

IAEA Safety Standards

for protecting people and the environment

Radiation Safety for Consumer Products

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Specific Safety Guide

No. SSG-36



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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.

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.

RADIATION SAFETY FOR CONSUMER PRODUCTS



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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. SSG-36

RADIATION SAFETY FOR CONSUMER PRODUCTS

SPECIFIC SAFETY GUIDE

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2016

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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.

PREFACE

Requirements for the protection of people from harmful consequences of exposure to ionizing radiation, for the safety of radiation sources and for protection of the environment are established in the IAEA Safety Requirements for Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3). GSR Part 3 requires that each State establish an effectively independent regulatory body with legal authority to conduct the regulatory process.

Exemption from regulatory control is an essential prerequisite for authorization of the provision of consumer products to the public. This reflects the fact that consumer products have been approved for unregulated use because there is no individual or societal benefit to be gained by their regulatory control. Regulatory resources are often limited and must be used in a manner that ensures that the stringency of the control measures applied is commensurate with the risk being regulated, i.e. a graded approach to regulation. This Safety Guide describes how the regulatory body should apply the requirement for justification and apply the exemption criteria contained in Schedule I of GSR Part 3 as part of the decision making processes for consumer products.

This Safety Guide is jointly sponsored by the IAEA and the OECD Nuclear Energy Agency (OECD/NEA).

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.

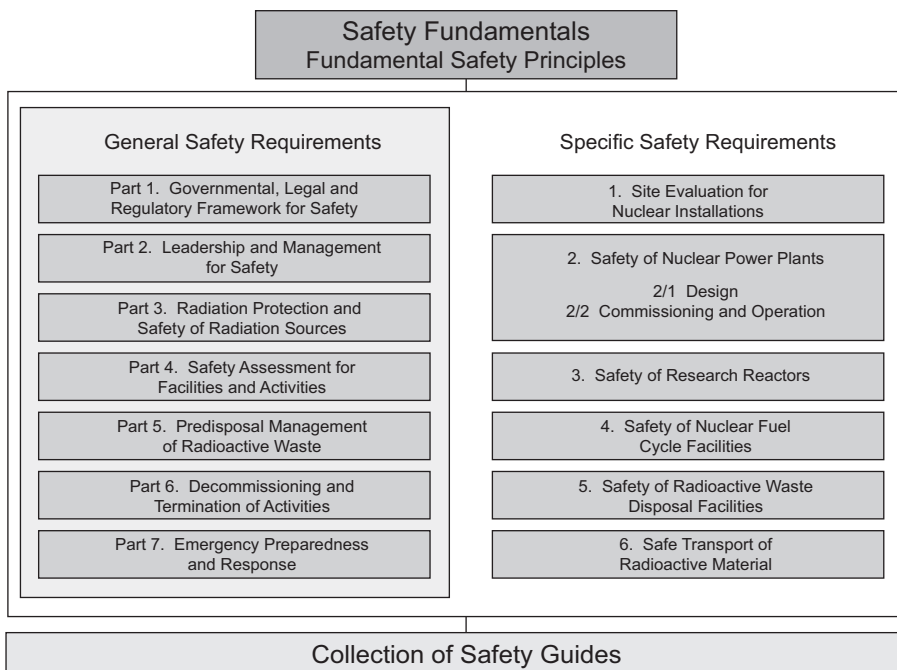


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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

