilities may be required for untreated, treated and conditioned radioactive waste. Special attention should be paid to the storage of unconditioned waste in order to limit the risk of dispersion. Storage facilities should be designed to provide physical security and retrievability.

Transport

Transport of radioactive waste should be carried out in accordance with national regulations, taking due account of the IAEA Regulations for the Safe Transport of Radioactive Material [7].

Recycle and reuse

Recycle and reuse of radioactive materials should be considered as an alternative to disposal, if circumstances permit. Possible options include:

- Reuse of sealed sources;
- Decontamination and reuse of equipment/protective clothing;
- Reuse of dilute waste streams (for rinsing and washing of waste tanks which contained waste liquors with higher radioactivity content, process feed make-up etc.); and
- Recycle and reuse of solid materials (metals, concrete, etc.)

Decontamination of wastes such as tools and equipment might be applicable to facilitate reuse or clearance.

Reuse/recycle of radioactive materials should be subject to approval by the Regulatory Authority. Special attention should be given to the implications of producing secondary waste streams, and the need to ensure that sealed sources are in a serviceable condition and are suitable for the intended reuse application.

Return to supplier

When importing sealed sources or radionuclides, it should be negotiated that at all possible spent sealed sources or the waste resulting from the use of radionuclides should be returned to the supplier of the sources or generators of radionuclides. This is particularly important for large sources and waste that cannot be cleared after decay storage and that contain long lived radionuclides (^{226}Ra, Pu, ^{241}Am).

Discharge/disposal

Although management of radioactive waste may involve concentration and containment, it may also comprise the discharge of waste as airborne or liquid effluents into the environment within limits authorised by the Regulatory Authority, taking into account subsequent dispersion. For all practical purposes this is an irreversible disposal action and is considered suitable after a safety and environmental impact assessment.

Disposal is the final step in the management of solid radioactive waste. It consists mainly of the emplacement of radioactive waste in a disposal facility with reasonable assurance for safety, without the intention of retrieval and without reliance on long term surveillance and maintenance.

Annex 7

TABLES FOR TRANSPORT REQUIREMENTS

(This annex reproduces Tables I– IX of the IAEA Safety Standards Series No. ST-1 [19])

TABLE I. BASIC RADIONUCLIDE VALUES

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Actinium (89)				
Ac-225 (a)	8×10^{-1}	6×10^{-3}	1×10^{1}	1×10^{4}
Ac-227 (a)	9×10^{-1}	9×10^{-5}	1×10^{-1}	1×10^{3}
Ac-228	6×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Silver (47)				
Ag-105	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Ag-108m (a)	7×10^{-1}	7×10^{-1}	1×10^{1} (b)	1×10^{6} (b)
Ag-110m (a)	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{6}
Ag-111	2×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Aluminium (13)				
Al-26	1×10^{-1}	1×10^{-1}	1×10^{1}	1×10^{5}
Americium (95)				
Am-241	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{4}
Am-242m (a)	1×10^{1}	1×10^{-3}	1×10^{0} (b)	1×10^{4} (b)
Am-243 (a)	5×10^{0}	1×10^{-3}	1×10^{0} (b)	1×10^{3} (b)
Argon (18)				
Ar-37	4×10^{1}	4×10^{1}	1×10^{6}	1×10^{8}
Ar-39	4×10^{1}	2×10^{1}	1×10^{7}	1×10^{4}
Ar-41	3×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{9}
Arsenic (33)				
As-72	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
As-73	4×10^{1}	4×10^{1}	1×10^{3}	1×10^{7}
As-74	1×10^{0}	9×10^{-1}	1×10^{1}	1×10^{6}
As-76	3×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{5}
As-77	2×10^{1}	7×10^{-1}	1×10^{3}	1×10^{6}
Astatine (85)				
At-211 (a)	2×10^{1}	5×10^{-1}	1×10^{3}	1×10^{7}
Gold (79)				
Au-193	7×10^{0}	2×10^{0}	1×10^{2}	1×10^{7}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Au-194	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Au-195	1×10^{1}	6×10^{0}	1×10^{2}	1×10^{7}
Au-198	1×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Au-199	1×10^{1}	6×10^{-1}	1×10^{2}	1×10^{6}
Barium (56)				
Ba-131 (a)	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Ba-133	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Ba-133m	2×10^{1}	6×10^{-1}	1×10^{2}	1×10^{6}
Ba-140 (a)	5×10^{-1}	3×10^{-1}	1×10^{1} (b)	1×10^{5} (b)
Beryllium (4)				
Be-7	2×10^{1}	2×10^{1}	1×10^{3}	1×10^{7}
Be-10	4×10^{1}	6×10^{-1}	1×10^{4}	1×10^{6}
Bismuth (83)				
Bi-205	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Bi-206	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Bi-207	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Bi-210	1×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Bi-210m (a)	6×10^{-1}	2×10^{-2}	1×10^{1}	1×10^{5}
Bi-212 (a)	7×10^{-1}	6×10^{-1}	1×10^{1} (b)	1×10^{5} (b)
Berkelium (97)				
Bk-247	8×10^{0}	8×10^{-4}	1×10^{0}	1×10^{4}
Bk-249 (a)	4×10^{1}	3×10^{-1}	1×10^{3}	1×10^{6}
Bromine (35)				
Br-76	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Br-77	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Br-82	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{6}
Carbon (6)				
C-11	1×10^{0}	6×10^{-1}	1×10^{1}	1×10^{6}
C-14	4×10^{1}	3×10^{0}	1×10^{4}	1×10^{7}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Calcium (20)				
Ca-41	Unlimited	Unlimited	1×10^5	1×10^7
Ca-45	4×10^1	1×10^0	1×10^4	1×10^7
Ca-47 (a)	3×10^0	3×10^{-1}	1×10^1	1×10^6
Cadmium (48)				
Cd-109	3×10^1	2×10^0	1×10^4	1×10^6
Cd-113m	4×10^1	5×10^{-1}	1×10^3	1×10^6
Cd-115 (a)	3×10^0	4×10^{-1}	1×10^2	1×10^6
Cd-115m	5×10^{-1}	5×10^{-1}	1×10^3	1×10^6
Cerium (58)				
Ce-139	7×10^0	2×10^0	1×10^2	1×10^6
Ce-141	2×10^1	6×10^{-1}	1×10^2	1×10^7
Ce-143	9×10^{-1}	6×10^{-1}	1×10^2	1×10^6
Ce-144 (a)	2×10^{-1}	2×10^{-1}	1×10^2 (b)	1×10^5 (b)
Californium (98)				
Cf-248	4×10^1	6×10^{-3}	1×10^1	1×10^4
Cf-249	3×10^0	8×10^{-4}	1×10^0	1×10^3
Cf-250	2×10^1	2×10^{-3}	1×10^1	1×10^4
Cf-251	7×10^0	7×10^{-4}	1×10^0	1×10^3
Cf-252	5×10^{-2}	3×10^{-3}	1×10^1	1×10^4
Cf-253 (a)	4×10^1	4×10^{-2}	1×10^2	1×10^5
Cf-254	1×10^{-3}	1×10^{-3}	1×10^0	1×10^3
Chlorine (17)				
Cl-36	1×10^1	6×10^{-1}	1×10^4	1×10^6
Cl-38	2×10^{-1}	2×10^{-1}	1×10^1	1×10^5
Curium (96)				
Cm-240	4×10^1	2×10^{-2}	1×10^2	1×10^5
Cm-241	2×10^0	1×10^0	1×10^2	1×10^6
Cm-242	4×10^1	1×10^{-2}	1×10^2	1×10^5

