IAEA Safety Standards

for protecting people and the environment

Justification of Practices, Including Non-Medical Human Imaging

General Safety Guide

No. GSG-5

IAEA
International Atomic Energy Agency

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

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

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

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

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

RELATED PUBLICATIONS

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

Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

Other safety related IAEA publications are issued as **Emergency Preparedness and Response** publications, **Radiological Assessment Reports**, the International Nuclear Safety Group's **INSAG Reports**, **Technical Reports** and **TECDOCs**. The IAEA also issues reports on radiological accidents, training manuals and practical manuals, and other special safety related publications.

Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

JUSTIFICATION OF PRACTICES, INCLUDING NON-MEDICAL HUMAN IMAGING

The following States are Members of the International Atomic Energy Agency:

AFGHANISTAN
ALBANIA
ALGERIA
ANGOLA
ARGENTINA
ARMENIA
AUSTRALIA
AUSTRIA
AZERBAIJAN
BAHAMAS
BAHRAIN
BANGLADESH
BELARUS
BELGIUM
BELIZE
BENIN
BOLIVIA
BOSNIA AND HERZEGOVINA
BOTSWANA
BRAZIL
BRUNEI DARUSSALAM
BULGARIA
BURKINA FASO
BURUNDI
CAMBODIA
CAMEROON
CANADA
CENTRAL AFRICAN REPUBLIC
CHAD
CHILE
CHINA
COLOMBIA
CONGO
COSTA RICA
CÔTE D'IVOIRE
CROATIA
CUBA
CYPRUS
CZECH REPUBLIC
DEMOCRATIC REPUBLIC OF THE CONGO
DENMARK
DOMINICA
DOMINICAN REPUBLIC
ECUADOR
EGYPT
EL SALVADOR
ERITREA
ESTONIA
ETHIOPIA
FIJI
FINLAND
FRANCE
GABON
GEORGIA
GERMANY
GHANA
GREECE
GUATEMALA
HAITI
HOLY SEE
HONDURAS
HUNGARY
ICELAND
INDIA
INDONESIA
IRAN, ISLAMIC REPUBLIC OF
IRAQ
IRELAND
ISRAEL
ITALY
JAMAICA
JAPAN
JORDAN
KAZAKHSTAN
KENYA
KOREA, REPUBLIC OF
KUWAIT
KYRGYZSTAN
LAO PEOPLE'S DEMOCRATIC REPUBLIC
LATVIA
LEBANON
LESOTHO
LIBERIA
LIBYA
LIECHTENSTEIN
LITHUANIA
LUXEMBOURG
MADAGASCAR
MALAWI
MALAYSIA
MALI
MALTA
MARSHALL ISLANDS
MAURITANIA, ISLAMIC REPUBLIC OF
MAURITIUS
MEXICO
MONACO
MONGOLIA
MONTENEGRO
MOROCCO
MOZAMBIQUE
MYANMAR
NAMIBIA
NEPAL
NETHERLANDS
NEW ZEALAND
NICARAGUA
NIGER
NIGERIA
NORWAY
OMAN
PAKISTAN
PALAU
PANAMA
PAPUA NEW GUINEA
PARAGUAY
PERU
PHILIPPINES
POLAND
PORTUGAL
QATAR
REPUBLIC OF MOLDOVA
ROMANIA
RUSSIAN FEDERATION
RWANDA
SAN MARINO
SAUDI ARABIA
SENEGAL
SERBIA
SEYCHELLES
SIERRA LEONE
SINGAPORE
SLOVAKIA
SLOVENIA
SOUTH AFRICA
SPAIN
SRI LANKA
SUDAN
SWAZILAND
SWEDEN
SWITZERLAND
SYRIAN ARAB REPUBLIC
TAJIKISTAN
THAILAND
THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA
TOGO
TRINIDAD AND TOBAGO
TUNISIA
TURKEY
UGANDA
UKRAINE
UNITED ARAB EMIRATES
UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
UNITED REPUBLIC OF TANZANIA
UNITED STATES OF AMERICA
URUGUAY
UZBEKISTAN
VENEZUELA, BOLIVARIAN REPUBLIC OF
VIET NAM
YEMEN
ZAMBIA
ZIMBABWE

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

IAEA SAFETY STANDARDS SERIES No. GSG-5

JUSTIFICATION OF PRACTICES, INCLUDING NON-MEDICAL HUMAN IMAGING

GENERAL SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2014

COPYRIGHT NOTICE

Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
October 2014
STI/PUB/1650

IAEA Library Cataloguing in Publication Data

Justification of practices, including non-medical human imaging. — Vienna : International Atomic Energy Agency, 2014.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020–525X ; no. GSG-5)
STI/PUB/1650
ISBN 978–92–0–102414–5
Includes bibliographical references.

1. Ionizing radiation — Standards. 2. Ionizing radiation — Safety measures. 3. Radiation — Safety measures. 4. Imaging systems. I. International Atomic Energy Agency. II. Series.

IAEAL 14–00928

FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to "establish or adopt… standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

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

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered 'overarching' requirements, are expressed as 'shall' statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

---

[1] See also publications issued in the IAEA Nuclear Security Series.

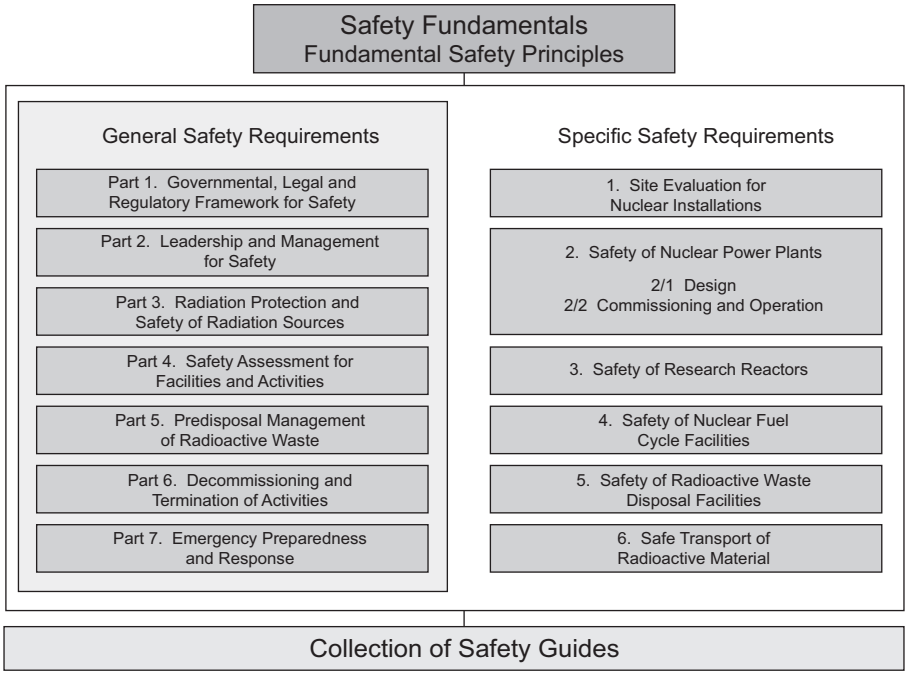

FIG. 1. The long term structure of the IAEA Safety Standards Series.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and

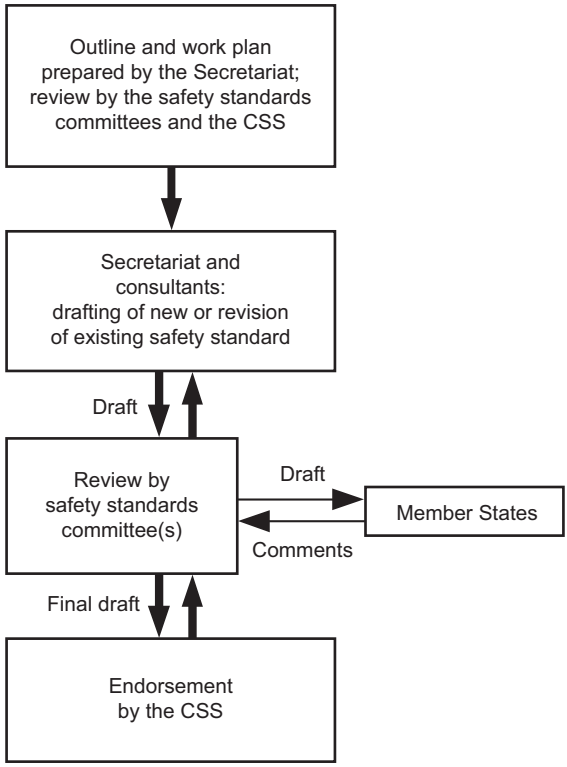

FIG. 2. The process for developing a new safety standard or revising an existing standard.

includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some

safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

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

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

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

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

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The fundamental safety objective established in the Fundamental Safety Principles [1] is to protect people and the environment from harmful effects of ionizing radiation. Ten safety principles are stated and their intent and purpose are briefly explained. The fourth principle states that "Facilities and activities that give rise to radiation risks must yield an overall benefit." The Safety Requirements publication on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3) [2], in elaborating requirements for planned exposure situations in order to apply this principle, states that "The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized."

1.2. A practice is any human activity that introduces additional sources of exposure or additional exposure pathways, 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 [2]. Justification is the process of determining, for a planned exposure situation, whether a practice is beneficial overall, i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice [2].

1.3. When the principle was first formally expressed, many types of practice were already widespread, especially in the medical and industrial fields, and, in general, their justification was implicit. Other types of practice, particularly the generation of electrical energy by nuclear fission, are matters of national policy and their justification involves many aspects other than radiation safety alone. The justification of yet other types of practice was considered in the development of safety standards that specifically address those types of practice. However, from time to time, the question has been raised as to whether there is a need for generic guidance on the application of the justification principle in the authorization of practices, particularly those that may cause radiation exposure of members of the public.

1.4. In recent years, practices involving the exposure of persons — both workers and members of the public — for non-medical purposes, such as security screening and detection of drugs being trafficked, have been proposed

or introduced [3, 4]. Provisions relating to these types of exposure — referred to as human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research — are stated in GSR Part 3 [2], but decisions on their justification are left to the national government or regulatory body. A survey showed that human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is being performed for many different purposes in many States [5]. It also showed there was a lack of formal justification of some uses of radiation for these purposes.

1.5. Although international consensus on the acceptability of all types of practice is unlikely to be achievable, the present Safety Guide has been prepared to provide guidance on the process that governments or regulatory bodies should use in determining whether a proposed new or an existing type of practice is justified. It is particularly relevant to the application of the principle of justification to the approval of practices involving the exposure of persons for non-medical purposes. However, the approach may also be relevant to a broader range of practices. The intention is that, by applying the approach given in the Safety Guide, the government or regulatory body will be better able to reach consistent and transparent decisions on the justification of particular types of practice.

1.6. The principle of justification also applies to emergency exposure situations and to existing exposure situations, where protective actions aimed at reducing exposure need to be justified in that they must do more good than harm. The tenth principle in the Fundamental Safety Principles states that "Protective actions to reduce existing or unregulated radiation risks must be justified and optimized." [1]

OBJECTIVE

1.7. The objective of this Safety Guide is to provide guidance to governments and regulatory bodies on the approach that should be adopted in considering whether the introduction of a particular type of practice in a planned exposure situation is justified. It is intended to assist them in their decision making process when they are confronted with a need or a request to authorize a novel type of practice or with a need to review an already established type of practice. This Safety Guide also provides some guidance to those wishing to demonstrate to the government or regulatory body that a particular type of practice is justified. It complements the guidance provided in the IAEA Safety Guide on the Regulatory Control of Radiation Sources [6].

SCOPE

1.8. This Safety Guide covers the elements that should be considered and the process that should be applied in determining whether the introduction of a particular type of practice is justified. It was developed to assist governments and regulatory bodies with particularly challenging proposals for the use of radiation, primarily human imaging for purposes other than medical diagnosis, medical treatment or biomedical research, such as security screening at airports. It may also be used in the review of the justification of different types of practice that are already established.

STRUCTURE

1.9. Section 2 describes the principle of justification of practices in planned exposure situations as set out in GSR Part 3 [2], lists those types of practice that are deemed not to be justified, and describes the relationship between the justification principle and the principle of optimization of protection and safety. Section 3 provides recommendations on the responsibilities of the relevant parties. Section 4 presents a structured approach for systematically obtaining all the relevant inputs needed to reach a decision on justification and shows how these inputs might be brought together to reach a decision regarding whether a particular proposed type of practice is justified. Section 5 describes issues associated with the application of the justification principle to proposed uses of radiation for human imaging for non-medical purposes, such as security screening at airports. The Annexes give examples of decisions on the justification of particular types of practice that have been taken by various national governments or regulatory bodies; however the Annexes do not form part of this safety standard and no endorsement of these national decisions by the IAEA is implied.