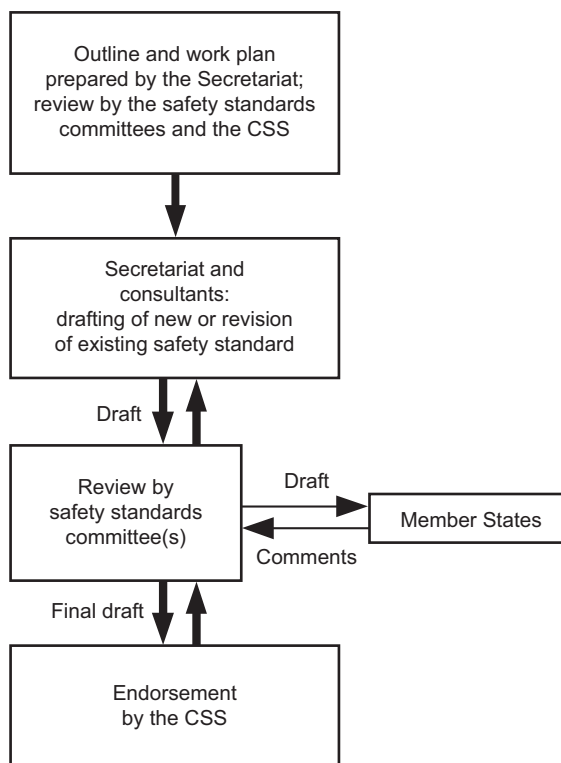


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. In the IAEA Safety Requirements publication on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3) [1], a ‘consumer product’ is defined for the purposes of the IAEA safety standards as:

“A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation [hereinafter referred to as ‘radiation’], and which can be sold or made available to members of the public without special surveillance or regulatory control after sale.”

Three distinct categories of consumer product can be identified:

- (1) Products to which small amounts of radionuclides have been added, either for functional reasons or because of their physical or chemical properties;
- (2) Equipment capable of generating radiation;
- (3) Products which, as a result of being intentionally exposed to radiation, contain activation products.

1.2. A number of different products to which small amounts of radionuclides have been added are currently widely available for use by members of the public and are marketed and sold around the world. These include:

- (a) Ionization chamber smoke detectors, in which the air between the electrodes is ionized by a radioactive source. In modern ionization chamber smoke detectors, the radionuclide ^{241}Am is used exclusively. Although some older ionization chamber smoke detectors that incorporate ^{85}Kr , ^{226}Ra , ^{238}Pu or ^{239}Pu may still be in use, these radionuclides have not been incorporated into ionization chamber smoke detectors for many years.

- (b) Radioluminous products using luminous paint or containing gaseous tritium light sources. These include items such as timepieces¹, navigational instruments (e.g. compasses), torches, fishing floats and novelty items (e.g. key rings). Some specialist devices such as weapon sights may also contain gaseous tritium light sources. The use of small, low activity gaseous tritium light sources in consumer products is expanding.
- (c) Thorium, ⁸⁵Kr and tritium are all used by the lamp industry to improve the metallurgical properties of electrodes, to optimize the light spectrum or to provide a starter aid in high intensity lamps or in older fluorescent lamps. High intensity lamps have applications as xenon car lighting and low wattage specialist lamps.

1.3. Other products to which small amounts of radionuclides have been added are less widely available but are still manufactured and sold in some States. These include:

- (a) Some electronic components such as voltage regulators, current surge protectors, spark gap irradiators and indicator lights containing small quantities of radionuclides, usually to cause ionization and promote current flow.
- (b) Gas mantles containing thorium, usually in the form of thorium nitrate. Although only thorium is initially present in a newly manufactured mantle, the amount of thorium progeny increases with time. In the last 20 years, gas mantle manufacturers have been switching to non-radioactive alternatives to thorium and as a result the availability of thoriated gas mantles has greatly declined, although some may still be available.
- (c) Thoriated tungsten welding electrodes used in tungsten inert gas welding techniques.
- (d) Glassware and tableware that may contain uranium compounds incorporated into the glass for the purpose of fluorescence.

¹ Nowadays, watches and clocks with non-radioactive luminous dials are available for sale to the public. The coating material most commonly used is a phosphorescent pigment on the basis of strontium aluminate doped with traces of europium and dysprosium ($\text{SrAl}_2\text{O}_4:\text{Eu,Dy}$). In contrast to radioluminescent paints, this material needs to be activated through exposure to sunlight or artificial light for just a few minutes. Following activation, its luminosity gradually fades and reaches the threshold of visibility to the eye after several hours. Watches with phosphorescent paints are therefore not a direct replacement for watches with radioluminescent paints in certain specialist applications.

- (e) Dental porcelains that contain incorporated uranium compounds used to impart fluorescence and improve the appearance of, for example, false teeth. Increasingly, non-radioactive alternatives are used and most dental porcelains now no longer contain any radionuclides.