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Cm-243	9×10^{0}	1×10^{-3}	1×10^{0}	1×10^{4}
Cm-244	2×10^{1}	2×10^{-3}	1×10^{1}	1×10^{4}
Cm-245	9×10^{0}	9×10^{-4}	1×10^{0}	1×10^{3}
Cm-246	9×10^{0}	9×10^{-4}	1×10^{0}	1×10^{3}
Cm-247 (a)	3×10^{0}	1×10^{-3}	1×10^{0}	1×10^{4}
Cm-248	2×10^{-2}	3×10^{-4}	1×10^{0}	1×10^{3}
Cobalt (27)				
Co-55	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Co-56	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Co-57	1×10^{1}	1×10^{1}	1×10^{2}	1×10^{6}
Co-58	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Co-58m	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{7}
Co-60	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Chromium (24)				
Cr-51	3×10^{1}	3×10^{1}	1×10^{3}	1×10^{7}
Caesium (55)				
Cs-129	4×10^{0}	4×10^{0}	1×10^{2}	1×10^{5}
Cs-131	3×10^{1}	3×10^{1}	1×10^{3}	1×10^{6}
Cs-132	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{5}
Cs-134	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{4}
Cs-134m	4×10^{1}	6×10^{-1}	1×10^{3}	1×10^{5}
Cs-135	4×10^{1}	1×10^{0}	1×10^{4}	1×10^{7}
Cs-136	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{5}
Cs-137 (a)	2×10^{0}	6×10^{-1}	1×10^{1} (b)	1×10^{4} (b)
Copper (29)				
Cu-64	6×10^{0}	1×10^{0}	1×10^{2}	1×10^{6}
Cu-67	1×10^{1}	7×10^{-1}	1×10^{2}	1×10^{6}
Dysprosium (66)				
Dy-159	2×10^{1}	2×10^{1}	1×10^{3}	1×10^{7}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Dy-165	9×10^{-1}	6×10^{-1}	1×10^{3}	1×10^{6}
Dy-166 (a)	9×10^{-1}	3×10^{-1}	1×10^{3}	1×10^{6}
Erbium (68)				
Er-169	4×10^{1}	1×10^{0}	1×10^{4}	1×10^{7}
Er-171	8×10^{-1}	5×10^{-1}	1×10^{2}	1×10^{6}
Europium (63)				
Eu-147	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Eu-148	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Eu-149	2×10^{1}	2×10^{1}	1×10^{2}	1×10^{7}
Eu-150 (short lived)	2×10^{0}	7×10^{-1}	1×10^{3}	1×10^{6}
Eu-150 (long lived)	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Eu-152	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Eu-152m	8×10^{-1}	8×10^{-1}	1×10^{2}	1×10^{6}
Eu-154	9×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Eu-155	2×10^{1}	3×10^{0}	1×10^{2}	1×10^{7}
Eu-156	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Fluorine (9)				
F-18	1×10^{0}	6×10^{-1}	1×10^{1}	1×10^{6}
Iron (26)				
Fe-52 (a)	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{6}
Fe-55	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{6}
Fe-59	9×10^{-1}	9×10^{-1}	1×10^{1}	1×10^{6}
Fe-60 (a)	4×10^{1}	2×10^{-1}	1×10^{2}	1×10^{5}
Gallium (31)				
Ga-67	7×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Ga-68	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{5}
Ga-72	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Gadolinium (64)				
Gd-146 (a)	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Gd-148	2×10^{1}	2×10^{-3}	1×10^{1}	1×10^{4}
Gd-153	1×10^{1}	9×10^{0}	1×10^{2}	1×10^{7}
Gd-159	3×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Germanium (32)				
Ge-68 (a)	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{5}
Ge-71	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{8}
Ge-77	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Hafnium (72)				
Hf-172 (a)	6×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Hf-175	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Hf-181	2×10^{0}	5×10^{-1}	1×10^{1}	1×10^{6}
Hf-182	Unlimited	Unlimited	1×10^{2}	1×10^{6}
Mercury (80)				
Hg-194 (a)	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Hg-195m (a)	3×10^{0}	7×10^{-1}	1×10^{2}	1×10^{6}
Hg-197	2×10^{1}	1×10^{1}	1×10^{2}	1×10^{7}
Hg-197m	1×10^{1}	4×10^{-1}	1×10^{2}	1×10^{6}
Hg-203	5×10^{0}	1×10^{0}	1×10^{2}	1×10^{5}
Holmium (67)				
Ho-166	4×10^{-1}	4×10^{-1}	1×10^{3}	1×10^{5}
Ho-166m	6×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Iodine (53)				
I-123	6×10^{0}	3×10^{0}	1×10^{2}	1×10^{7}
I-124	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
I-125	2×10^{1}	3×10^{0}	1×10^{3}	1×10^{6}
I-126	2×10^{0}	1×10^{0}	1×10^{2}	1×10^{6}
I-129	Unlimited	Unlimited	1×10^{2}	1×10^{5}
I-131	3×10^{0}	7×10^{-1}	1×10^{2}	1×10^{6}
I-132	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
I-133	7×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
I-134	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
I-135 (a)	6×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Indium (49)				
In-111	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
In-113m	4×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
In-114m (a)	1×10^{1}	5×10^{-1}	1×10^{2}	1×10^{6}
In-115m	7×10^{0}	1×10^{0}	1×10^{2}	1×10^{6}
Iridium (77)				
Ir-189 (a)	1×10^{1}	1×10^{1}	1×10^{2}	1×10^{7}
Ir-190	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Ir-192	1×10^{0} (c)	6×10^{-1}	1×10^{1}	1×10^{4}
Ir-194	3×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{5}
Potassium (19)				
K-40	9×10^{-1}	9×10^{-1}	1×10^{2}	1×10^{6}
K-42	2×10^{-1}	2×10^{-1}	1×10^{2}	1×10^{6}
K-43	7×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Krypton (36)				
Kr-81	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{7}
Kr-85	1×10^{1}	1×10^{1}	1×10^{5}	1×10^{4}
Kr-85m	8×10^{0}	3×10^{0}	1×10^{3}	1×10^{10}
Kr-87	2×10^{-1}	2×10^{-1}	1×10^{2}	1×10^{9}
Lanthanum (57)				
La-137	3×10^{1}	6×10^{0}	1×10^{3}	1×10^{7}
La-140	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Lutetium (71)				
Lu-172	6×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Lu-173	8×10^{0}	8×10^{0}	1×10^{2}	1×10^{7}
Lu-174	9×10^{0}	9×10^{0}	1×10^{2}	1×10^{7}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Lu-174m	2×10^{1}	1×10^{1}	1×10^{2}	1×10^{7}
Lu-177	3×10^{1}	7×10^{-1}	1×10^{3}	1×10^{7}
Magnesium (12)				
Mg-28 (a)	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Manganese (25)				
Mn-52	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Mn-53	Unlimited	Unlimited	1×10^{4}	1×10^{9}
Mn-54	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Mn-56	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Molybdenum (42)				
Mo-93	4×10^{1}	2×10^{1}	1×10^{3}	1×10^{8}
Mo-99 (a)	1×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Nitrogen (7)				
N-13	9×10^{-1}	6×10^{-1}	1×10^{2}	1×10^{9}
Sodium (11)				
Na-22	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Na-24	2×10^{-1}	2×10^{-1}	1×10^{1}	1×10^{5}
Niobium (41)				
Nb-93m	4×10^{1}	3×10^{1}	1×10^{4}	1×10^{7}
Nb-94	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Nb-95	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Nb-97	9×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Neodymium (60)				
Nd-147	6×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Nd-149	6×10^{-1}	5×10^{-1}	1×10^{2}	1×10^{6}
Nickel (28)				
Ni-59	Unlimited	Unlimited	1×10^{4}	1×10^{8}
Ni-63	4×10^{1}	3×10^{1}	1×10^{5}	1×10^{8}
Ni-65	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{6}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Neptunium (93)				
Np-235	4×10^{1}	4×10^{1}	1×10^{3}	1×10^{7}
Np-236 (short lived)	2×10^{1}	2×10^{0}	1×10^{3}	1×10^{7}
Np-236 (long lived)	9×10^{0}	2×10^{-2}	1×10^{2}	1×10^{5}
Np-237	2×10^{1}	2×10^{-3}	1×10^{0} (b)	1×10^{3} (b)
Np-239	7×10^{0}	4×10^{-1}	1×10^{2}	1×10^{7}
Osmium (76)				
Os-185	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Os-191	1×10^{1}	2×10^{0}	1×10^{2}	1×10^{7}
Os-191m	4×10^{1}	3×10^{1}	1×10^{3}	1×10^{7}
Os-193	2×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Os-194 (a)	3×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{5}
Phosphorus (15)				
P-32	5×10^{-1}	5×10^{-1}	1×10^{3}	1×10^{5}
P-33	4×10^{1}	1×10^{0}	1×10^{5}	1×10^{8}
Protactinium (91)				
Pa-230 (a)	2×10^{0}	7×10^{-2}	1×10^{1}	1×10^{6}
Pa-231	4×10^{0}	4×10^{-4}	1×10^{0}	1×10^{3}
Pa-233	5×10^{0}	7×10^{-1}	1×10^{2}	1×10^{7}
Lead (82)				
Pb-201	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Pb-202	4×10^{1}	2×10^{1}	1×10^{3}	1×10^{6}
Pb-203	4×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Pb-205	Unlimited	Unlimited	1×10^{4}	1×10^{7}
Pb-210 (a)	1×10^{0}	5×10^{-2}	1×10^{1} (b)	1×10^{4} (b)
Pb-212 (a)	7×10^{-1}	2×10^{-1}	1×10^{1} (b)	1×10^{5} (b)
Palladium (46)				
Pd-103 (a)	4×10^{1}	4×10^{1}	1×10^{3}	1×10^{8}
Pd-107	Unlimited	Unlimited	1×10^{5}	1×10^{8}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Pd-109	2×10^{0}	5×10^{-1}	1×10^{3}	1×10^{6}
Promethium (61)				
Pm-143	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Pm-144	7×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Pm-145	3×10^{1}	1×10^{1}	1×10^{3}	1×10^{7}
Pm-147	4×10^{1}	2×10^{0}	1×10^{4}	1×10^{7}
Pm-148m (a)	8×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Pm-149	2×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Pm-151	2×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Polonium (84)				
Po-210	4×10^{1}	2×10^{-2}	1×10^{1}	1×10^{4}
Praseodymium (59)				
Pr-142	4×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{5}
Pr-143	3×10^{0}	6×10^{-1}	1×10^{4}	1×10^{6}
Platinum (78)				
Pt-188 (a)	1×10^{0}	8×10^{-1}	1×10^{1}	1×10^{6}
Pt-191	4×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Pt-193	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{7}
Pt-193m	4×10^{1}	5×10^{-1}	1×10^{3}	1×10^{7}
Pt-195m	1×10^{1}	5×10^{-1}	1×10^{2}	1×10^{6}
Pt-197	2×10^{1}	6×10^{-1}	1×10^{3}	1×10^{6}
Pt-197m	1×10^{1}	6×10^{-1}	1×10^{2}	1×10^{6}
Plutonium (94)				
Pu-236	3×10^{1}	3×10^{-3}	1×10^{1}	1×10^{4}
Pu-237	2×10^{1}	2×10^{1}	1×10^{3}	1×10^{7}
Pu-238	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{4}
Pu-239	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{4}
Pu-240	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{3}
Pu-241 (a)	4×10^{1}	6×10^{-2}	1×10^{2}	1×10^{5}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Pu-242	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{4}
Pu-244 (a)	4×10^{-1}	1×10^{-3}	1×10^{0}	1×10^{4}
Radium (88)				
Ra-223 (a)	4×10^{-1}	7×10^{-3}	1×10^{2} (b)	1×10^{5} (b)
Ra-224 (a)	4×10^{-1}	2×10^{-2}	1×10^{1} (b)	1×10^{5} (b)
Ra-225 (a)	2×10^{-1}	4×10^{-3}	1×10^{2}	1×10^{5}
Ra-226 (a)	2×10^{-1}	3×10^{-3}	1×10^{1} (b)	1×10^{4} (b)
Ra-228 (a)	6×10^{-1}	2×10^{-2}	1×10^{1} (b)	1×10^{5} (b)
Rubidium (37)				
Rb-81	2×10^{0}	8×10^{-1}	1×10^{1}	1×10^{6}
Rb-83 (a)	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Rb-84	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Rb-86	5×10^{-1}	5×10^{-1}	1×10^{2}	1×10^{5}
Rb-87	Unlimited	Unlimited	1×10^{4}	1×10^{7}
Rb (nat)	Unlimited	Unlimited	1×10^{4}	1×10^{7}
Rhenium (75)				
Re-184	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Re-184m	3×10^{0}	1×10^{0}	1×10^{2}	1×10^{6}
Re-186	2×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Re-187	Unlimited	Unlimited	1×10^{6}	1×10^{9}
Re-188	4×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{5}
Re-189 (a)	3×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Re (nat)	Unlimited	Unlimited	1×10^{6}	1×10^{9}
Rhodium (45)				
Rh-99	2×10^{0}	2×10^{0}	1×10^{1}	1×10^{6}
Rh-101	4×10^{0}	3×10^{0}	1×10^{2}	1×10^{7}
Rh-102	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Rh-102m	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Rh-103m	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{8}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Rh-105	1×10^{1}	8×10^{-1}	1×10^{2}	1×10^{7}
Radon (86)				
Rn-222 (a)	3×10^{-1}	4×10^{-3}	1×10^{1} (b)	1×10^{8} (b)
Ruthenium (44)				
Ru-97	5×10^{0}	5×10^{0}	1×10^{2}	1×10^{7}
Ru-103 (a)	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Ru-105	1×10^{0}	6×10^{-1}	1×10^{1}	1×10^{6}
Ru-106 (a)	2×10^{-1}	2×10^{-1}	1×10^{2} (b)	1×10^{5} (b)
Sulphur (16)				
S-35	4×10^{1}	3×10^{0}	1×10^{5}	1×10^{8}
Antimony (51)				
Sb-122	4×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{4}
Sb-124	6×10^{-1}	6×10^{-1}	1×10^{1}	1×10^{6}
Sb-125	2×10^{0}	1×10^{0}	1×10^{2}	1×10^{6}
Sb-126	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Scandium (21)				
Sc-44	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{5}
Sc-46	5×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Sc-47	1×10^{1}	7×10^{-1}	1×10^{2}	1×10^{6}
Sc-48	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Selenium (34)				
Se-75	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Se-79	4×10^{1}	2×10^{0}	1×10^{4}	1×10^{7}
Silicon (14)				
Si-31	6×10^{-1}	6×10^{-1}	1×10^{3}	1×10^{6}
Si-32	4×10^{1}	5×10^{-1}	1×10^{3}	1×10^{6}
Samarium (62)				
Sm-145	1×10^{1}	1×10^{1}	1×10^{2}	1×10^{7}
Sm-147	Unlimited	Unlimited	1×10^{1}	1×10^{4}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Sm-151	4×10^{1}	1×10^{1}	1×10^{4}	1×10^{8}
Sm-153	9×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Tin (50)				
Sn-113 (a)	4×10^{0}	2×10^{0}	1×10^{3}	1×10^{7}
Sn-117m	7×10^{0}	4×10^{-1}	1×10^{2}	1×10^{6}
Sn-119m	4×10^{1}	3×10^{1}	1×10^{3}	1×10^{7}
Sn-121m (a)	4×10^{1}	9×10^{-1}	1×10^{3}	1×10^{7}
Sn-123	8×10^{-1}	6×10^{-1}	1×10^{3}	1×10^{6}
Sn-125	4×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{5}
Sn-126 (a)	6×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Strontium (38)				
Sr-82 (a)	2×10^{-1}	2×10^{-1}	1×10^{1}	1×10^{5}
Sr-85	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Sr-85m	5×10^{0}	5×10^{0}	1×10^{2}	1×10^{7}
Sr-87m	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Sr-89	6×10^{-1}	6×10^{-1}	1×10^{3}	1×10^{6}
Sr-90 (a)	3×10^{-1}	3×10^{-1}	1×10^{2} (b)	1×10^{4} (b)
Sr-91 (a)	3×10^{-1}	3×10^{-1}	1×10^{1}	1×10^{5}
Sr-92 (a)	1×10^{0}	3×10^{-1}	1×10^{1}	1×10^{6}
Tritium (1)				
T(H-3)	4×10^{1}	4×10^{1}	1×10^{6}	1×10^{9}
Tantalum (73)				
Ta-178 (long lived)	1×10^{0}	8×10^{-1}	1×10^{1}	1×10^{6}
Ta-179	3×10^{1}	3×10^{1}	1×10^{3}	1×10^{7}
Ta-182	9×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{4}
Terbium (65)				
Tb-157	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{7}
Tb-158	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Tb-160	1×10^{0}	6×10^{-1}	1×10^{1}	1×10^{6}