2. THE PRINCIPLE OF JUSTIFICATION OF PRACTICES

GENERAL

2.1. The principle of justification is both simple and logical: practices must produce a positive net benefit to the exposed individuals or to society [1]. This principle is not unique to radiation safety. All decisions concerning the adoption of a particular human activity involve a balancing of costs (including detriments)

and benefits. Often, this balancing is done implicitly. However, GSR Part 3 [2] requires that a positive net benefit be demonstrated before a practice in a planned exposure situation can be authorized by the regulatory body. This can present the regulatory body with some difficulty. While the regulatory body is required to be competent in assessing the radiation detriment associated with a given type of practice [7], it is unlikely to have any special competence in assessing other types of detriment or in determining benefit to individuals or to society. A consequence may be that any judgements made will reflect the personal views of the individual decision maker rather than society as a whole. To avoid this, a mechanism should be set up within the State to ensure that an appropriate level of consultation takes place, commensurate with the radiological and social significance of the type of practice, in order to properly determine whether it can be considered either justified or not justified.

2.2. Requirement 10 on justification of practices established in GSR Part 3 [2] has its origins in the recommendations of the International Commission on Radiological Protection (ICRP), the latest version of which are provided in ICRP Publication 103 [8]. In a discussion on activities involving an increased level of radiation exposure, or of potential exposure, the ICRP notes that "The consequences to be considered are not confined to those associated with the radiation – they include other risks and the costs and benefits of the activity. Sometimes, the radiation detriment will be a small part of the total harm. Justification thus goes far beyond the scope of radiological protection, and also involves the consideration of economic, societal and environmental factors. It is for these reasons that the Commission only recommends that justification requires that the net benefit be positive. To search for the best of all the available alternatives is a task beyond the responsibility of radiological protection authorities" [8].

2.3. The ICRP recommendations [8] go on to state "the responsibility for judging the justification usually falls on governments or national authorities to ensure an overall benefit in the broadest sense to society and thus not necessarily to each individual. However, input to the justification decision may include many aspects that could be informed by users or other organisations or persons outside of government. As such, justification decisions will often be informed by a process of public consultation, depending upon, among other things, the size of the source concerned. There are many aspects of justification, and different organisations may be involved and responsible. In this context, radiological protection considerations will serve as one input to the broader decision process."

2.4. The ICRP recommendations have a number of implications. First, those concerned with radiation protection should be satisfied that a given type of practice has benefits that exceed the radiation risk. Thus, it is not their responsibility to decide whether the benefits outweigh all of the costs.

2.5. Second, alternative methods, not involving the use of radiation, of achieving the same or similar objectives may exist and should be taken into account when reaching a decision on justification. The mere existence of an alternative method should not be used as a reason for deciding that the type of practice involving the use of radiation is not justified. Nevertheless, if such comparisons with 'non-radioactive' alternatives or 'non-radiation-emitting' alternatives are necessary, they should be undertaken with appropriate caution. Alternatives are unlikely to be without detriment and may not achieve entirely the same benefit. The methods should be judged on the basis of their effectiveness in accomplishing the intended objective.

2.6. Finally, interested parties should be consulted as part of the process of determining the justification of a particular type of practice, and the decision on justification should be made with a broad basis of expertise, with account taken of factors other than radiation protection, such as economic and social concerns.

2.7. A further point is made in the Fundamental Safety Principles, which states: "For facilities and activities to be considered justified, the benefits that they yield must outweigh the radiation risks to which they give rise. For the purposes of assessing benefit and risk, all significant consequences of the operation of facilities and the conduct of activities have to be taken into account." (Ref. [1], para. 3.18.) In the very broadest sense, a practice includes everything relating to the use of a source, from its manufacture to its disposal. This means that in any assessment of radiation detriment associated with a type of practice, the exposures received from routine situations, reasonably foreseeable accidents, transport and waste disposal have to be evaluated before a decision on the justification of the practice as a whole can be reached.

2.8. As the justification process needs to consider factors beyond the scope of radiation protection, such as political, economic and societal factors, the process for determining justification and the decision reached for a given practice may be different from one State to another.

JUSTIFICATION AND AUTHORIZATION

2.9. The government or the regulatory body, as the case may be, should specify clearly the types of practice that are considered justified. Once a type of practice has been recognized by the government or the regulatory body as being justified, there is still an obligation for a person or organization to seek an authorization for the specific practice or to seek to be exempted from the need for an authorization.

2.10. The provisions for exemption apply only to justified practices. Thus, demonstration that a particular source within a practice satisfies the provisions for exemption is not sufficient and does not obviate the requirement to demonstrate that the practice is justified.

PROHIBITIONS AND PRACTICES NORMALLY DEEMED TO BE NOT JUSTIFIED

2.11. GSR Part 3 states "The following practices are deemed to be not justified:

(a) Practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;
(b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation;
(c) Human imaging using radiation that is performed as a form of art or for publicity purposes." (Ref. [2], para. 3.17).

2.12. A footnote to the term 'activation' in GSR Part 3 states that "This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as made available." It is therefore not the intention to prohibit practices involving the activation of commodities or products for a short time as part of security screening in ports or airports.

2.13. The use of the phrase 'deliberate addition' should be taken to mean that the trace amounts of naturally occurring radioactive material that are present in

all materials need not be taken into account when the concentrations are below the exemption levels given in table I-1 of schedule 1 of GSR Part 3 [2]. 'Toys' should be taken to mean any product or material designed or clearly intended for use in play by infants or children. Articles of 'personal jewellery or adornment' should be taken to mean articles to be worn on the person where the radioactive substance has no function other than decoration. Thus, the deliberate use of uranium as a colouring material for items such as brooches should be regarded as a practice that is not justified.

2.14. GSR Part 3 states:

> "Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging for specific practices is to be considered, the requirements of paras 3.61–3.64 and 3.66 [of GSR Part 3] shall apply.
>
> "Human imaging using radiation for theft detection purposes shall be deemed to be not justified.
>
> "Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging is to be considered, the requirements of paras 3.61 to 3.67 [of GSR Part 3] shall apply.
>
> "Human imaging using radiation for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, the requirements of paras 3.61 to 3.67 [of GSR Part 3] shall apply." (Ref. [2], paras 3.18–3.21).

2.15. These requirements are considered further in Section 5 of this Safety Guide. However, the overall conclusion that can be drawn is that, since irradiation of persons for non-medical purposes is not to be welcomed (and, indeed, is deemed to be not justified when used for purposes of theft detection), any proposed practices involving such exposure should be extremely carefully considered by the government before they can be authorized.

RELATION WITH THE OTHER PRINCIPLES OF RADIATION PROTECTION

2.16. Justification is the process of deciding whether there is a net benefit from a practice, but demonstration of net benefit is not a sufficient precondition that would permit the practice to be authorized or exempted from the requirements for authorization. All the requirements for radiation protection have to be considered by the regulatory body in the process of determining whether to grant an authorization or an exemption for a proposed practice. In particular, GSR Part 3 [2] requires the optimization of protection and safety, including the establishment of constraints, as appropriate, for dose and risk, and requires the application of dose limits for public and occupational exposure.

2.17. The process of optimization of protection and safety is intended for application to those situations that have been deemed to be justified. The optimization of protection and safety is a process for ensuring that the magnitude and likelihood of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection would be the best possible under the prevailing circumstances.

2.18. Optimization of protection and safety involves the establishment or approval of dose and risk constraints, as appropriate, for the type of practice being considered. This is a general requirement of GSR Part 3 (Ref. [2], para. 3.22 (c)).

2.19. Thus, a decision on justification is only the first stage in the regulatory process, or is a prior stage to this process. The other principles of radiation protection, namely optimization of protection and safety, including ensuring the establishment of and compliance with dose constraints and risk constraints, and ensuring compliance with dose limits, should be addressed in each authorization for a particular type of practice. Any regulatory requirements resulting from such considerations should be expressed in the specific conditions attached to the authorization and in any radiation safety standards for the particular type of practice.

3. RESPONSIBILITIES OF THE RELEVANT PARTIES

GENERAL

3.1. "A properly established governmental, legal and regulatory framework for safety provides for the regulation of facilities and activities that give rise to radiation risks. There is a hierarchy of responsibilities within this framework, from governments to regulatory bodies to the organizations responsible for and the persons engaged in activities involving radiation exposure. The government is responsible for the adoption within its national legal system of such legislation, regulations, and standards and measures as may be necessary to fulfil all its national and international obligations effectively, and for the establishment of an independent regulatory body. In some cases, more than one governmental organization may have the functions of a regulatory body for activities within their jurisdictions relating to the control of radiation and radioactive material" (Ref. [2], para. 1.9).

3.2. "The government or the regulatory body shall ensure that only justified practices are authorized." (Ref. [2], Requirement 10.) Thus, irrespective of where the responsibility for ensuring that only justified practices are authorized resides (i.e. whether the responsibility lies with the government or has been delegated to the regulatory body), it should first be established whether a practice is justified before commencing the process of determining whether the practice can be authorized.

3.3. Some types of practice have a significant international dimension. For example, consumer products may be traded internationally, and the use of human imaging for non-medical purposes in one State may result in the exposure of people from other States. Furthermore, a lack of consistency in approaches can lead to confusion and increased anxiety among the public. The government or the regulatory body, as the case may be, should therefore seek to cooperate with the government or regulatory body of other States with the objective of achieving as much consistency as possible in the acceptability of particular types of practice and in the standards that are to be applied to those practices that are considered justified.

GOVERNMENT

3.4. The Safety Requirements publication GSR Part 1 establishes requirements for a governmental, legal and regulatory framework for safety. It states "The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with the national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals" (Ref. [7], Requirement 1).

3.5. "The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated" (Ref. [7], Requirement 2).

3.6. "The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities" (Ref. [7], Requirement 3). "The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making" (Ref. [7], Requirement 4). However, it is noted in Ref. [7] that the regulatory body will not be entirely separate from other governmental bodies and that the government has the ultimate political responsibility for involving legitimate and recognized interests in its decision making. Nevertheless, the regulatory body is required to make decisions within its statutory obligation for the regulation of facilities and activities and is required to exercise its regulatory functions without undue pressure or constraint.

3.7. The Fundamental Safety Principles states "In many cases, decisions relating to benefit and risk are taken at the highest levels of government, such as a decision by a State to embark on a nuclear power programme. In other cases, the regulatory body may determine whether proposed facilities and activities are justified" (Ref. [1], para. 3.19). The former situation often occurs when the radiation detriment to individuals is only a small part of the total detriment associated with a proposed practice and the overall justification of a type of practice goes far beyond the scope of radiation safety, and decisions are largely influenced by broader political, economic and societal concerns. This is the case, for example, for the use of X rays for security screening of individuals at airports. The decision on whether this type of practice is justified is a matter of national

policy and the responsibility for it will therefore fall on the national government. Proposals for practices of this type, which are of a strategic nature, will normally be considered at the governmental level, although the responsibility for managing the analysis will normally be assigned to governmental organizations.

3.8. The government should determine and clarify the conditions under which the regulatory body has been assigned the task of deciding on the justification of a given type of practice, as distinct from those types of practice for which the government itself exercises that responsibility directly. Proposals for the introduction of types of practice for which the regulatory body has the responsibility for deciding on justification will normally arise from industry and could be regarded as falling within the routine work of the regulatory body.

3.9. "The government shall establish mechanisms to ensure that:

(a) The activities of the regulatory body are coordinated with those of other governmental authorities…and with national or international organizations that have related responsibilities;
(b) Interested parties are involved as appropriate in regulatory decision making processes or regulatory decision aiding processes" (Ref [2], para. 2.19).

This requirement to involve interested parties is relevant in the context of justification of a type of practice and recommendations are provided on its application in subsequent sections.

3.10. "The government shall ensure that appropriate arrangements are in place at the national level for making decisions relating to protection and safety that fall outside the authority of the regulatory body." (Ref. [2], para. 2.20.) Thus, for those types of practice that are of a strategic nature, the government should establish a process for determining whether or not they are justified. This may take various forms, depending on the nature of the proposal. At one extreme, it may involve the establishment of a judicial review process or public inquiry. More commonly, however, it is likely to involve the establishment of a consultative process overseen by government officials. Irrespective of the approach adopted, it should involve consultation with interested parties, including affected parties. Thus, for example, a proposal to use human imaging for non-medical purposes should involve consultation with members of the public who may be affected by it. A broad range of interests, experience and expertise should be included for decisions on justification.

3.11. The government should also involve the regulatory body in such processes in view of the fact that it will need access to the appropriate competence regarding the assessment of radiation risk. Furthermore, the regulatory body would later be involved in the authorization of a practice that is considered justified.

3.12. Where human imaging for security reasons is under consideration, the government should ensure that officials and experts concerned with national security are also included in the consultative process. Other experts who should be included in the process are those with expertise in the areas of civil liberties and ethics.

3.13. Where human imaging for non-medical purposes using medical radiological equipment is under consideration, the government should ensure that the appropriate professional bodies (those representing, for example, radiologists or medical physicists), together with other interested parties, are included in the consultative process.