1.4. Some historical consumer products incorporating radionuclides are no longer manufactured but may still be in use or available for purchase second hand. These include:

- (a) Static eliminators incorporating ^{210}Po or ^{241}Am used for removing dust from photographic negatives, vinyl records, camera lenses and spectacles.
- (b) Glass lenses containing uranium and thorium compounds, added at the time of manufacture to improve certain optical properties. Thorium compounds may also be used in surface coatings to reduce glare or increase reflectivity.
- (c) Miscellaneous products such as vending machine coins luminized with ^{14}C and identity cards luminized with ^{147}Pm .

1.5. Cathode ray tubes that were used in older televisions and computer monitors had the capability to produce X rays and were constructed in accordance with an international standard to ensure that external X ray emissions were negligible. In recent years, the cathode ray tube has been superseded by screens using a liquid crystal display, light emitting diodes and plasma technology, and X ray generating devices are not now generally available for purchase by members of the public.

1.6. The colour of gemstones may be intensified or altered by irradiation. This process can happen naturally over a long period of time, but artificial irradiation can also be used to enhance the colour of gemstones and thus to increase their commercial value. There are three different methods of artificially irradiating gemstones: gamma irradiation, irradiation with an electron beam in a linear accelerator and neutron irradiation in a nuclear (research) reactor. With electron beam irradiation and neutron irradiation, activation products in the form of radionuclides can be produced within the gemstone structure. The half-life of these activation product radionuclides is usually short, up to a few weeks, but some activation products have longer half-lives.

1.7. Neutron transmutation doping of single crystal silicon involves the irradiation of bulk amounts of high purity silicon in a thermal neutron flux and this is carried out in many nuclear research reactors [2]. The dopant, phosphorus, is produced by thermal neutron capture in ^{30}Si , transmuting it to the unstable radioisotope ^{31}Si , which subsequently decays to the stable isotope

^{31}P by beta decay with a half-life of 2.62 h. The thermal neutrons also interact with the ^{31}P to produce ^{32}P , which decays to ^{32}S with a half-life of 14 d. Annual worldwide production of doped silicon is of the order of 150 t. Doped silicon is used in a variety of electronic devices, such as transistors, diodes and integrated circuit chips. Neutron transmutation doping of gallium, germanium and selenium is also carried out, but is much less widely used. Storage prior to shipping is required to allow the induced radioactivity to decay. Doped silicon is not normally available directly to the public, but it is used in electronic products made available to the public.

1.8. Some consumer products may be sold directly to the public through commercial outlets, while others are intended for specialist use by professionals but may still be purchased by members of the public. For example, ionization chamber smoke detectors are sold in hardware stores and irradiated gemstones can be purchased from jewellers. Weapon sights are usually sold only under controlled conditions for military purposes in some States, but they may be freely purchased in others. Discharge lamps containing added radionuclides are routinely fitted in private cars, while other such discharge lamps have a specialist application as floodlights in sports arenas or as projection lamps in cinemas. Members of the public may thus be exposed to radiation as a consequence of the personal or professional use of these products or as a consequence of activities such as their transport, storage, recycling and disposal.

1.9. Exemption from regulatory control is an essential prerequisite for authorization of the provision of consumer products to the public. The relevant IAEA safety standards addressing this issue are Governmental, Legal and Regulatory Framework for Safety (GSR Part 1 (Rev. 1)) [3] and GSR Part 3 [1]. These publications include requirements for notification of a practice to the regulatory body and requirements for the authorization of a practice by the regulatory body. Provision is made for the exemption of practices from these and other regulatory requirements on the basis of general criteria given in GSR Part 3 [1] or any exemption levels specified by the regulatory body on the basis of these criteria. GSR Part 3 [1] applies to all facilities and all activities that give rise to radiation risks [4]. Activities include: the production, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities [4].