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Technetium (43)				
Tc-95m (a)	2×10^{0}	2×10^{0}	1×10^{1}	1×10^{6}
Tc-96	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{6}
Tc-96m (a)	4×10^{-1}	4×10^{-1}	1×10^{3}	1×10^{7}
Tc-97	Unlimited	Unlimited	1×10^{3}	1×10^{8}
Tc-97m	4×10^{1}	1×10^{0}	1×10^{3}	1×10^{7}
Tc-98	8×10^{-1}	7×10^{-1}	1×10^{1}	1×10^{6}
Tc-99	4×10^{1}	9×10^{-1}	1×10^{4}	1×10^{7}
Tc-99m	1×10^{1}	4×10^{0}	1×10^{2}	1×10^{7}
Tellurium (52)				
Te-121	2×10^{0}	2×10^{0}	1×10^{1}	1×10^{6}
Te-121m	5×10^{0}	3×10^{0}	1×10^{2}	1×10^{5}
Te-123m	8×10^{0}	1×10^{0}	1×10^{2}	1×10^{7}
Te-125m	2×10^{1}	9×10^{-1}	1×10^{3}	1×10^{7}
Te-127	2×10^{1}	7×10^{-1}	1×10^{3}	1×10^{6}
Te-127m (a)	2×10^{1}	5×10^{-1}	1×10^{3}	1×10^{7}
Te-129	7×10^{-1}	6×10^{-1}	1×10^{2}	1×10^{6}
Te-129m (a)	8×10^{-1}	4×10^{-1}	1×10^{3}	1×10^{6}
Te-131m (a)	7×10^{-1}	5×10^{-1}	1×10^{1}	1×10^{6}
Te-132 (a)	5×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{7}
Thorium (90)				
Th-227	1×10^{1}	5×10^{-3}	1×10^{1}	1×10^{4}
Th-228 (a)	5×10^{-1}	1×10^{-3}	1×10^{0} (b)	1×10^{4} (b)
Th-229	5×10^{0}	5×10^{-4}	1×10^{0} (b)	1×10^{3} (b)
Th-230	1×10^{1}	1×10^{-3}	1×10^{0}	1×10^{4}
Th-231	4×10^{1}	2×10^{-2}	1×10^{3}	1×10^{7}
Th-232	Unlimited	Unlimited	1×10^{1}	1×10^{4}
Th-234 (a)	3×10^{-1}	3×10^{-1}	1×10^{3} (b)	1×10^{5} (b)
Th (nat)	Unlimited	Unlimited	1×10^{0} (b)	1×10^{3} (b)