REGULATORY BODY

3.14. GSR Part 1 states that "The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements" (Ref. [7], para. 4.3). Furthermore, "The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities" (Ref. [7], Requirement 20). "The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice" (Ref. [7], para. 4.18). "Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services" (Ref. [7], para. 4.20).

3.15. "The regulatory body shall ensure that regulatory control is stable and consistent" (Ref. [7], Requirement 22). "The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures" (Ref. [7], para. 4.26). The use of a formal process, involving established policies, principles and associated criteria, in the justification of a type of practice should facilitate consistency in decision making by the regulatory body and defence of a decision in the event that it is challenged. In particular, it will help in reducing subjectivity in decision making by individual staff members of the regulatory body. This is particularly important in the case of consumer products if responsibility for determining whether any particular

proposal is justified or not has been assigned to the regulatory body. The process used in decision making, including stating the reasons for any particular decision, should be transparent.

3.16. For those practices for which responsibility for ensuring that they are justified has been delegated to the regulatory body, the regulatory body should set up an appropriate mechanism to avoid imposition of the personal preferences of individual members of staff. This should normally involve the establishment of an advisory body to the regulatory body comprising individuals reflecting[1] various interests. Recommendations on the use of external experts by the regulatory body, including recommendations for managing actual and potential conflicts of interest and for maintaining an 'intelligent customer' capability, are provided in Ref. [9]. For example, in the case of justification of a practice involving consumer products, such an advisory body might comprise individuals from consumer interest groups, manufacturers or providers of such products, academics and government officials. As an input to the advisory body, the regulatory body should provide an assessment of the radiation risks associated with the proposed practice.

3.17. In consultation with its advisory body, as necessary, the regulatory body should develop guidance for use by persons or organizations seeking to demonstrate justification for a new type of practice. This should cover the development and presentation of safety assessments, any other required safety related information, and the criteria that will be used in determining the justification.

3.18. In the event that the regulatory body considers the type of practice not to be justified and therefore decides not to issue an authorization or renew an authorization, the regulatory body should provide the applicant with a statement of the reasons for its decision.

3.19. The regulatory body should recognize that there may be costs and risks associated with modifying decisions regarding the justification of established types of practice. Therefore, for example, any decision to revoke an authorization of the provision to the public of a particular type of consumer product should be subject to careful scrutiny in order to evaluate the impact of such a decision, including on those who already own a consumer product of this type. Again,

[1] The use of the word 'reflecting' rather than 'representing' is intended to indicate that the process is consultative rather than based on consensus.

transparency in the decision making process should be ensured and the regulatory body should consult interested parties before such decisions are made.

ORGANIZATIONS RESPONSIBLE FOR FACILITIES AND ACTIVITIES

3.20. The first principle established in the Fundamental Safety Principles [1] states "The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks". Requirement 5 in GSR Part 1 [7] then states "The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance". GSR Part 3 [2] expands on this principle in para. 1.8: "Other parties also bear certain responsibilities. For instance, suppliers of radiation generators and radioactive sources have responsibilities in relation to their design and manufacture and operating instructions for their safe use."

3.21. For the consideration of the justification of a practice by government or the regulatory body, the organization responsible for facilities and activities, or the manufacturer, or an organization representing industry should be responsible for preparing an assessment of the benefits and detriments of the practice, including radiation detriments, and any other information requested by the government or the regulatory body, for submission to the government or regulatory body.

4. GENERAL APPROACH TO THE PROCESS OF JUSTIFICATION

STRUCTURED APPROACH

4.1. The government or the regulatory body, as the case may be, should use a structured and transparent approach when considering the justification of a proposed type of practice or reviewing an existing type of practice in the light of new information about its efficacy or consequences.

4.2. The approach, including the mechanism for consultation and decision making, should be established in advance of any decision on justification of a proposed type of practice. At the governmental level, the approach is likely to vary according to the type of practice to be considered. For the more routine proposals falling under the responsibility of the regulatory body, the approach will normally follow a standard procedure. The approaches for both situations should involve consultation with interested parties. In the case of decisions taken at the governmental level, consultation should be carried out with the regulatory body, which should provide information on the radiation risks, as well as with parties who will be affected by the type of practice.

PROCESS TO BE FOLLOWED BY THE GOVERNMENT FOR DETERMINING THE JUSTIFICATION OF A PRACTICE

4.3. The government should establish or select a body responsible for managing the process on its behalf. In the case of decisions that are to be taken at the governmental level, the terms of reference for such bodies, e.g. committees, advisory bodies or judicial inquiries, and the responsibility for the final decision should be clearly defined. The process should be transparent and the reasons for the final decision should be clearly stated. The government should follow the steps outlined in Fig. 1. Application of the approach is discussed further in Section 5 with reference to the use of human imaging for non-medical purposes.

4.4. The body responsible for managing the process should request inputs on the benefits and detriments of the proposed practice from interested parties. The interested parties should include the organization proposing the practice, the regulatory body, other government departments, professional medical bodies, academics and members of the public. The manufacturer of the equipment to be used in the practice may also contribute information on the benefits and detriments of the proposed practice. The process followed should be similar to the process described for the regulatory body in paras 4.8 to 4.25.

4.5. The body managing the process on behalf of the government should prepare a report for the government setting out a recommendation to the government on whether the practice is justified.

4.6. The government should review this report, and should reach a decision on whether the proposed practice is justified. The government should communicate its decision, and the reason for the decision to the public.

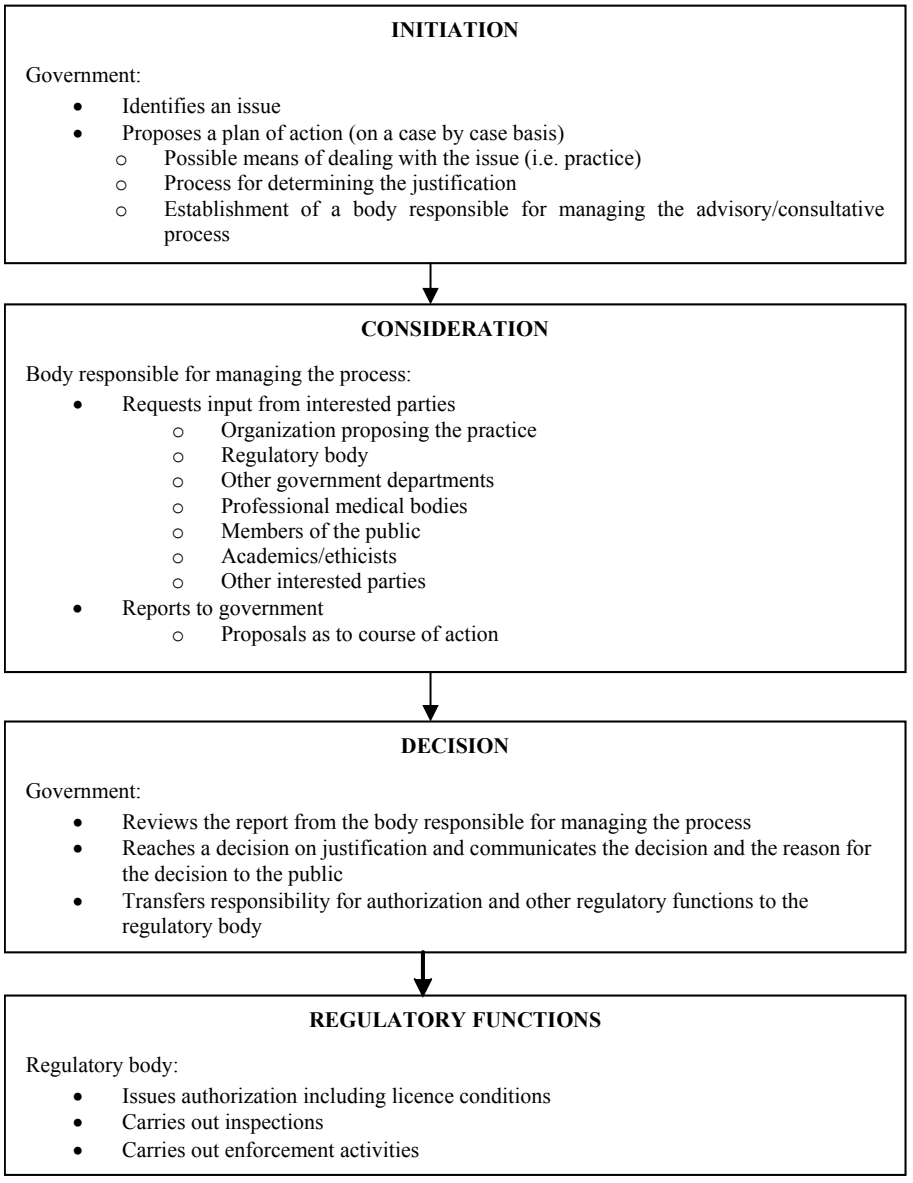

FIG. 1. The process to be followed by the government for determining the justification of a type of practice.

4.7. If the government decides that a particular type of practice is justified, the regulatory body should then exercise its normal regulatory functions, which include the authorization of specific applications of the justified type of practice. The objective of these regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of these functions should provide a high degree of confidence that safety is optimized and that any relevant radiological criteria that have been established, e.g. dose constraints for members of the public, are met. In particular, the regulatory body should ensure that the following conditions are met:

(a) Equipment is designed and constructed to meet the relevant safety requirements.
(b) Facilities are operated within the limits and conditions specified in the safety assessment and as established in the authorization, and operations are carried out safely in accordance with a proper management system.
(c) The authorized party has the human, organizational, financial and technical resources to operate the facility or equipment safely.

PROCESS TO BE FOLLOWED BY THE REGULATORY BODY FOR DETERMINING THE JUSTIFICATION OF A PRACTICE

4.8. In the case where the regulatory body is responsible for deciding on the justification of a type of practice, an advisory body should be formally constituted and consulted in order to avoid the imposition of personal preferences of the individual staff members of the regulatory body when deciding on the justification of a particular type of practice (see para. 3.16). The regulatory body should ensure that sufficient information is provided to the advisory body to permit its members to understand the risks associated with radiation exposure and to be able to place those risks in perspective with other risks.

4.9. All relevant factors should be taken into account and the approach should make clear the relative importance that has been attached to any particular factor. The regulatory body should follow the process shown in Fig. 2.

4.10. If the regulatory body decides that a particular type of practice is justified, the regulatory body should then exercise its normal regulatory functions for that type of practice.

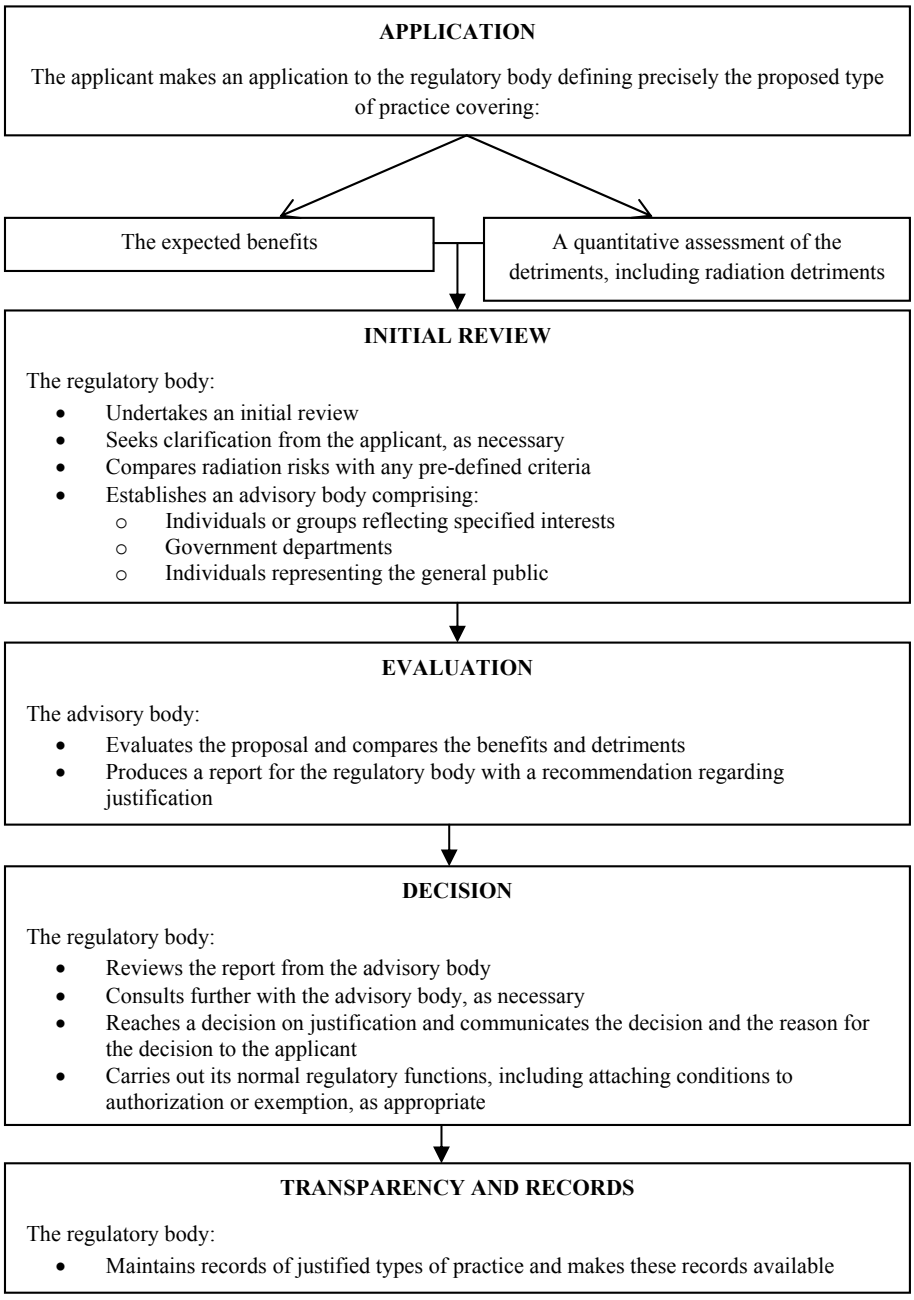

FIG. 2. The process to be followed by the regulatory body for determining the justification of a type of practice.