1.10. In the interest of harmonization of approaches among States, some guidance on justification and application of the criteria for exemption from regulatory

control for consumer products has been provided in a number of IAEA Safety Guides: Regulatory Control of Radiation Sources (GS-G-1.5) [5], Application of the Concepts of Exclusion, Exemption and Clearance (RS-G-1.7) [6] and Justification of Practices, Including Non-Medical Human Imaging (GSG-5) [7]. The process of justification and the application of the provisions for exemption to consumer products are not straightforward and this has resulted in different approaches being adopted in different States. The potential difficulty caused by adopting different approaches is a particular issue with regard to some very common consumer products, whose provision to the public is considered to be justified in some States but is prohibited in others. Inconsistencies in approaches may be a cause of confusion since the reasons for the differences between approaches would not be clear to the manufacturers and providers of products or to the public who might use them.

1.11. Further harmonization in the regulatory approaches in States is desirable for the application of the requirements for justification [1, 8] and the use of the exemption provisions in GSR Part 3 [1] in relation to the provision of consumer products to the public. Such consumer products may be marketed globally, and the lack of harmonization could be a cause of confusion among the public and others with regard to the risks posed by their use. In addition, greater consistency in regulatory approaches can assist regulatory bodies in the efficient and effective use of their resources on activities and practices that present more significant radiation risks. A more harmonized approach by regulatory bodies also has clear benefits for international trade.

OBJECTIVE

1.12. This Safety Guide is directed at regulatory bodies as well as at providers of consumer products containing small amounts of radionuclides, either deliberately added or produced by activation, or suppliers of equipment available to the public that is capable of generating radiation. Its principal objective is to provide recommendations and guidance on meeting the requirements for justification and optimization [1, 8] and for authorization of the provision of consumer products to the public. It also recommends how the provisions for exemption given in GSR Part 3 [1] are to be applied to products containing small amounts of radionuclides, radiation generators and products containing radionuclides as activation products. This Safety Guide considers both the administrative requirements and the radiation protection requirements established in GSR Part 3 [1]. Particular attention is given to the application of the requirement for justification because of the central role that this requirement plays

in exemption and in the authorization of the provision of a consumer product containing radionuclides. Account is also taken of the approach to the application of the concepts of exemption and clearance given in ICRP Publication 104 [9].

1.13. This Safety Guide also provides guidance on the construction and testing standards for certain consumer products.

SCOPE

1.14. The scope of this Safety Guide is restricted to finished products (i.e. not to components produced solely for further assembly)² that contain small amounts of radionuclides and for which exemption from regulatory control may be appropriate. These items may be destined either for individual or professional use. The Safety Guide addresses the decision making process to allow the manufacture or import of consumer products as well as the various stages of the life cycle of these items following manufacture, including transport, storage, provision, use, recycling and disposal. The Safety Guide also covers items (such as irradiated gemstones) in which radionuclides are produced by activation, which may also be provided to the public. Equipment that generates radiation and which may be purchased by the public is also covered, although no such items may currently be provided for sale to the public.

1.15. The following are outside the scope of this Safety Guide:

- (a) Occupational exposure in planned exposure situations, such as exposure of workers involved in the manufacture or assembly of consumer products or in the irradiation of gemstones in an authorized facility where such exposure is already subject to regulatory control.
- (b) Products and appliances installed in public places (e.g. exit signs and lightning conductors) and other items such as building materials, ceramic tiles, spa waters, minerals and foodstuffs, which are excluded from the definition of consumer products.
- (c) Products such as explosives and chemical detectors containing tritium, ^{63}Ni or ^{133}Ba , receiver protection devices (transmit/receive limiters) containing tritium used in radar communications and dust monitors containing ^{14}C , all of which are not normally available for provision to the public.

² Some consumer products provided directly to the public can also be used as components of other consumer products.

- (d) Practices involving the frivolous use of radiation or radioactive substances in products such as toys, cosmetics and personal jewellery or adornments, as well as human imaging using radiation performed as a form of art or for publicity purposes, which are deemed to be not justified.
- (e) Unirradiated gemstones containing naturally occurring radionuclides, as these are not covered by the definition of consumer products into which “radionuclides have deliberately been incorporated or produced by activation” [1].
- (f) Doped gallium, germanium, selenium and silicon, as these are not provided directly to the public. After incorporation into electronic components, the doped materials no longer have measurable levels of activity.