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TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Titanium (22)				
Ti-44 (a)	5×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
Thallium (81)				
Tl-200	9×10^{-1}	9×10^{-1}	1×10^{1}	1×10^{6}
Tl-201	1×10^{1}	4×10^{0}	1×10^{2}	1×10^{6}
Tl-202	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Tl-204	1×10^{1}	7×10^{-1}	1×10^{4}	1×10^{4}
Thulium (69)				
Tm-167	7×10^{0}	8×10^{-1}	1×10^{2}	1×10^{6}
Tm-170	3×10^{0}	6×10^{-1}	1×10^{3}	1×10^{6}
Tm-171	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{8}
Uranium (92)				
U-230 (fast lung absorption) (a)(d)	4×10^{1}	1×10^{-1}	1×10^{1} (b)	1×10^{5} (b)
U-230 (medium lung absorption)(a)(e)	4×10^{1}	4×10^{-3}	1×10^{1}	1×10^{4}
U-230 (slow lung absorption) (a)(f)	3×10^{1}	3×10^{-3}	1×10^{1}	1×10^{4}
U-232 (fast lung absorption)(d)	4×10^{1}	1×10^{-2}	1×10^{0} (b)	1×10^{3} (b)
U-232 (medium lung absorption)(e)	4×10^{1}	7×10^{-3}	1×10^{1}	1×10^{4}
U-232 (slow lung absorption)(f)	1×10^{1}	1×10^{-3}	1×10^{1}	1×10^{4}
U-233 (fast lung absorption)(d)	4×10^{1}	9×10^{-2}	1×10^{1}	1×10^{4}
U-233 (medium lung absorption)(e)	4×10^{1}	2×10^{-2}	1×10^{2}	1×10^{5}
U-233 (slow lung absorption)(f)	4×10^{1}	6×10^{-3}	1×10^{1}	1×10^{5}
U-234 (fast lung absorption)(d)	4×10^{1}	9×10^{-2}	1×10^{1}	1×10^{4}
U-234 (medium lung absorption)(e)	4×10^{1}	2×10^{-2}	1×10^{2}	1×10^{5}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
U-234 (slow lung absorption)(f)	4×10^{1}	6×10^{-3}	1×10^{1}	1×10^{5}
U-235 (all lung absorption types)(a),(d),(e),(f)	Unlimited	Unlimited	1×10^{1} (b)	1×10^{4} (b)
U-236 (fast lung absorption)(d)	Unlimited	Unlimited	1×10^{1}	1×10^{4}
U-236 (medium lung absorption)(e)	4×10^{1}	2×10^{-2}	1×10^{2}	1×10^{5}
U-236 (slow lung absorption)(f)	4×10^{1}	6×10^{-3}	1×10^{1}	1×10^{4}
U-238 (all lung absorption types)(d),(e),(f)	Unlimited	Unlimited	1×10^{1} (b)	1×10^{4} (b)
U (nat)	Unlimited	Unlimited	1×10^{0} (b)	1×10^{3} (b)
U (enriched to 20% or less)(g)	Unlimited	Unlimited	1×10^{0}	1×10^{3}
U (dep)	Unlimited	Unlimited	1×10^{0}	1×10^{3}
Vanadium (23)				
V-48	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{5}
V-49	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{7}
Tungsten (74)				
W-178 (a)	9×10^{0}	5×10^{0}	1×10^{1}	1×10^{6}
W-181	3×10^{1}	3×10^{1}	1×10^{3}	1×10^{7}
W-185	4×10^{1}	8×10^{-1}	1×10^{4}	1×10^{7}
W-187	2×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
W-188 (a)	4×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{5}
Xenon (54)				
Xe-122 (a)	4×10^{-1}	4×10^{-1}	1×10^{2}	1×10^{9}
Xe-123	2×10^{0}	7×10^{-1}	1×10^{2}	1×10^{9}
Xe-127	4×10^{0}	2×10^{0}	1×10^{3}	1×10^{5}
Xe-131m	4×10^{1}	4×10^{1}	1×10^{4}	1×10^{4}

For footnotes see pages 127 and 128

TABLE I. (cont.)