Application

4.11. Where the regulatory body has responsibility for ensuring that a type of practice is justified, the information that the applicant provides to the regulatory body should include the following:

(a) The applicant's name and contact details.
(b) A description of the type of practice, with drawings and diagrams as appropriate.
(c) A full characterization of the radiation sources that will be used and the measures that will be taken to ensure safety and to reduce the radiological consequences.
(d) An appraisal of the benefits and detriments, including radiation detriments, of the type of practice. This appraisal should include economic, social, health and safety, waste management, recycling, radiological environmental impact and decommissioning aspects. The assessment of the radiation detriment should cover both the magnitude and the likelihood of expected exposures and an assessment of the potential exposures.
(e) An indication of the expected extent of use of the type of practice.

4.12. Applicants may find it useful to obtain the assistance of a qualified expert in preparing the application for justification for the regulatory body.

Initial review

4.13. The regulatory body should initially focus on the information provided by the applicant and should determine whether the applicant has provided all the necessary information. Where necessary, the regulatory body should seek clarification. It should also make an initial comparison with any pre-established criteria. Following this, the regulatory body should seek the advice of the advisory body.

Evaluation

4.14. The advisory body:

(a) Should review and examine the benefits claimed for the type of practice and, if necessary, should consult with interested parties;

(b) Should review and examine the stated detriments, including radiation detriments, that are expected to arise from the type of practice and, where necessary, should seek further information and/or advice on the adequacy of the assessment of the detriments from the applicant;
(c) Should evaluate the benefits and detriments, including radiation detriments, and the relevant evidence;
(d) Should produce a report for the regulatory body with recommendations regarding the justification of the type of practice.

Assessment of radiation detriment

4.15. All relevant radiological aspects should be considered in the evaluation of a proposed type of practice. These include the radiation doses and risks from normal use, transport, accidents and other incidents, misuse, recycling and waste management. In assessing the doses from accidents, account should be taken of the probability of occurrence of accidents. The focus of the radiological assessment should be on the doses to the most exposed individuals.

4.16. The collective dose to all those exposed as a consequence of the introduction of a type of practice may be a determinant in reaching a decision on justification for some types of practice. The collective effective dose is an instrument for optimization and for comparing radiological technologies and procedures for radiation protection.

4.17. All radiological assessments should be as realistic as possible to avoid distortion in the subsequent comparison of radiation detriment and benefit. The assessments should be made by persons who have appropriate competence in radiation safety.

Assessment of benefit

4.18. The benefits from a practice could be of many different types, including possible saving of life, prevention of injury or illness, technical benefits, prevention of property damage or security improvements. The expected benefits should be quantified to the extent possible.

4.19. Where both benefits and radiation detriments can be expressed in commensurate terms, such as lives saved or lost, or in financial terms, the decision will generally be relatively straightforward. However, in general, this will not be the case and therefore value judgements cannot be altogether avoided, but they should be reduced to the extent possible.

4.20. Whereas the assessment of radiological consequences is technical in nature and necessitates only the appropriate competence for it to be carried out, the assessment of benefit is often very subjective. To limit bias by the advisory body in the assessment of benefit, the advisory body should, wherever feasible, establish criteria in advance of its deliberations on justification of a particular type of practice, to assist in making its recommendations to the regulatory body.

Report to the regulatory body

4.21. The advisory body should review and evaluate all the inputs, with account taken of any criteria that have been established. The process of evaluation should be thoroughly documented. The report should set out the key evidence, the uncertainty in the evaluation, and the basis and rationale for the advisory body's recommendation, whether positive or negative. It should also indicate clearly the importance attached to each input.

4.22. If, in making its recommendation, comparisons with non-radioactive or non-radiation-emitting alternatives are seen as necessary by the advisory body, these should be undertaken with appropriate caution. Alternatives are likely also to have detriments and, furthermore, may not achieve entirely the same benefit. The existence of an alternative should not be used as a reason for deciding that a type of practice is not justified.

Decision

4.23. The regulatory body should review the report of the advisory body. Following any further necessary consultations with the advisory body, the regulatory body should make a decision on the justification of the type of practice. Once the decision has been made, it should be communicated to the applicant. Where a type of practice is considered justified, the regulatory body should then follow the normal process of considering applications for authorization. This should involve clarification of the conditions that are applicable on the basis of considerations of optimization of protection. Such conditions should cover aspects such as the type and activity of the radionuclide that is permitted to be used.

Transparency and records

4.24. After the regulatory body has completed its consideration, it should take steps to communicate the decision to those likely to be affected by it. The regulatory body should also maintain an up to date list of the types of practice

that are considered to be justified and should make this list available in order to assist those who may wish to apply for an authorization or exemption from authorization for a particular application of the type of practice.

4.25. The regulatory body should include within this list those types of practice that are already authorized and those for which an exemption has been granted. However, the fact that a type of practice has been granted an authorization or exemption from authorization does not preclude the regulatory body from reviewing the justification for the type of practice at a later stage.

5. APPLICATION OF THE JUSTIFICATION PROCESS TO NON-MEDICAL HUMAN IMAGING

5.1. In view of the current significant interest in the use of human imaging for non-medical purposes, this section provides specific recommendations on the matter. Unlike the medical uses of radiation, such practices are not motivated by the health benefit of the exposed individual.

INTERNATIONAL GUIDANCE

5.2. In 1969, the ICRP made the following statement: "The irradiation of persons for non-medical purposes, such as in "anti-crime" fluoroscopy and in customs examinations, is generally deprecated. If, in exceptional circumstances that are permitted by the competent authority, such examinations are decided to be essential, they shall be carried out under the supervision of a qualified medical radiologist" [10]. Reference [10] does not elaborate on how or on what grounds the competent authority might grant permission, nor does it clarify who would decide whether such examinations were essential.

5.3. Subsequently, as a consequence of international events at the time, namely a series of aircraft hijackings, the ICRP was asked to provide its views on a proposal to use radiography as part of a system for the security screening of airline passengers. In its response, the ICRP envisaged that a small proportion of passengers might be examined radiographically, using specially developed techniques that would restrict individual dose to 10 μSv or less for any part of the body, and that such techniques would be used only when other methods had indicated the presence of unexplained objects on the passenger [11]. The

passenger would be given the choice between X ray examination and a body search. The ICRP concluded that "In view of the grave risks involved in the seizure of aircraft, the proposal…could be justified in the light of the benefits that might be expected". Similarly, Ref. [11] does not provide elaboration with respect to responsibilities and processes.

5.4. In its 1977 recommendations, the ICRP considered the justification of examinations for occupational, medico-legal or insurance purposes [12]. It stated: "Examinations carried out to assess the fitness of an individual for work, to provide information for medico-legal purposes, or to assess the health of a subscriber to, or beneficiary of, an insurance may carry some direct or indirect advantages for the individual examined, but they also carry advantages for the employer, third parties and the insurer. All these aspects should be considered in assessing the justification of such examinations".

5.5. The most recent recommendations of the ICRP state [8]: "The Commission considers that certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These include the following: radiological examination for occupational, health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations. This almost always means that a clinical evaluation of the image acquired must be carried out, otherwise the exposure is not justified".

5.6. In 2014, the ICRP issued a report [13] that provides advice on how the radiation protection principles recommended by the commission should be applied within the context of security screening. The report states that the principles of justification, optimization of protection, and dose limitation for planned exposure situations are directly applicable to the use of ionizing radiation in security screening. The report includes the situation in which individuals may be exposed because they are concealed (stowaways) in a cargo container or conveyance that may be subject to screening. The commission continued to recommend that careful justification of screening be considered before decisions are made to employ the technology for security screening.

5.7. The World Health Organization, in 1977, considered many non-medical situations in which radiation exposure of individuals was proposed, including medico-legal, occupational, immigration, irradiation as a routine administrative procedure, weapon detection and the detection of smugglers [14]. It concluded

that irradiation for purposes unrelated to health should be done only when no satisfactory alternative methods exist.

5.8. Medico-legal procedures may be defined as procedures performed for insurance or legal purposes without clinical indication [15]. The term "human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research", as used in GSR Part 3 [2], covers a broad range of procedures, extending beyond those performed for insurance purposes or as a result of legal proceedings. A distinguishing feature of such exposures is that, in most cases, they are not clinically indicated and the main reason for performing them does not directly relate to the health of the individual being exposed. The population being scanned may not be the population that will derive the benefit and, in fact, the individual exposed may be disadvantaged by the radiological consequences of the exposure[2]. This contrasts sharply with practices within diagnostic radiology that are predicated on a risk–benefit paradigm that assumes that the benefit accrues to the person subjected to the risk. Where this is not the case, the framework of radiation protection, including the justification process, has to be constructed so that it adequately protects the exposed individual. Such practices should be subject to regulatory control and appropriate systems should put in place to ensure this.

APPLICATION OF THE REQUIREMENTS OF GSR PART 3

5.9. GSR Part 3 [2] addresses two categories of human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research. These categories are defined by common attributes, namely where the imaging is performed, what sort of radiation equipment is used, who operates that equipment and who reports on the images.

5.10. Practices in the first category, referred to here as category 1, take place in a medical radiation facility, involve the use of radiological equipment, are performed by radiology personnel and produce images that are reported by a radiological medical practitioner. The purposes of such practices include obtaining legal evidence, making decisions on insurance, employment and immigration, determination of age, assessment of physiology, and detection of drugs within a person.

---

[2] In some States, some forms of non-medical imaging are considered to provide a benefit to the exposed individual (see, for example, Annexes II, III and IV).

5.11. Practices in the second category, referred to here as category 2, do not take place in a medical facility (rather, they often take place in a public place), involve the use of a specialized inspection imaging device, are performed by personnel who are not specialists in radiology and produce images to be viewed by a person who is not medically qualified. The purposes of such practices include the detection of concealed weapons, for example, on airline passengers, and the screening of cargo containers and vehicles.

5.12. In keeping with the ICRP recommendations, GSR Part 3 states "Human imaging using radiation for theft detection purposes shall be deemed to be not justified." In addition, human imaging using radiation for the following purposes is normally required to be deemed to be not justified:

(a) For occupational, legal or health insurance purposes, and undertaken without reference to clinical indication;
(b) For the detection of concealed objects for anti-smuggling purposes (see Ref. [2], paras 3.18–3.20).

Thus, in general human imaging using radiation for the above purposes is deemed to be not justified. However, it is recognized in GSR Part 3 that, in the case of human imaging using radiation for the purposes stated in (a) or (b), there may be exceptional circumstances, as determined by individual States, where the justification of imaging is to be considered and other requirements of GSR Part 3 apply. GSR Part 3 requires that "Human imaging using radiation for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government." (Ref. [2], para. 3.21.)

5.13. A characteristic of these types of practice is that there is no general agreement regarding their justification. There may be cases where there is a strong public health, legal, security or safety reason that may lead to the type of practice being considered justified. Each type of practice results in different benefits and detriments and therefore should be considered on a case by case basis, i.e. decisions on justification should be made with respect to a particular type of use, such as X ray screening at airports. There may also be regional or local differences in the benefits and detriments attributed to a particular type of practice.

5.14. GSR Part 3 places the responsibility for considering the justification for these exceptional circumstances on the government (Ref. [2], para. 3.61). Governments are required to consider, among other things:

(a) The benefits and detriments of implementing the type of human imaging procedure;
(b) The benefits and detriments of not implementing the type of human imaging procedure;
(c) Any legal or ethical issues associated with the introduction of the type of human imaging procedure;
(d) The effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;
(e) The availability of sufficient resources to conduct the human imaging procedure safely during the intended period of the practice.

