

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



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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.

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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.

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JUSTIFICATION OF PRACTICES,
INCLUDING NON-MEDICAL
HUMAN IMAGING



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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

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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 measures¹ 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.

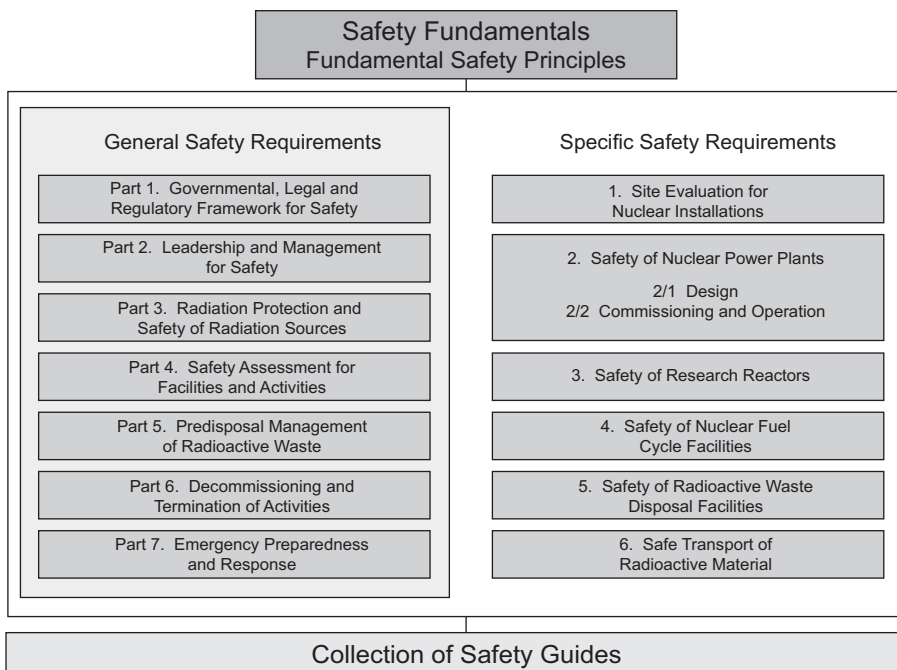


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

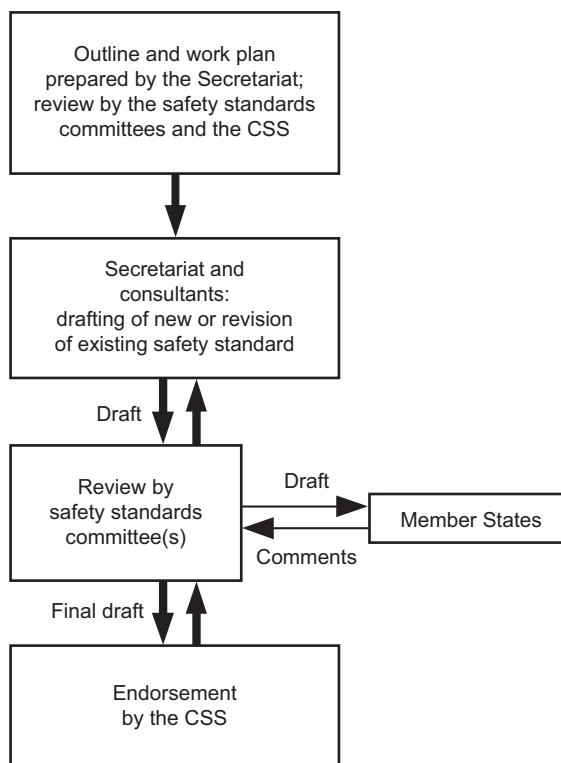


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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.

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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.