Radionuclide (atomic number)	A_1	A_2	Activity concentration for exempt material	Activity limit for an exempt consignment
	(TBq)	(TBq)	(Bq/g)	(Bq)
Xe-133	2×10^{1}	1×10^{1}	1×10^{3}	1×10^{4}
Xe-135	3×10^{0}	2×10^{0}	1×10^{3}	1×10^{10}
Yttrium (39)				
Y-87 (a)	1×10^{0}	1×10^{0}	1×10^{1}	1×10^{6}
Y-88	4×10^{-1}	4×10^{-1}	1×10^{1}	1×10^{6}
Y-90	3×10^{-1}	3×10^{-1}	1×10^{3}	1×10^{5}
Y-91	6×10^{-1}	6×10^{-1}	1×10^{3}	1×10^{6}
Y-91m	2×10^{0}	2×10^{0}	1×10^{2}	1×10^{6}
Y-92	2×10^{-1}	2×10^{-1}	1×10^{2}	1×10^{5}
Y-93	3×10^{-1}	3×10^{-1}	1×10^{2}	1×10^{5}
Ytterbium (79)				
Yb-169	4×10^{0}	1×10^{0}	1×10^{2}	1×10^{7}
Yb-175	3×10^{1}	9×10^{-1}	1×10^{3}	1×10^{7}
Zinc (30)				
Zn-65	2×10^{0}	2×10^{0}	1×10^{1}	1×10^{6}
Zn-69	3×10^{0}	6×10^{-1}	1×10^{4}	1×10^{6}
Zn-69m (a)	3×10^{0}	6×10^{-1}	1×10^{2}	1×10^{6}
Zirconium (40)				
Zr-88	3×10^{0}	3×10^{0}	1×10^{2}	1×10^{6}
Zr-93	Unlimited	Unlimited	1×10^{3} (b)	1×10^{7} (b)
Zr-95 (a)	2×10^{0}	8×10^{-1}	1×10^{1}	1×10^{6}
Zr-97 (a)	4×10^{-1}	4×10^{-1}	1×10^{1} (b)	1×10^{5} (b)

(a) A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.

(b) Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106

Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

(c) The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

(d) These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

(e) These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

(f) These values apply to all compounds of uranium other than those specified in (d) and (e) above.

(g) These values apply to *unirradiated uranium* only.

TABLE II. BASIC RADIONUCLIDE VALUES FOR UNKNOWN RADIONUCLIDES OR MIXTURES

Radioactive contents	A_1	A_2	Activity concentration for exempt material	Activity limits for exempt consignments
	(TBq)	(TBq)	(Bq/g)	(Bq)
Only beta or gamma emitting nuclides are known to be present	0.1	0.02	1×10^{1}	1×10^{4}
Only alpha emitting nuclides are known to be present	0.2	9×10^{-5}	1×10^{-1}	1×10^{3}
No relevant data are available	0.001	9×10^{-5}	1×10^{-1}	1×10^{3}

TABLE III. ACTIVITY LIMITS FOR EXCEPTED PACKAGES

Physical state of contents	Instrument or article		Materials
	Item limits[a]	*Package* limits[a]	*Package* limits[a]
Solids:			
special form	$10^{-2} A_1$	A_1	$10^{-3} A_1$
other forms	$10^{-2} A_2$	A_2	$10^{-3} A_2$
Liquids	$10^{-3} A_2$	$10^{-1} A_2$	$10^{-4} A_2$
Gases			
tritium	$2 \times 10^{-2} A_2$	$2 \times 10^{-1} A_2$	$2 \times 10^{-2} A_2$
special form	$10^{-3} A_1$	$10^{-2} A_1$	$10^{-3} A_1$
other forms	$10^{-3} A_2$	$10^{-2} A_2$	$10^{-3} A_2$

[a] For mixtures of radionuclides, see paras 404–406.

TABLE IV. INDUSTRIAL PACKAGE REQUIREMENTS FOR LSA MATERIAL AND SCO

Radioactive contents	*Industrial package type*	
	Exclusive use	Not under *exclusive use*
LSA-I		
Solid[a]	*Type IP-1*	*Type IP-1*
Liquid	*Type IP-1*	*Type IP-2*
LSA-II		
Solid	*Type IP-2*	*Type IP-2*
Liquid and gas	*Type IP-2*	*Type IP-3*
LSA-III	*Type IP-2*	*Type IP-3*
SCO-I[a]	*Type IP-1*	*Type IP-1*
SCO-II	*Type IP-2*	*Type IP-2*

[a] Under the conditions specified in para. 523, *LSA-I material* and *SCO-I* may be transported unpackaged.

TABLE V. CONVEYANCE ACTIVITY LIMITS FOR LSA MATERIAL AND SCO IN INDUSTRIAL PACKAGES OR UNPACKAGED

Nature of material	Activity limit for *conveyances* other than by inland waterway	Activity limit for a hold or compartment of an inland water craft
LSA-I	No limit	No limit
LSA-II and *LSA-III* non-combustible solids	No limit	100 A_2
LSA-II and *LSA-III* combustible solids, and all liquids and gases	100 A_2	10 A_2
SCO	100 A_2	10 A_2

TABLE VI. MULTIPLICATION FACTORS FOR LARGE DIMENSION LOADS

Size of load[a]	Multiplication factor
size of load ≤ 1 m^2	1
1 m^2 < size of load ≤ 5 m^2	2
5 m^2 < size of load ≤20 m^2	3
20 m^2 < size of load	10

[a] Largest cross-sectional area of the load being measured.

TABLE VII. CATEGORIES OF PACKAGES AND OVERPACKS

Conditions		Category
Transport index	Maximum *radiation level* at any point on external surface	
0[a]	Not more than 0.005 mSv/h	I-WHITE
More that 0 but not more than 1[a]	More than 0.005 mSv/h but not more than 0.5 mSv/h	II-YELLOW
More that 1 but not more than 10	More than 0.5 mSv/h but not more than 2 mSv/h	III-YELLOW
More than 10	More than 2 mSv/h but not more than 10 mSv/h	III-YELLOW[b]

[a] If the measured *TI* is not greater than 0.05, the value quoted may be zero in accordance with para. 526(c).

[b] Shall also be transported under *exclusive use*.

TABLE VIII. EXCERPTS FROM LIST OF UNITED NATIONS NUMBERS, PROPER SHIPPING NAMES AND DESCRIPTIONS, SUBSIDIARY RISKS AND THEIR RELATIONSHIP TO THE SCHEDULES

Schedule	UN No.	PROPER SHIPPING NAME [a] and description	Subsidiary risks
1	2910	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — LIMITED QUANTITY OF MATERIAL	
2	2911	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — INSTRUMENTS or ARTICLES	
3	2909	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — ARTICLES MANUFACTURED FROM NATURAL URANIUM or DEPLETED URANIUM or NATURAL THORIUM	
4	2908	RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — EMPTY PACKAGING	
5	2912	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-I) non fissile or fissile-excepted [b]	
6	3321	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II) non fissile or fissile-excepted [b]	
7	3322	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-III) non fissile or fissile-excepted [b]	
8	2913	RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II) non fissile or fissile-excepted [b]	
9	2915	RADIOACTIVE MATERIAL, TYPE A PACKAGE, non-special form, non fissile or fissile-excepted [b]	
9	3332	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM non fissile or fissile-excepted [b]	
10	2916	RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, non fissile or fissile-excepted [b]	
11	2917	RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, non fissile or fissile-excepted [b]	
12	3323	RADIOACTIVE MATERIAL, TYPE C PACKAGE, non fissile or fissile-excepted [b]	
14	2919	RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, non fissile or fissile-excepted [b]	

For footnotes see page 132.