5.15. GSR Part 3 states that if a type of practice involving human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research is determined to be justified, then that practice is required to be subject to regulatory control (Ref. [2], para. 3.62). This should entail authorization for particular applications of the type of practice under specified conditions, the inspection of facilities where such imaging takes place and the enforcement of regulatory requirements. It is the regulatory body, in cooperation with other relevant authorities, agencies and professional bodies, as appropriate, that is required to establish the requirements for regulatory control of the practice, including the establishment of dose constraints, and the periodic review of the justification. It may be necessary to review the justification decision as new information or technology becomes available.

5.16. If a particular type of practice involving human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research is considered to be justified, separate 'levels' of justification should be applied in respect of particular applications of the technique. For example, the use of X ray screening for the detection of concealed objects that can be used for criminal acts that pose a national security threat in principle is the first level of justification. Its application in specific airports is a second level of justification, although often these two levels will be considered together. Proposals for application of the technique in other situations, such as access controls to buildings, should necessitate separate consideration of justification. Care should be taken to avoid undue proliferation of the use of the technique.

5.17. A further level of justification relates to the selection of particular individuals to whom the technique is to be applied. Criteria for the selection of individuals should be part of the application and should be reviewed as part of the overall justification process. In the particular example of the use of X ray

screening for the detection of concealed objects that can be used for criminal acts that pose a national security threat at airports, the criteria should specify whether the technique is to be applied to all passengers, or whether only a selection of passengers will be made, on a random basis or on some other basis. Particular consideration should be given to application of the technique to children, pregnant women and other sensitive population groups. In addition, the criteria should, as necessary, cover whether the procedure should be made mandatory or should be subject to the informed consent of the individual, particularly if alternative techniques not involving radiation are available.

Category 1 practices

5.18. For those types of practice falling within category 1 as defined in para. 5.9, the government is required to ensure, as a result of consultation between relevant authorities, professional bodies and the regulatory body, the establishment of dose constraints[3] for such human imaging (Ref. [2], para. 3.64 (a)). Such dose constraints should be established prior to a decision on the justification of the type of practice, so that they can be taken into account in the review process. The constraints should be set so that they adequately protect the exposed individual.

5.19. In view of the significant doses that may be obtained from some procedures involving medical radiological equipment, the justification for using the procedure in individual cases should be robust. The radiological medical practitioner responsible for each human imaging procedure is required to ensure that appropriate optimization requirements for medical exposure are applied (see paras 3.161–3.176 of GSR Part 3 [2]).

[3] Dose constraints play an important role for category 1 practices. Since the procedures make use of medical radiological equipment, it would not be appropriate to limit doses to the dose limit for members of the public. It is also noted that diagnostic reference levels apply to medical procedures. These are levels used in medical imaging to indicate whether, in routine conditions, the dose to the patient in a given radiological procedure is unusually high or low for that procedure [2]. The dose constraints established for category 1 practices may well be lower than the diagnostic reference levels for the same procedures used in human imaging for medical purposes. For example, the dose from a CT (computed tomography) scan of the abdomen performed to detect swallowed drugs is likely to be significantly lower than that for a medically indicated CT scan of the abdomen looking for anatomical detail.

Use of imaging in sport

5.20. Imaging is used in both professional and recreational athletics. Imaging in sports medicine can be used for acute or chronic overuse injuries or for screening purposes. Imaging for acute sports injuries is, on the whole, medically justified and is therefore out of the scope of this Safety Guide. With injuries caused by chronic overuse, the need for imaging may be for either diagnosis or prognosis. While the former is clearly a medical exposure, the latter may have financial implications and the motivation to perform such imaging may not be for medical care. Such imaging falls into a grey area that may involve non-medical exposure [16].

5.21. Imaging is also used to aid selection of athletes for competitions, to support decisions on training and nutrition and as a preventive tool. The preventive use of imaging is important but requires guidance to prevent its misuse.

5.22. Imaging is also used for screening purposes in certain contact sports as a precautionary tool to rule out certain conditions that, if present, would lead to increased risk for the individual involved [16].

5.23. Imaging for screening purposes is also used where X rays are requested without any specific clinical indication, for example, to assess an individual's potential before a transfer or appointment as part of professional or contractual obligations or, with young persons, to assess their potential growth.

5.24. Each of these examples should be treated as a separate type of practice requiring explicit consideration of justification by the government. All of the practices described fall within category 1.

5.25. As part of the justification process, it is useful to consider the motivation for the practice. In some cases the benefit would be primarily to the requestor of the examination, in the event that there is some factor affecting the fitness or development, and hence 'value' of the athlete. There may, however, be some potential benefit to the person being examined, for example, detection of a previously undetected but treatable condition that could impair the athlete's progression in the profession or an unknown condition that could result in their being at serious risk.

5.26. To avoid its misuse, guidance should be developed on the conditions under which such imaging is justified, including consideration of the use of alternative imaging techniques using non-ionizing radiation. Such guidance might take the

form of referral or selection criteria. Such criteria should be based on evidence and should be developed in consultation with organizations representing sportspersons (e.g. player associations), sporting organizations (e.g. national administration bodies), radiological medical practitioners and other relevant individuals.

5.27. The exposure of the individual athletes should be subject to the informed consent of the individual to be exposed.

Age determination

5.28. The reason for examinations to determine age usually originates from some legal circumstance in which there is no valid proof of date of birth. The reason may concern adoption, refugees seeking asylum or illegal immigrants, or may be in support of a decision on whether the age of criminal responsibility has been reached. Two types of examination can be carried out: dental and skeletal. A skeletal examination is normally of a selected part of the body, such as the hand and wrist, iliac crest or clavicle.

5.29. The main benefit of such examinations is to the authorities, to enable a sound basis for a decision to be established. There may or may not be a direct benefit to the person being examined.

5.30. However, the technique has significant limitations in accuracy. It is likely that such techniques would only be useful where there is a large difference between the age claimed by the individual and their true chronological age. For many methods, accuracy decreases with chronological age, becoming less accurate for adolescents than for children, and even less accurate for adults than for adolescents. This factor is inherent in the techniques themselves and is in addition to uncertainties in the techniques and any variability among observers. The techniques currently available may not be sufficiently accurate for use in determining whether an individual is above 18 years of age (or above some other age threshold that defines adult status) [17].

5.31. Given the fact that radiological methods of age estimation have significant limitations in accuracy, the use of such techniques requires not only justification in general terms but rather that justification should be applied for each individual case. As racial, sexual and possibly socioeconomic differences exist in dental and skeletal development, the correct reference data should be available and the validity of the method should be established for each individual case [17].

Immigration and emigration checks

5.32. Chest radiographs can be used to determine whether immigrants or emigrants have active or past tuberculosis. This type of practice involves the examination of individuals and is similar to the pre-employment examination of asymptomatic persons. As such, automatic examination is normally deemed not to be justified [2]. However, issues in relation to the protection of public health and vulnerable individuals within society may result in the consideration of such practices as necessary for ensuring public health.

5.33. The justification process should involve review of the proposed referral or selection criteria to be applied as part of the practice.

5.34. The consequences of a positive identification of disease should also be considered. For example, a proposal might be made that all immigrants from States in which tuberculosis is endemic be X rayed to determine whether they have active or past tuberculosis, and are treated if a positive diagnosis is made. Such a proposal is quite different to one in which a positive identification of disease is regarded as a barrier to entry and acts as a trigger for deportation.

5.35. For exposures that are required for the purposes of emigration, the justification process should consider how any requirements of the State of destination will be met and the justification for such exposures in that State.

5.36. Those exposures that are aimed at diagnosis and treatment may be considered to be medical exposures and as such are not covered by this Safety Guide.

Category 2 practices

5.37. The benefits from some of these types of practice (which include inspection procedures) could be substantial; for example, improved security for airline passengers. In general, the benefits will be to the authorities and hence to society at large, rather than to the exposed individual. Nevertheless, for those types of practice where a large number of people might be affected, such as the screening of airline passengers, the government should carefully consider the need for extensive public consultation. Practices using inspection imaging devices are considered to give rise to public exposure, and GSR Part 3 [2] requires that registrants and licensees apply the requirements for public exposure in planned exposure situations.

Detection of contraband on persons

5.38. Security screening involves the use of X ray scanning to detect weapons or other objects concealed on the body. Two known uses are the screening of airline passengers and of visitors to prisons or other buildings where security considerations apply. Each of these uses should be regarded as a separate type of practice. In these types of practice, the benefits lie in a reduced threat from the use of weapons and in improved security, which, in the case of airline passengers, could result in a saving of life.

5.39. A radiological assessment should consider the individual dose per examination as well as the cumulative doses to those who are likely to be exposed frequently, e.g. frequent air travellers or frequent visitors to prisons.

5.40. Issues relating to privacy, provision of information to individuals to be screened, selection criteria for individuals to be screened and informed consent should be considered in the justification process. This may result in particular requirements being applied to these practices. Alternative methods, not involving the use of radiation, may also involve issues relating to privacy.

5.41. The benefits from these types of practice could clearly be substantial. Nevertheless, proposals to introduce them into a State should be scrutinized very carefully by the government. In the particular case of the screening of airline passengers, the government should carefully consider the need for extensive public consultation. In addition, the government should also consider liaising with counterparts in other States in view of the international dimension of air travel.

Detection of contraband in containers

5.42. The primary objective of irradiating containers at border crossings, using either X rays or radioactive sources, is usually to detect items that are not supposed to be present. Such items may include cigarettes or alcohol, drugs, explosives or weapons or even people being smuggled into a State. Such irradiation could therefore give a radiation dose to individuals whose presence is not known in advance. The exposure of workers driving vehicles at border crossings should also be considered.

5.43. The benefit of such uses of radiation is clearly to the authorities and hence to society at large. In some States it is considered that there may be

benefit to persons within the container who may be detected and released from circumstances that have been known to claim lives, e.g. through suffocation.

Detection of illicit trafficking of drugs

5.44. This relates to the use of X ray techniques to image packages of drugs inside a person's body. This may be carried out using medical radiological equipment or an inspection imaging device, i.e. it is considered a category 1 or category 2 practice. Packages containing drugs may have been swallowed or otherwise concealed internally by a courier transporting them.

5.45. The procedure should be used on an individual only when there is a high degree of suspicion that the individual has swallowed a package containing drugs, particularly when there are concerns for the health of the individual (see para. 5.46). Criteria for identifying suspected drug couriers should be developed. It should be noted that alternative techniques not involving the use of radiation are available. These include the administration of emetics or taking the person into custody for a period of time.

5.46. The benefit of this procedure is the reduction in the illicit trafficking in drugs. In some States it is considered that there may be benefit to the person being examined, in that swallowed drug packages may split and release the content into the intestines, resulting in serious injury or death. In that sense, the exposure could be regarded as medical, but since the primary purpose is to detect illicit trafficking in drugs, the exposure should not be regarded as a medical exposure unless there are clinical indications for the investigation.

5.47. For practices that are deemed to be justified, individual exposures should be justified before they are undertaken, with account taken of the objectives of the exposure and the characteristics of the individual concerned. Information relating to the radiation risk should be provided to the individual in advance, even if the examination is mandatory.

5.48. The examination can be carried out using conventional diagnostic X ray techniques or a CT scan, i.e. a category 1 practice. This type of practice uses the same equipment as is used for medical exposures. However, since there is no clinical indication for the examination, dose constraints should be established and used in place of diagnostic reference levels. Such a dose constraint is likely to be lower than the diagnostic reference level for an equivalent diagnostic procedure. The typical effective dose for this procedure is in the region of 1–2 mSv.

5.49. The exposure, if considered justified, should be done under the supervision of, and reported by a radiological medical practitioner. Medical professional societies should be consulted as part of the process of making the justification decision for such practices.

5.50. The procedure may also be carried out using a transmission X ray scanner, which falls with the definition of an inspection imaging device and therefore is a category 2 practice. Such X ray scans are performed, and the images viewed, by personnel who are not specialists in radiology, for example, by law enforcement officers, trained to use such equipment. The typical effective dose for this procedure is of the order of 2–5 μSv. Suspected drug couriers are imaged to determine whether further medical examination is required by medical practitioners at a medical facility, which may include the use of medical radiological equipment.

CONDITIONS

5.51. For those types of practice that the government considers justified, the regulatory body should give careful consideration to the conditions that might be incorporated into the authorization and to other aspects of regulatory control, including those relating to the optimization of protection and safety (including dose and risk constraints) and, where appropriate, compliance with dose limits. Such conditions should be based on the outcome of the justification process and should be in addition to the normal regulatory requirements.

5.52. For those types of practice that are considered justified and fall within category 1 (i.e. they are carried out in a medical facility by radiology personnel using medical radiological equipment, and the images are reported on by a radiological medical practitioner), the exposed persons should be afforded the same level of protection as if they were patients undergoing a medical exposure, with the exception that specific dose constraints are applied in place of diagnostic reference levels.

5.53. A person who is to be exposed to radiation in inspection procedures (category 2) should be afforded the same level of protection as a member of the public, again subject to dose constraints that are specific to the type of practice. Furthermore, GSR Part 3 requires that “all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available.” (Ref. [2], para. 3.66.)