TABLE VIII. (cont.)

Schedule	UN No.	PROPER SHIPPING NAME [a] and description	Subsidiary risks
[c]	2978	RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE non fissile or fissile-excepted [b]	corrosive (UN Class 8)
6+13	3324	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II), FISSILE	
7+13	3325	RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-III), FISSILE	
8+13	3326	RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II), FISSILE	
9+13	3327	RADIOACTIVE MATERIAL, TYPE A PACKAGE, FISSILE non-special form	
9+13	3333	RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, FISSILE	
10+13	3328	RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, FISSILE	
11+13	3329	RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, FISSILE	
12+13	3330	RADIOACTIVE MATERIAL, TYPE C PACKAGE, FISSILE	
14+13	3331	RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, FISSILE	
[c]+13	2977	RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE, FISSILE	corrosive (UN Class 8)

[a] The "PROPER SHIPPING NAME" is found in the column "PROPER SHIPPING NAME and description" and is restricted to that part shown in CAPITAL LETTERS. In the case of UN 2909 and UN 2911 where alternative PROPER SHIPPING NAMES are separated by the word "or", only the relevant PROPER SHIPPING NAME shall be used.

[b] "Fissile-excepted" applies only to those packages complying with para. 672.

[c] UN 2977 and UN 2978 are special cases without a unique relationship with the Schedules.

TABLE IX. TI LIMITS FOR FREIGHT CONTAINERS AND CONVEYANCES NOT UNDER EXCLUSIVE USE

Type of *freight container* or *conveyance*	Limit on total sum of *transport indexes* in a *freight container* or aboard a *conveyance*
Freight container — Small	50
Freight container — Large	50
Vehicle	50
Aircraft	
Passenger	50
Cargo	200
Inland water-way *vessel*	50
Seagoing *vessel*[a]	
(1) Hold, compartment or *defined deck area*:	
Packages, overpacks, small *freight containers*	50
Large *freight containers*	200
(2) Total *vessel*:	
Packages, overpacks, small *freight containers*	200
Large *freight containers*	No limit

[a] *Packages* or *overpacks* carried in or on a *vehicle* which are in accordance with the provisions of para. 572 may be transported by *vessels* provided that they are not removed from the *vehicle* at any time while on board the *vessel.*

Annex 8

FIGURES FOR TRANSPORT REQUIREMENTS

(This annex reproduces Figures 1–7 of the IAEA Safety Standards Series No. ST-1 [19])

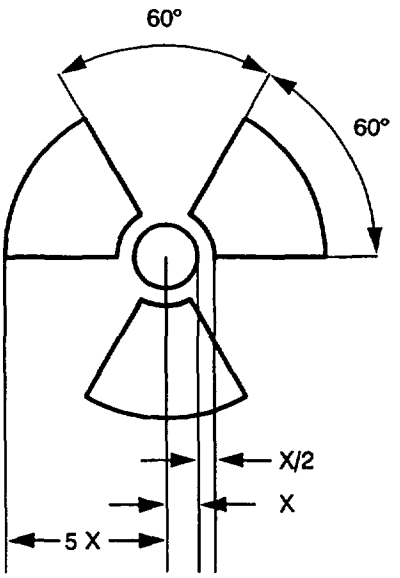

FIG. 1. Basic trefoil symbol with proportions based on a central circle of radius X. The minimum allowable size of X shall be 4 mm.

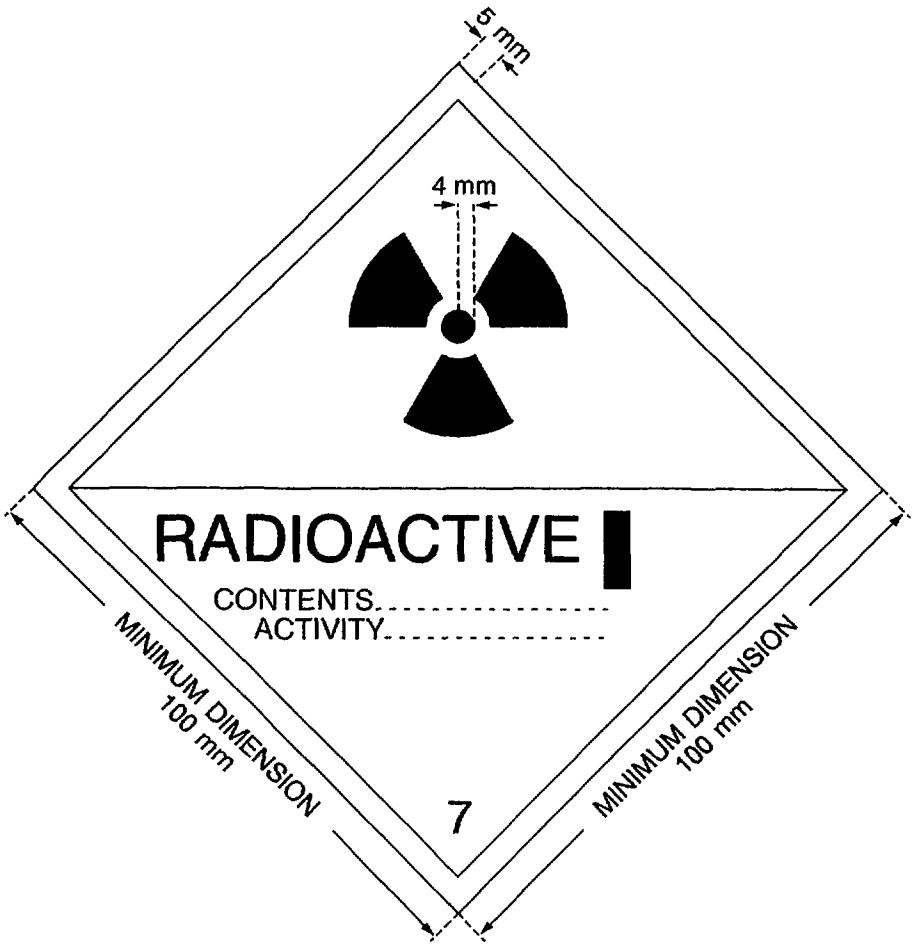

FIG. 2. Category I-WHITE label. The background colour of the label shall be white, the colour of the trefoil and the printing shall be black, and the colour of the category bar shall be red.