5.54. For both categories of practice, the conditions applied should define such aspects as the permitted extent of use of the practice and the individual selection criteria that will be applied. These conditions should make it clear that the decision applies only for a clearly defined situation of use. In addition, information relating to the radiation risks should be provided to the affected individual in advance.

REFERENCES

[1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIROMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

[2] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[3] EUROPEAN COMMISSION, Medico-legal Exposures, Exposures with Ionising Radiation Without Medical Indication (Proc. Int. Symp. Dublin, 2002), Radiation Protection No. 130, European Communities, Luxembourg (2003).

[4] EUROPEAN COMMISSION, International Symposium on Non-medical Imaging Exposures (Proc. Int. Symp. Dublin, 2009), Radiation Protection No. 167, European Commission, Luxembourg (2011).

[5] LE HERON, J.C., CZARWINSKI, R., "Human imaging for purposes other than medical diagnosis or treatment — practical experience and issues in the implementation of radiation protection in Member States", Proc. Int. Symp. on Non-Medical Imaging Exposures, Dublin, 2009, Radiation Protection No. 167, European Commission, Luxembourg (2011).

[6] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Regulatory Control of Radiation Sources, IAEA Safety Standards Series No. GS-G-1.5, IAEA, Vienna (2004).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1, IAEA, Vienna (2010).

[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Elsevier, Oxford (2007).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Use of External Experts by the Regulatory Body, IAEA Safety Standards Series No. GSG-4, IAEA, Vienna (2013).

[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection against Ionizing Radiation from External Sources, Publication 15, Pergamon Press, Oxford (1970).

[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Statement from the 1971 London meeting of the ICRP, Br. J. Radiol. **44** 814 (1971).
[12] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Recommendations of the International Commission on Radiological Protection, Publication 26, Pergamon Press, Oxford (1977).
[13] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Security Screening, Publication 125, Sage Publications, London (2014).
[14] WORLD HEALTH ORGANIZATION, Use of Ionizing Radiation and Radionuclides on Human Beings for Medical, Research, Training and Nonmedical Purposes, Technical Report Series No. 611, WHO, Geneva (1977).
[15] Council Directive 97/43/Euratom of 30 June 1997, On Health Protection of Individuals Against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom, Official Journal of the European Communities L 180, Office for Official Publications of the European Communities, Luxembourg (1997).
[16] HORNER, K., "Human irradiation and age determination", Proc. Int. Symp. on Non-Medical Imaging Exposures, Dublin, 2009, Radiation Protection No. 167, European Commission, Luxembourg (2011).
[17] O'REILLY, G., "Symposium Report", Proc. Int. Symp. on Non-Medical Imaging Exposures, Dublin, 2009, Radiation Protection No. 167, European Commission, Luxembourg (2011).

Annex I

CASE STUDY ON THE USE OF X RAY SCANNING OF AIRLINE PASSENGERS FOR THE DETECTION OF WEAPONS

INTRODUCTION

I–1. The use of X ray scanning of airline passengers is carried out in some States and prohibited in others [I–1]. However, there are no published regulatory decisions on formal justification of this type of practice. The matter was discussed at the Dublin Symposium [I–2] and the information presented at that symposium forms the basis of the discussion here.

I–2. The purpose of such X ray scanning is to detect any concealed weapon that might otherwise be carried onto an aeroplane. Such X ray scanners are seen as a complement to the use of walk-through metal detectors and pat-down searches. They are also an alternative to a more intrusive 'strip-search'. The equipment uses backscatter X ray imaging to quickly acquire high resolution images. To perform a scan, the subject is asked to stand relatively still on an external stage for several seconds while the system acquires two-dimensional raster-scanned image data. The electronic image of the subject is formed using the intensity of X rays scattered from each location on the body via Compton scattering interactions. The X ray scatter intensity is a function of both the atomic number and the density of the material probed by the primary X ray beam, in this case either the body itself or items on the body. Objects that are denser than body tissue, such as metals, explosives, plastics and packed drugs, interact more strongly and therefore appear on the image along with the body itself. Two scans (front and back) are typically required for a routine inspection. However, the technique only images materials on the surface of the body and is not effective for detecting materials that are concealed within body cavities.

I–3. The failed attempt in an aeroplane travelling from Amsterdam to Detroit on 25 December 2009 to detonate explosive powder concealed under clothing raised concerns about security at airports. Much attention was focused on the use of body scanners that can reveal objects concealed beneath a passenger's clothing.

I–4. Statistics on global airport traffic indicate that the total number of airline passengers is over 5 billion annually and that international passenger traffic accounts for 43% of this [I–3].

BENEFITS

I–5. There are obvious benefits of the practice of X ray scanning of airline passengers to both society and individuals, which include the following:

(a) Social benefit — improved flight security. A scan for concealed weapons, in addition to the benefit of actually finding weapons, has a deterrent effect; this will improve flight security and is expected to result in fewer aeroplane hijacks.
(b) Individual benefit — increased passenger confidence. Passengers are clearly influenced by flight security, as was seen in relation to the significant drop in the number of airline passengers after the terrorist attacks in the United States of America on 11 September 2001. With effective screening for concealed weapons, passenger confidence would increase.

I–6. These benefits may also lead to national and international economic benefits.

DETRIMENTS

I–7. The subject being scanned is exposed to an effective dose of 0.05 μSv per scan, i.e. 0.1 μSv in total per person per examination from a backscatter X ray scan (while a transmission X ray scan exposes the subject to an effective dose of about 5 μSv). The total dose to an individual in a year would, of course, depend on the number of times the individual was subjected to such an examination. If, for example, an individual were subjected to 200 such examinations in a year, the total effective dose would be of the order of 20 μSv.

I–8. An additional aspect to take into account is the fact that such scans of the whole body might be considered to invade the individual's privacy, as the backscatter systems produce an image of the human body. Automated target recognition software displays the location of a detected item on a generic figure, allowing for a screening that is faster and less invasive than a more extensive pat-down and protects individual privacy. Alternative methods, not involving the use of radiation, may also involve issues relating to privacy.

EVALUATION

I–9. The dose to an individual from a single examination is very low, and is substantially lower than the individual would receive from cosmic rays even during a short haul flight of 3 μSv/h [I–4]. Even if individuals were subjected to many examinations in a year, the total effective dose would still be very low.

I–10. The use of X rays on sensitive groups, such as pregnant women and children, could be assessed separately during the government's consideration of justification.

I–11. The consequences of failure to detect a hidden weapon could well be considerable. The inputs of security and intelligence organizations can be effectively integrated to develop a sufficiently clear picture of the threat environment to support decision making.

I–12. Comparing the various beneficial and detrimental factors is not straightforward, as the main issues are ethical in nature. Issues relating to privacy, provision of information to individuals to be screened, selection criteria for individuals to be screened and informed consent should be considered in the justification process. A sufficiently detailed matrix of factors needs to be considered to ensure a well informed decision.

DECISION

I–13. There do not appear to be any published studies on the justification of this practice. Nonetheless, the procedure is being tried out at several airports.

I–14. The Heads of the European Radiological Protection Competent Authorities has issued a Statement on the Justification of Full Body Scanners Using X rays for Security Purposes [I–1]. The statement includes a summary of official statements made in several countries about the justification of body scanners using ionizing radiation.

I–15. The European Commission was given a mandate by the European Parliament to establish common rules for civil aviation security following the 11 September 2001 terrorist attacks in the United States of America. However, an attempt by the commission to implement more specific rules regarding body screening techniques was rejected by the European Parliament owing to concerns relating to health, privacy and data protection.

I–16. In the United States of America, there are no specific legislative requirements for the justification and use of body scanners using ionizing radiation. The Interagency Steering Committee on Radiation Standards (ISCORS) is an interagency body made up of those federal organizations with regulatory authority with respect to radiation protection issues. In July 2008, ISCORS developed a guidance document to assist federal agencies in determining when the use of ionizing radiation for the security screening of people is warranted [I–5]. The use of backscatter equipment at airports in the United States of America was suspended in 2013 pending the incorporation of automated target recognition software into this technology.

I–17. The State Office for Nuclear Security in the Czech Republic has considered the use of X ray scanners at airports that represent a source of public exposure to be unjustified from a radiation protection point of view. Licence applications have until now been rejected.

I–18. The German Federal Office for Radiation Protection (Bundesamt für Strahlenschutz) has conducted an evaluation on aspects of radiation protection for whole body scanners. The German Federal Office for Radiation Protection considers advanced body imaging using X rays to be unjustified and will reject any licence request. In addition, the German Federal Office for Radiation Protection considers that current scientific knowledge of non-ionizing radiation technologies does not allow it to draw conclusions on health effects. Passive scanners have therefore been favoured, as these do not add any artificial radiation to improve the contrast in the image.

REFERENCES TO ANNEX I

[I–1] HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES, Facts and Figures Concerning the Use of Full Body Scanners Using X-Rays for Security Reason (2010), http://www.herca.org/documents/Fact_figures_Body_scanners.pdf

[I–2] EUROPEAN COMMISSION, Medico-legal Exposures, Exposures with Ionising Radiation Without Medical Indication (Proc. Int. Symp. Dublin, 2002), Radiation Protection No. 130, European Communities, Luxembourg (2003).

[I–3] AIRPORTS COUNCIL INTERNATIONAL, Preliminary 2012 World Airport Traffic and Rankings (2013), http://www.aci.aero/News/Releases/Most-Recent/2013/03/26/Preliminary-2012-World-Airport-Traffic-and-Rankings-

[I–4] UNITED NATIONS, Sources and Effects of Ionizing Radiation (Report to the General Assembly with Scientific Annexes), Vol. 1, Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[I–5] UNITED STATES INTERAGENCY STEERING COMMITTEE ON RADIATION STANDARDS, Guidance for Security Screening of Humans Utilizing Ionizing Radiation, ISCORS Technical Report 2008-1, Washington, DC (2008).

Annex II

CASE STUDY ON THE USE OF X RAY SCANNING FOR THE DETECTION OF DRUGS SMUGGLED ON THE PERSON

INTRODUCTION

II–1. One way of smuggling drugs is to transport them inside the body of human carriers. X ray scanning of persons at borders and elsewhere is therefore carried out in some States to check for this. Any packages in the gastrointestinal tract are usually easily visible on radiographs. However, as with the previous case study (Annex I), there are no published regulatory decisions on formal justification of this type of practice. The matter was discussed at the Dublin Symposiums [II–1, II–2].

II–2. In the United Kingdom, the Drugs Act of 2005 gives the police powers to order an X ray or ultrasound scan of persons who are suspected of having swallowed drugs. Under this act, an X ray may not be carried out unless consent has been given in writing and the X ray may be carried out only by a suitably qualified person at a hospital or other medical establishment.

BENEFITS

II–3. The checking and examination of selected individuals for smuggling of drugs is a benefit to society as a whole to prevent the smuggling of drugs. There is also a benefit to the individual undergoing the X ray examination, in so far as it is less intrusive than an extensive full body examination.

DETRIMENTS

II–4. The subject being examined by X rays is exposed to an effective dose that is probably in the region of 1–2 mSv.

EVALUATION

II–5. The individual risk to people being selected for an X ray examination with the purpose of detecting swallowed drug packages is relatively low, being of the

same order as the dose from an X ray of the spinal cord. However, the dose limit for public exposure is likely to be exceeded. The benefits, however, are to society as a whole, in terms of the prevention of illicit drugs from reaching the market. Nevertheless, as with other case studies, there are ethical issues that would need to be considered. These would be somewhat offset by a requirement for informed consent before the procedure is used.

DECISION

II–6. Clearly, the UK considers the benefit sufficient for this procedure to be included within its own national legislation. The procedure also appears to be in use at some borders. However, at the time of writing there do not appear to be any published decisions on justification of this practice.

REFERENCES TO ANNEX II

[II–1] EUROPEAN COMMISSION, Medico-legal Exposures, Exposures with Ionising Radiation Without Medical Indication (Proc. Int. Symp. Dublin, 2002), Radiation Protection No. 130, European Communities, Luxembourg (2003).

[II–2] EUROPEAN COMMISSION, International Symposium on Non-Medical Imaging Exposures (Proc. Int. Symp. Dublin, 2009), Radiation Protection No. 167, European Commission, Luxembourg (2011).

Annex III

CASE STUDY ON THE USE OF X RAY OR GAMMA RADIATION SCANNING FOR THE DETECTION OF PEOPLE SEEKING TO ENTER A STATE ILLEGALLY IN VEHICLES OR FREIGHT CONTAINERS

INTRODUCTION

III–1. This summary describes the main elements of the justification case for the use of X ray or gamma radiation scanning for the detection of stowaways as published by the UK Home Office[1] [III–1]. In the United Kingdom, the rate of clandestine entry by people concealed in vehicles or freight containers at ferry ports and the Eurotunnel Folkestone Terminal is very high. People who have been detected attempting to enter illegally in east Kent alone, including the Port of Dover, numbered over 17 000 in 1999 and 19 700 in 2000. Detection measures in use include carbon dioxide (CO_2) sensors, which give a quick and generally reliable indication of concealed human presence, and search teams of dogs. Both these measures, however, have fairly significant limitations. For example, certain types of freight emit CO_2, thus masking the presence of humans. Also, the construction of some containers prevents examination by CO_2 sensors. Alternative measures are sometimes employed, such as the physical unloading of full freight loads. This is a very costly and time consuming process, and can only be used in a limited number of cases. As a consequence, the UK immigration service is planning to deploy X ray or gamma radiation scanners at UK ports and control zones to detect people seeking to circumvent UK immigration controls. This practice would be integrated with other search techniques to provide a balanced and effective search regime. In most cases, scanners would be used as a second phase of checking, that is, as a form of confirmation where a first phase of checking (e.g. CO_2 sensors) has provided inconclusive results.

III–2. The scanners use X ray or gamma radiation to produce an image of the freight, via a highly sensitive detector array system. The scanner moves from one end of the vehicle over its whole length to obtain a complete image. It typically

[1] This case study includes cost–benefit analysis. The values used in the case study were applicable at the time that the case study was carried out in 2004.

takes less than a few minutes to complete a scan and produce an image by detecting transmission radiation or back scattered radiation.

BENEFIT

III–3. The use of X ray or gamma radiation equipment was considered to represent a very significant deterrent because:

(a) For individuals who aim to breach immigration controls, the likelihood of discovery will be greatly increased.
(b) For hauliers, ferry operators and the Channel Tunnel operators, the increased prospect of having heavy civil penalties applied to them is expected to encourage them to take better security precautions than they do at present.
(c) For those engaged in human trafficking, the prospect of disruption to their activities will have a significant effect, particularly where detection results in successful prosecution.

III–4. The social benefits were considered to include prevention of death or serious injury or illness because of the very poor physical condition of many illegal immigrants who have been detected in vehicles. Some had, in fact, already died. The deployment of scanning equipment would significantly increase the likelihood of the immigration service detecting people in freight containers and thereby relieving potential suffering and preventing possible death, especially where detection takes place at a time early in the transit.

III–5. Furthermore, detection of such illegal immigrants by X ray or gamma radiation was considered to provide an ability to mount a rapid mobile response to new trends and routes of attempted illegal entry by individuals and to be a more effective technique than CO_2 checking, which can only be used on certain types of cargo.

III–6. The economic benefits were considered to include the following:

(a) People hidden in vehicles and/or freight containers can be detected without the need for physical offloading of the freight in the search process, which is both labour intensive and costly.
(b) X ray or gamma radiation scanners can be used on a wide variety of vehicles, including curtain (soft) sided, refrigerated and container trucks,

tankers, Lutons, vans and, where necessary, coaches, whereas the use of CO_2 sensors is limited to curtain sided vehicles.

(c) There is expected to be a reduction in the overall cost to the government of processing and supporting immigrants by encouraging improved security precautions by hauliers and ferry operators through enforcement of the Civil Penalty and Carrier Liability Scheme.

(d) The practice provides the capacity to search a greater proportion of vehicles destined for, or arriving in, the UK.

(e) The practice represents a more productive use of immigration service resources in searching vehicles and in the deployment of other control staff to better effect.

DETRIMENT

III–7. The annual effective dose to an employee operating the equipment or to the driver was determined to be less than 0.5 mSv.[2]

III–8. The maximum annual effective dose to a member of the public outside the exclusion zone, an area surrounding the scanner designated by physical barriers and warning signs, beacons and audible alarms, as necessary, was estimated to be 100 μSv.

III–9. The average effective dose to a person inside the vehicle or freight container was estimated to be 1 μSv per scan and is not expected to exceed 2 μSv per scan under the most pessimistic conditions.

EVALUATION

III–10. A cost–benefit analysis to quantify the radiation detriment was carried out for a single scanner. Based on a maximum dose to a worker of 0.5 mSv in a year and assuming up to 36 workers would be deployed on a scanner, the resulting annual collective effective dose was calculated to be 18 man mSv.

[2] The equipment needs to be designed so that the driver of the vehicle is not in the primary beam.

III–11. The scanners would be located in restricted areas in a secure port or terminal environment to which members of the public would have very limited access. In addition, it is considered extremely unlikely that people would loiter at the perimeter of the boundary of the exclusion zone, which would be monitored by scanner team members. The immigration service estimated that, in a worst case, 10 members of the public per day (365 days per year) could potentially be exposed to the X ray beam. As the scanner uses a collimated beam, the maximum radiation dose that a member of the public on the boundary of the exclusion area would receive would be 1 μSv per scan. This would result in an annual collective effective dose of 3.6 man mSv.

III–12. The evaluation assumed that 1000 individuals hidden inside a vehicle or freight container are detected in a year by each scanner and that each would receive an effective dose of 2 μSv per scan. The resultant annual collective effective dose would be 2 man mSv.

III–13. These collective doses were evaluated using reference values established by the National Radiological Protection Board of £50 000 per man Sv for workers and £20 000 per man Sv for members of the public. On this basis, the annual health related cost of operating the proposed equipment is £1012 per scanner. To the extent that the proposed practice may result in saving several lives, a benefit can be attached to the practice of £1 600 000 per life saved.

DECISION

III–14. The use of X ray or gamma radiation scanners to detect people seeking to enter the UK illegally was considered justified because:

(a) Lives will be saved and suffering and injury will be prevented when people hidden in vehicles and/or freight containers are detected prior to lengthy sea crossings and/or road journeys.
(b) The radiation detriment cost of £1012 is very small compared to the value assigned to a human life of £1 600 000.
(c) The detection measures currently in use (involving CO_2 sensors, dog search teams and unloading of vehicles and/or freight) have limitations. The likelihood of detecting people concealed in vehicles and/or freight containers will be greatly enhanced by the use of X ray or gamma radiation scanners.
(d) Any radiation doses received by people hidden in vehicles and/or freight containers will be extremely small and do not pose a significant health risk.

For example, the doses are much less than the average dose received in the UK every day by a member of the public from natural background radiation and are similar to the dose received by airline passengers undertaking a short domestic flight.

REFERENCE TO ANNEX III

[III–1] UNITED KINGDOM HOME OFFICE, Home Office Justification for the use of X/Gamma Radiation Scanners by the Immigration Services for Detecting People Seeking to Enter the UK Illegally in Vehicles and/or Freight, by Clandestine Means, London (2004).

Annex IV

CASE STUDY ON THE USE OF X RAY SCANNING FOR AGE DETERMINATION

INTRODUCTION

IV–1. The information presented on the use of X rays for the determination of the age of young persons was discussed at the Dublin Symposium [IV–1] and forms the basis for the discussion here. An assessment of age can be carried out on the basis of either dental or skeletal examination. The latter would involve taking X rays of ossification centres to study fusion of the metaphysis in long bones, e.g. by taking X rays of the hand, wrist, elbow or iliac crest, or by examining the clavicle using computed tomography (CT). As with the earlier examples (see Annexes I–III), there are no published regulatory decisions on formal justification of this type of practice.

IV–2. The objectives of the practice were considered to be:

(a) To check the age of older children seeking adoption who have no or poor quality documentary information as to their age;
(b) To assess the age of asylum seekers, who would obtain significant advantage if they were declared to be minors;
(c) To assess the age of young offenders, in order to decide whether the age of criminal responsibility had been reached.

IV–3. The procedure is recognized as a relevant scientific procedure in a publication containing guidelines for the protection and care of refugee children issued by the UNHCR in 1994 [IV–2].

BENEFITS

Legal benefits

IV–4. In many States, there are major differences between the legal punishments of child or adult offenders. Furthermore, in some States, children may be granted asylum, whereas adults are sent back to their State of origin immediately if there is no good reason to accept them.

Psychological benefits

IV–5. Sometimes the approximate age of a child may not be obvious, especially if that child has suffered from malnutrition. It can harm a child psychologically if he or she is placed in the wrong age group at school or in society. The uncertainties involved in age determination vary from six months to one year. Guidance on this topic from the UNHCR, however, states that "when the exact age is uncertain, the child should be given the benefit of the doubt" [IV–2].

DETRIMENT

IV–6. The dose to the wrist or elbow from a single X ray is approximately 0.15 mGy, resulting in a very low effective dose. The dose from an orthopantomogram[1] is approximately 0.5 mGy to the neck and 0.05 mGy to the thyroid, giving an effective dose of approximately 2.5 μSv.

EVALUATION

IV–7. The fact that the procedure is recognized as relevant by the UNHCR provides some evidence that there may well be important benefits for young refugees. Furthermore, the detriment due to the radiation exposure is low. Nevertheless, this type of procedure poses ethical questions that clearly need to be considered carefully by the relevant national authority.

DECISION

IV–8. There do not appear to be any published decisions on justification of this practice.

[1] An orthopantomogram is a panoramic scanning dental X ray of the upper and lower jaw.

REFERENCES TO ANNEX IV

[IV–1] EUROPEAN COMMISSION, Medico-legal Exposures, Exposures with Ionising Radiation Without Medical Indication (Proc. Int. Symp. Dublin, 2002), Radiation Protection No. 130, European Communities, Luxembourg (2003).

[IV–2] UNITED NATIONS, Refugee Children: Guidelines for Protection and Care, United Nations High Commissioner for Refugees (UNHCR), UN, Geneva (1994).

Annex V

CASE STUDY ON THE USE OF LIGHTNING PROTECTION SYSTEMS USING RADIOACTIVE SOURCES

INTRODUCTION

V–1. Lightning conductors using radioactive sources provide an example of a product that has been used for many decades without an adequate demonstration of benefits and where the radioactive source has subsequently been shown to provide no benefit.

BENEFITS

V–2. The idea that a radioactive source in the vicinity of a Franklin rod could improve the rod's efficacy dates from the early part of the twentieth century [V–1]. The basis for this belief was the fact that the radioactive sources ionize the air around the rod and that this ionization would be sufficient to increase the zone of protection of the lightning rod. This, in turn, would reduce the number of rods required or the need for a Faraday cage to protect a building. As a consequence, such systems were cheaper and easier to install than conventional lightning protection systems. Beginning in the 1930s, such rods were installed in many States [V–2]. Initially, radium-226 was used but, with the advent of artificially produced radionuclides, rods containing americium-241, krypton-85 and cobalt-60, among others, were introduced. The activity of the americium-241 on one lightning rod was typically of the order of 1 to 10 GBq.

V–3. Doubts over the efficacy of such radioactive lightning rods go back at least to the 1960s, when they were used to protect very high structures, e.g. churches, television towers and skyscrapers [V–1]. However, they continued to be installed throughout the world and, although it is now widely accepted that the radioactive sources are not effective in increasing the zone of protection, many are still installed on buildings [V–3–V–5].

DETRIMENTS

V–4. Because such lightning conductors are generally installed in locations at quite some distance from places to which the public have access, the doses

received from normal use are likely to be very low [V–4]. However, once the system has been dismantled, the disused sources need to be managed as radioactive waste. Alternatively, disused sources could be returned to the original manufacturer for recycling and beneficial reuse. Since 1970, many States have operated programmes to remove radioactive lightning conductor rods from service [V–4, V–6].

EVALUATION

V–5. It is considered that there is no benefit from the presence of the radioactive source. Because of the misconceptions regarding the efficacy of the devices, it is likely that those places where they are currently in use are underprotected against lightning strikes. As a consequence, their use could lead to economic losses and put lives at risk [V–1]. This is a particular problem in tropical States where lightning strikes are much more frequent then in temperate States.

DECISION

V–6. There do not appear to be any published decisions on justification of this practice.

REFERENCES TO ANNEX V

[V–1] BAATZ, H., Radioactive isotopes do not improve lightning protection, Elektrotech. Z. A **93** (1972) 101–104.

[V–2] CHRZAN, K.L., HARTONO, Z.A., "Inefficacy of radioactive terminals and early streamer emission terminals", XIIIth International Symposium on High Voltage Engineering, Millpress, Rotterdam (2003).

[V–3] DARVENIZA, M., MACKERRAS, D., LIEW, A.C., Standard and non-standard lightning protection methods, J. Electr. Electron, Eng. **7** (1987) 133–40.

[V–4] SHAW, J., DUNDERDALE, J., PAYNTER, R.A., A Review of Consumer Products Containing Radioactive Substances in the European Union, Radiation Protection No. 146, European Commission, Luxembourg (2007).

[V–5] HARTONO, Z.A., ROBIAH, I., "Conventional and un-conventional lightning air terminals: an overview", paper presented at the Forum on Lightning Protection, Petaling Jaya, 2004.

[V–6] INTERNATIONAL ATOMIC ENERGY AGENCY, Identification of Radioactive Sources and Devices, IAEA Nuclear Security Series No. 5, IAEA, Vienna (2007).

Annex VI

CASE STUDY ON THE USE OF EXIT SIGNS USING TRITIUM

INTRODUCTION

VI–1. A tritium exit sign is a self-illuminating product lit by gaseous tritium light sources (GTLS). Each GTLS is a glass tube capsule filled with the radioactive gas tritium. The inner surface of the glass tubes is coated with luminous phosphor. The beta radiation from the disintegration of tritium causes the emission of light from the phosphor. The intensity of light diminishes as the tritium in the tube decays. The useful life of a GTLS tube is typically 10–12 years.