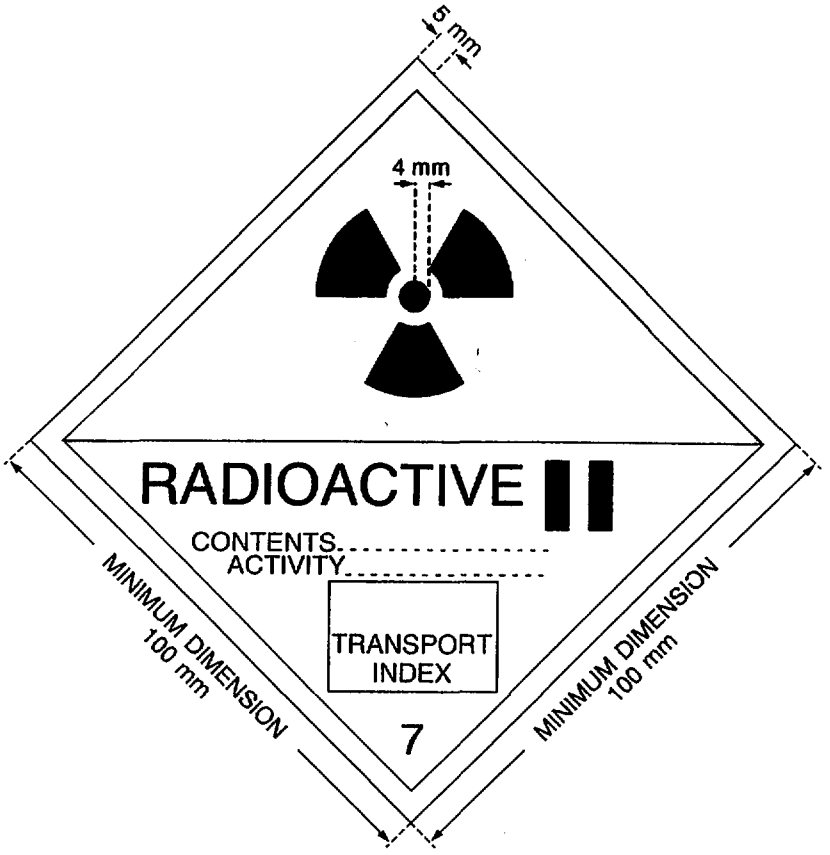

FIG. 3. Category II-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

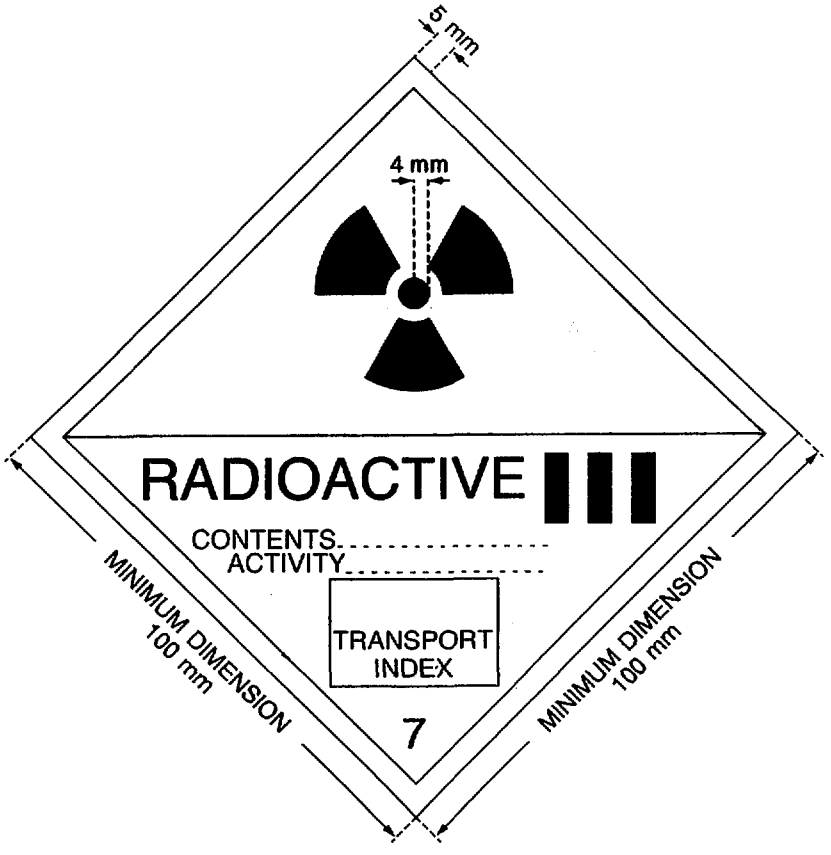

FIG. 4. Category III-YELLOW label. The background colour of the upper half of the label shall be yellow and the lower half white, the colour of the trefoil and the printing shall be black, and the colour of the category bars shall be red.

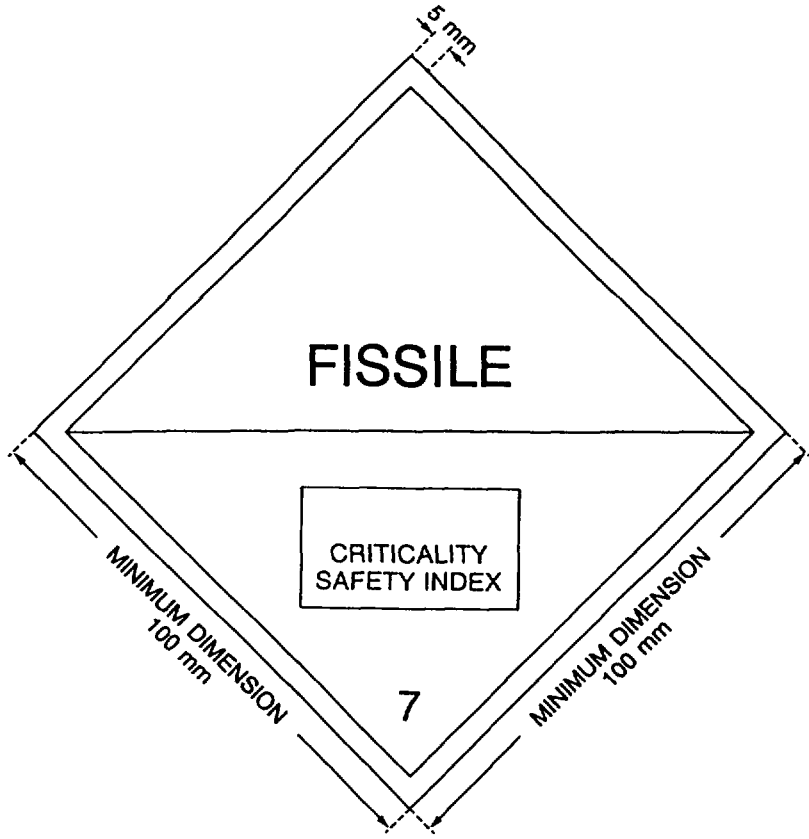

FIG. 5. Criticality safety index label. The background colour of the label shall be white, the colour of the printing shall be black.

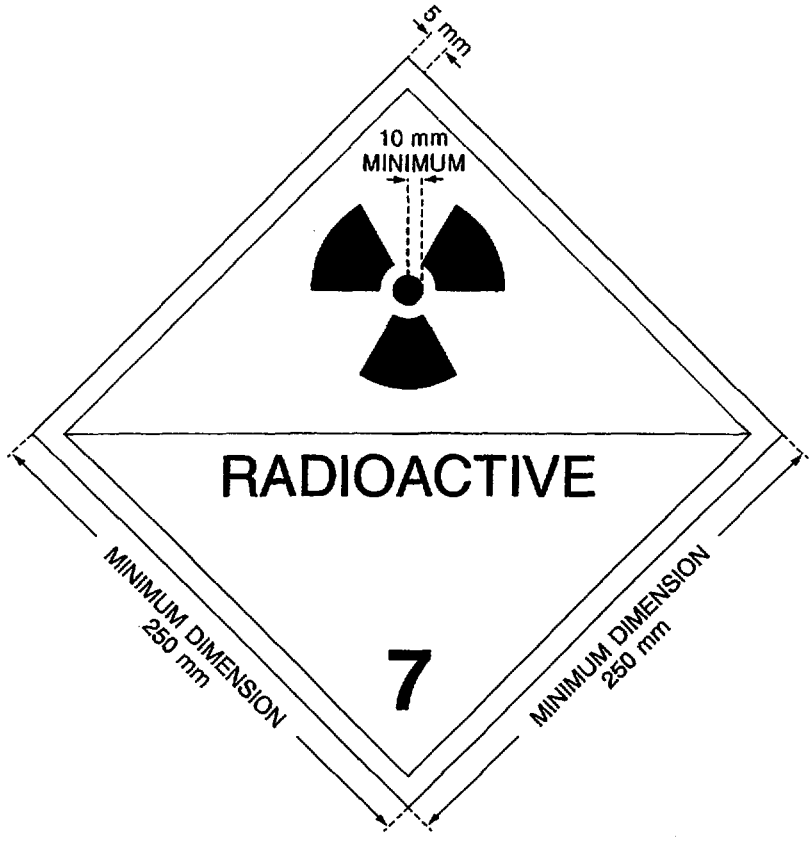

FIG. 6. Placard. Except as permitted by para. 570 minimum dimensions shall be as shown; when different dimensions are used the relative proportions must be maintained. The number '7' shall not be less than 25 mm high. The background colour of the upper half of the placard shall be yellow and of the lower half white, the colour of the trefoil and the printing shall be black. The use of the word "RADIOACTIVE" in the bottom half is optional to allow the alternative use of this placard to display the appropriate United Nations number for the consignment.