BENEFITS

VI–2. As tritium exit signs are self-illuminating, they do not need any connection to an electricity source. They require no maintenance, and they remain luminescent for 10–12 years. They can save lives in the event of a fire, power outage or other emergency.

DETRIMENTS

VI–3. Tritium emits a beta particle that cannot penetrate the glass tube of an exit sign. The beta particle also cannot penetrate a sheet of paper or the outer layer of skin. It therefore poses no radiation hazard if outside the body.

VI–4. Internal exposure of individuals occurs if tritium is taken into the body through inhalation, absorption or ingestion. Inhalation is primarily a concern in close proximity to a point of release, or in a confined or poorly ventilated space. This situation could arise from close contact with a damaged sign. Tritium has a biological half-life of about 10 days. The potential for adverse health effects from a broken tritium sign is relatively low.

VI–5. The potential cleanup costs and liabilities that can result from a tritium sign being broken can be significant. The United States Environmental Protection Agency has prepared information on tritium exit signs, including proper handling and disposal methods [VI–1].

VI–6. Proper disposal of tritium exit signs is necessary after they are no longer in use. They are never to be disposed of as normal rubbish. Proper disposal is achieved by return to the manufacturer or supplier. Elevated levels of tritium have been found in landfill leachate, liquids that percolate down through landfill, in California, Pennsylvania and the UK [VI–2, VI–3], and tritium can move into groundwater.

EVALUATION

VI–7. The use of such signs in some States indicates that there is a benefit of saving lives in emergencies that outweighs the detriment from use in normal situations and from damaged signs, and from incorrect disposal. Some States limit their use to situations where it is not practical or feasible to use alternative signs.

DECISION

VI–8. There do not appear to be any published decisions on justification of this practice.

VI–9. Regulatory requirements for such devices are published by some regulatory bodies, indicating that their use is considered justified in some States. This includes requirements for their use such as: limiting their use to situations where alternatives are not practical or feasible, requiring licensing when the total number of signs on premises exceeds a particular number, requiring that they not be disposed of as normal rubbish, and requiring that the owner of the sign file a report regarding its disposal.

REFERENCES TO ANNEX VI

[VI–1] UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Discarded Tritium Exit Signs (2012), http://www.epa.gov/radtown/exit-signs.html

[VI–2] MUTCH, R.D., MAHONEY J.D., PAQUIN, P.R., CLEARY, J., A Study of Tritium in Municipal Solid Waste Leachate and Gas (2007), http://www.hydroqual.com/publications/rdm_07_01_p.pdf.

[VI–3] HICKS, T.W., WILMOT, R.D., BENNETT, D.G., Tritium in Scottish Landfill Sites (2000), http://www.sepa.org.uk/radioactive_substances/publications/idoc.ashx?docid=d73237c9-38c7-41d0-b2e1-3cd3ee8ad2cb&version=-1

CONTRIBUTORS TO DRAFTING AND REVIEW

Boal, T.	International Atomic Energy Agency
Hedemann-Jensen, P.	RISØ National Laboratory, Denmark
Lazo, T.	OECD Nuclear Energy Agency
Mason, C.	International Atomic Energy Agency
Niu, S.	International Labour Office
O'Reilly, G.	St. James's Hospital, Dublin, Ireland
Repacholi, M.	World Health Organization
Webb, G.	Private consultant, United Kingdom
Wrixon, A.	International Atomic Energy Agency
Zuur, C.	Ministry of Housing, Spatial Planning and the Environment, the Netherlands

IAEA
International Atomic Energy Agency

No. 23

ORDERING LOCALLY

In the following countries, IAEA priced publications may be purchased from the sources listed below or from major local booksellers.

Orders for unpriced publications should be made directly to the IAEA. The contact details are given at the end of this list.

AUSTRALIA
DA Information Services
648 Whitehorse Road, Mitcham, VIC 3132, AUSTRALIA
Telephone: +61 3 9210 7777 • Fax: +61 3 9210 7788
Email: books@dadirect.com.au • Web site: http://www.dadirect.com.au

BELGIUM
Jean de Lannoy
Avenue du Roi 202, 1190 Brussels, BELGIUM
Telephone: +32 2 5384 308 • Fax: +32 2 5380 841
Email: jean.de.lannoy@euronet.be • Web site: http://www.jean-de-lannoy.be

CANADA
Renouf Publishing Co. Ltd.
5369 Canotek Road, Ottawa, ON K1J 9J3, CANADA
Telephone: +1 613 745 2665 • Fax: +1 643 745 7660
Email: order@renoufbooks.com • Web site: http://www.renoufbooks.com

Bernan Associates
4501 Forbes Blvd., Suite 200, Lanham, MD 20706-4391, USA
Telephone: +1 800 865 3457 • Fax: +1 800 865 3450
Email: orders@bernan.com • Web site: http://www.bernan.com

CZECH REPUBLIC
Suweco CZ, spol. S.r.o.
Klecakova 347, 180 21 Prague 9, CZECH REPUBLIC
Telephone: +420 242 459 202 • Fax: +420 242 459 203
Email: nakup@suweco.cz • Web site: http://www.suweco.cz

FINLAND
Akateeminen Kirjakauppa
PO Box 128 (Keskuskatu 1), 00101 Helsinki, FINLAND
Telephone: +358 9 121 41 • Fax: +358 9 121 4450
Email: akatilaus@akateeminen.com • Web site: http://www.akateeminen.com

FRANCE
Form-Edit
5 rue Janssen, PO Box 25, 75921 Paris CEDEX, FRANCE
Telephone: +33 1 42 01 49 49 • Fax: +33 1 42 01 90 90
Email: fabien.boucard@formedit.fr • Web site: http://www.formedit.fr

Lavoisier SAS
14 rue de Provigny, 94236 Cachan CEDEX, FRANCE
Telephone: +33 1 47 40 67 00 • Fax: +33 1 47 40 67 02
Email: livres@lavoisier.fr • Web site: http://www.lavoisier.fr

L'Appel du livre
99 rue de Charonne, 75011 Paris, FRANCE
Telephone: +33 1 43 07 50 80 • Fax: +33 1 43 07 50 80
Email: livres@appeldulivre.fr • Web site: http://www.appeldulivre.fr

GERMANY
Goethe Buchhandlung Teubig GmbH
Schweitzer Fachinformationen
Willstätterstrasse 15, 40549 Düsseldorf, GERMANY
Telephone: +49 (0) 211 49 8740 • Fax: +49 (0) 211 49 87428
Email: s.dehaan@schweitzer-online.de • Web site: http://www.goethebuch.de

HUNGARY
Librotade Ltd., Book Import
PF 126, 1656 Budapest, HUNGARY
Telephone: +36 1 257 7777 • Fax: +36 1 257 7472
Email: books@librotade.hu • Web site: http://www.librotade.hu

INDIA

Allied Publishers
1st Floor, Dubash House, 15, J.N. Heredi Marg, Ballard Estate, Mumbai 400001, INDIA
Telephone: +91 22 2261 7926/27 • Fax: +91 22 2261 7928
Email: alliedpl@vsnl.com • Web site: http://www.alliedpublishers.com

Bookwell
3/79 Nirankari, Delhi 110009, INDIA
Telephone: +91 11 2760 1283/4536
Email: bkwell@nde.vsnl.net.in • Web site: http://www.bookwellindia.com

ITALY

Libreria Scientifica "AEIOU"
Via Vincenzo Maria Coronelli 6, 20146 Milan, ITALY
Telephone: +39 02 48 95 45 52 • Fax: +39 02 48 95 45 48
Email: info@libreriaaeiou.eu • Web site: http://www.libreriaaeiou.eu

JAPAN

Maruzen Co., Ltd.
1-9-18 Kaigan, Minato-ku, Tokyo 105-0022, JAPAN
Telephone: +81 3 6367 6047 • Fax: +81 3 6367 6160
Email: journal@maruzen.co.jp • Web site: http://maruzen.co.jp

NETHERLANDS

Martinus Nijhoff International
Koraalrood 50, Postbus 1853, 2700 CZ Zoetermeer, NETHERLANDS
Telephone: +31 793 684 400 • Fax: +31 793 615 698
Email: info@nijhoff.nl • Web site: http://www.nijhoff.nl

Swets Information Services Ltd.
PO Box 26, 2300 AA Leiden
Dellaertweg 9b, 2316 WZ Leiden, NETHERLANDS
Telephone: +31 88 4679 387 • Fax: +31 88 4679 388
Email: tbeysens@nl.swets.com • Web site: http://www.swets.com

SLOVENIA

Cankarjeva Zalozba dd
Kopitarjeva 2, 1515 Ljubljana, SLOVENIA
Telephone: +386 1 432 31 44 • Fax: +386 1 230 14 35
Email: import.books@cankarjeva-z.si • Web site: http://www.mladinska.com/cankarjeva_zalozba

SPAIN

Diaz de Santos, S.A.
Librerias Bookshop • Departamento de pedidos
Calle Albasanz 2, esquina Hermanos Garcia Noblejas 21, 28037 Madrid, SPAIN
Telephone: +34 917 43 48 90 • Fax: +34 917 43 4023
Email: compras@diazdesantos.es • Web site: http://www.diazdesantos.es

UNITED KINGDOM

The Stationery Office Ltd. (TSO)
PO Box 29, Norwich, Norfolk, NR3 1PD, UNITED KINGDOM
Telephone: +44 870 600 5552
Email (orders): books.orders@tso.co.uk • (enquiries): book.enquiries@tso.co.uk • Web site: http://www.tso.co.uk

UNITED STATES OF AMERICA

Bernan Associates
4501 Forbes Blvd., Suite 200, Lanham, MD 20706-4391, USA
Telephone: +1 800 865 3457 • Fax: +1 800 865 3450
Email: orders@bernan.com • Web site: http://www.bernan.com

Renouf Publishing Co. Ltd.
812 Proctor Avenue, Ogdensburg, NY 13669, USA
Telephone: +1 888 551 7470 • Fax: +1 888 551 7471
Email: orders@renoufbooks.com • Web site: http://www.renoufbooks.com

United Nations
300 East 42nd Street, IN-919J, New York, NY 1001, USA
Telephone: +1 212 963 8302 • Fax: 1 212 963 3489
Email: publications@un.org • Web site: http://www.unp.un.org

Orders for both priced and unpriced publications may be addressed directly to:

IAEA Publishing Section, Marketing and Sales Unit, International Atomic Energy Agency
Vienna International Centre, PO Box 100, 1400 Vienna, Austria
Telephone: +43 1 2600 22529 or 22488 • Fax: +43 1 2600 29302
Email: sales.publications@iaea.org • Web site: http://www.iaea.org/books

FUNDAMENTAL SAFETY PRINCIPLES
IAEA Safety Standards Series No. SF-1
STI/PUB/1273 (37 pp.; 2006)
ISBN 92–0–110706–4 Price: €25.00

GOVERNMENTAL, LEGAL AND REGULATORY FRAMEWORK FOR SAFETY
IAEA Safety Standards Series No. GSR Part 1
STI/PUB/1465 (63 pp.; 2010)
ISBN 978–92–0–106410–3 Price: €45.00

THE MANAGEMENT SYSTEM FOR FACILITIES AND ACTIVITIES
IAEA Safety Standards Series No. GS-R-3
STI/PUB/1252 (39 pp.; 2006)
ISBN 92–0–106506–X Price: €25.00

RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES: INTERNATIONAL BASIC SAFETY STANDARDS
IAEA Safety Standards Series No. GSR Part 3
STI/PUB/1578 (427 pp.; 2014)
ISBN 978–92–0–135310–8 Price: €68.00

SAFETY ASSESSMENT FOR FACILITIES AND ACTIVITIES
IAEA Safety Standards Series No. GSR Part 4
STI/PUB/1375 (56 pp.; 2009)
ISBN 978–92–0–112808–9 Price: €48.00

PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE
IAEA Safety Standards Series No. GSR Part 5
STI/PUB/1368 (38 pp.; 2009)
ISBN 978–92–0–111508–9 Price: €45.00

DECOMMISSIONING OF FACILITIES
IAEA Safety Standards Series No. GSR Part 6
STI/PUB/1652 (20 pp.; 2014)
ISBN 978–92–0–102614–9 Price: €25.00

REGULATIONS FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL, 2012 EDITION
IAEA Safety Standards Series No. SSR-6
STI/PUB/1570 (168 pp.; 2012)
ISBN 978–92–0–133310–0 Price: €44.00

PREPAREDNESS AND RESPONSE FOR A NUCLEAR OR RADIOLOGICAL EMERGENCY
IAEA Safety Standards Series No. GS-R-2
STI/PUB/1133 (72 pp.; 2002)
ISBN 92–0–116702–4 Price: €20.50

Safety through international standards

"Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them."

Yukiya Amano
Director General

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA
ISBN 978–92–0–102414–5
ISSN 1020–525X