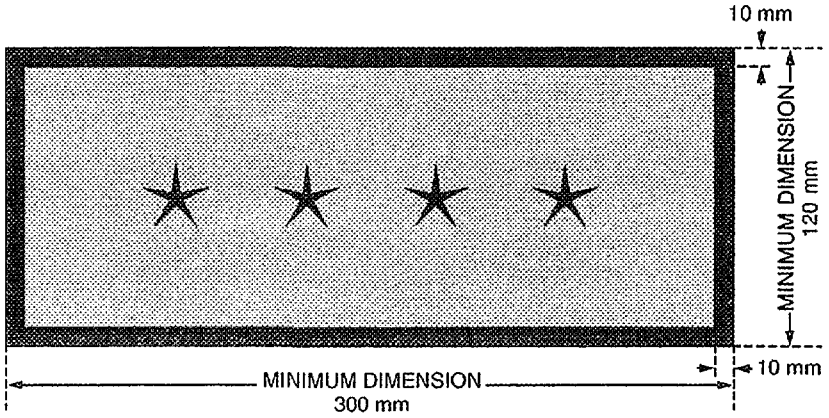

*FIG. 7. Placard for separate display of United Nations number. The background colour of the placard shall be orange and the border and United Nations number shall be black. The symbol "****" denotes the space in which the appropriate United Nations number for radioactive material, as specified in Table VIII, shall be displayed.*

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GLOSSARY

accident

Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

authorization

A permission granted in a document by the Regulatory Authority to a legal person who has submitted an application to carry out a practice or any other action described in these Regulations. The authorization can take the form of a registration or a licence.

conditioning

Those operations that produce a waste package suitable for handling, transportation, storage and/or disposal. Conditioning may include the conversion of the waste to a solid waste form, enclosure of the waste in containers and, if necessary, providing an overpack.

consumer product

Device such as smoke detector, luminous dial or ion generating tube that contains a small amount of radioactive substances.

controlled area

A controlled area is any area in which specific protection measures and safety provisions are or could be required for:

(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
(b) preventing or limiting the extent of potential exposures.

critical group

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

defence in depth

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

disposal

The emplacement of waste in an approved, specified facility (for example, near surface or geological repository) without the intervention of retrieval. Disposal may also include the

approved direct discharge of airborne or liquid effluents into the environment with subsequent dispersion.

dose limit

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

employer

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

effective dose

The quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_{T} W_T H_T$$

where H_T is the equivalent dose in tissue T and W_T is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that:

$$E = \sum_{T} W_T \cdot \sum_{R} W_R \cdot D_{T,R}$$

where W_R is the radiation weighting factor for radiation R and $D_{T,R}$ the average absorbed dose in the organ or tissue T. The unit of effective dose is $J.kg^{-1}$, termed the sievert (Sv).

equivalent dose

The quantity $H_{T,R}$, defined as:

$$H_{T,R} = D_{T,R} \cdot W_R$$

where $D_{T,R}$ is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and w_R is the radiation weighting factor for radiation type R.

When the radiation field is composed of different radiation types with different values of w_R, the equivalent dose is:

$$H_T = \sum_{R} W_R \cdot D_{T,R}$$

The unit of equivalent dose is $J.kg^{-1}$, termed the sievert (Sv).

generic safety assessment

A safety assessment or a portion of a safety assessment which is applicable to multiple users within a practice and does not need to be repeated with each request for an authorization.

guidance level

A level of a specified quantity above which appropriate actions should be considered. In some circumstances, actions may need to be considered when the specified quantity is substantially below the guidance level.

health professional

An individual who has been accredited through appropriate national procedures to practice a profession related to health (e.g. medicine, dentistry, chiropractic, paediatry, nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).

health surveillance

Medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

intervening organization

An organization designated or otherwise recognized by a Government as being responsible for managing or implementing any aspect of an intervention.

intervention

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

legal person

Any organization, corporation, partnerships, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for actions taken under these Regulations.

licence

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

licensee

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

limit

The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

medical exposure

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

medical practitioner

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

member of the public

In a general sense, any individual in the population except, for the purposes of these Regulations, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

monitoring

The measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

normal exposure

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

notification

A document submitted to the Regulatory Authority by a legal person to notify an intention to carry out a practice or any other action described in the General Obligations for practices of the Standards (see paras 2.7 and 2.8 in the IAEA Safety Series No. 115).

occupational exposure

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

performance regulation

A regulation which states in broad terms a generally applicable requirement or objective, and basic operational parameters.

potential exposure

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

practice

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

prescriptive regulation

A regulation which states specifically how a particular protection or safety requirement or objective is to be achieved. Prescriptive regulations are often narrowly applicable to a particular practice or situation.

protective action

An intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations

public exposure

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

qualified expert

An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality assurance or any relevant engineering or safety specialty.

quality assurance

All those planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example, those specified in the licence.

radiation protection officer

An individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee the application of the requirements of these Regulations.

radioactive discharges

Radioactive substances arising from a source within a practice which are discharged as gases, aerosols, liquids or solids to the environment, generally with the purpose of dilution and dispersion.

radioactive waste

Material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen, (i) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for exemption or clearance from regulatory requirements, and (ii) exposure to which is not excluded from these Regulations.

reference level

Action level, intervention level, investigation level or recording level. Such levels may be established for any of the quantities determined in the practice of radiation protection.

registrant

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

registration

A form of authorization for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the Regulatory Authority. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing.

regulatory authority

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

safety assessment

A review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

safety culture

The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

sealed source

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

source

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

storage

The placement of radioactive waste in a suitable facility where isolation, environmental protection and human control (for example, monitoring) are provided with the intent that the waste will be retrieved for clearance or treatment and conditioning, and/or disposal at a later time.

supervised area

Any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed.

supplier

Any legal person to whom a licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source).

treatment

Operations intended to benefit safety and/or economy by changing the characteristics of the waste. Three basic treatment objectives are:

(a) volume reduction
(b) removal of radionuclides from the waste
(c) change of composition.

After treatment, the waste may or may not be immobilized to achieve an appropriate waste form.

unsealed source

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

waste form

The waste in its physical and chemical form after treatment and/or conditioning (resulting in a solid product) prior to packaging. The waste form is a component of the waste package.

waste inventory

A detailed, itemized record maintained by the operator or Regulatory Authority in accordance with these regulations, which may contain data such as physical quantity, the activity of the waste, the radionuclide content, and other characteristics.

waste management, radioactive

All activities, administrative and operational, including decommissioning activities, that are involved in the handling, pre-treatment, conditioning, storage and disposal of waste from a facility.

waste package

The product of conditioning that includes the waste form and any container(s) and internal barriers (e.g. absorbing materials and liner), as prepared in accordance with requirements for handling, transportation, storage and/or disposal.

worker

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

Note: If the Regulatory Authority wants a more complete or extensive glossary, the definitions in the BSS should be used to the extent practicable.

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