1.16. This Safety Guide will also be appropriate for application to any novel products for provision to members of the public that are developed in the future and that fall within the definition of consumer products given in para. 1.1.

STRUCTURE

1.17. Section 2 considers the system for protection and safety of the public, while the application of this system for consumer products is addressed in Section 3. Considerations in relation to consumer products to which small amounts of radionuclides have been added, either for functional reasons or because of their physical or chemical properties, are dealt with in Section 4. Considerations in relation to irradiated gemstones and other products containing activation products are addressed in Section 5. International approaches to improved harmonization of justification, authorization and exemption from regulatory control in relation to consumer products provided to the public are considered in Section 6.

1.18. A number of annexes are included in this Safety Guide. The first three annexes provide examples of how decisions on justification can be reached in relation to different consumer products. Annex IV contains a design, construction and performance standard for ionization chamber smoke detectors, which can be used as input to a decision on the exemption from regulatory control of their provision to the public. Annex V provides information on the radiation doses that might typically be received by members of the public from normal use, incidents, misuse and disposal of ionization chamber smoke detectors. Annex VI contains a national standard for consumer products containing gaseous tritium light sources, which can be used when considering their exemption from regulatory control. In Annex VII, Annex VIII and Annex IX, information on the

safety related aspects of thoriated tungsten welding electrodes and gemstone irradiation technologies is provided in support of the recommendations and guidance given in Section 5.

2. THE SYSTEM FOR PROTECTION AND SAFETY OF THE PUBLIC

GENERAL

2.1. Consumer products that fall within the scope of this Safety Guide can be produced in different ways:

- (a) Radionuclides may be added for functional reasons or because of particular physical or chemical properties as part of the manufacturing process of particular items. The radionuclides will normally have a relatively long half-life, which allows the item in question to continue to function throughout its expected lifetime. Exposure of the public may therefore occur throughout the operational lifetime of the product and also after its disposal.
- (b) Radiation generators or electronic tubes capable of producing radiation may be incorporated into more complex equipment or devices at the time of manufacture. However, exposure of the public is usually possible only when the device is energized.
- (c) Electron beam irradiation or neutron irradiation can result in the production of activation products in the form of radionuclides. At present, the only consumer products known to undergo such irradiation are gemstones. Depending on the chemical composition of the gemstone, different activation product radionuclides with different half-lives will be produced. The associated dose rate, and therefore the potential for exposure of members of the public, will decrease with time following irradiation.

2.2. The manufacture of consumer products involving the addition of radionuclides is a planned exposure situation³ that may require authorization by the regulatory body. In some instances, the repair and maintenance of consumer

³ A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source [1].

products may also require authorization. Such practices are subject to the requirements that apply the three fundamental safety principles of justification, optimization of protection and safety, and limitation of doses [1, 8]. Dose limits apply to the occupational exposure of workers involved in the manufacturing process and to members of the public who could be exposed as a result of either activities at the facilities in question or authorized discharges.

2.3. The manufacture of radiation generators or electronic tubes capable of producing radiation such as X rays, neutrons, electrons or other charged particles is also a planned exposure situation subject to the requirements for radiation protection.

2.4. The irradiation of gemstones either by electron beams or by neutrons may take place in a facility that is specifically designed and constructed for that purpose, or in a facility that has other applications. For example, a research reactor in which gemstones are irradiated may be used for the production of radionuclides for use in medicine, neutron activation analysis and materials research. A new (planned) facility for the irradiation of gemstones is subject to the same authorization process as any other facility in which sources of radiation are present. In the case of an existing facility, use of the facility for any new practice, such as the irradiation of gemstones, is also required to be authorized by the regulatory body. In all cases, the facility is subject to the requirements applying the three fundamental safety principles of justification of practices, optimization of protection and safety, and compliance with dose limits [1, 8].

2.5. The colour of gemstones can also be enhanced by irradiation with gamma rays, normally using ^{60}Co . However, such exposure does not induce activation products in the irradiated gemstones. A facility in which gamma irradiation of gemstones takes place would be required to be authorized and regulated. The requirements of GSR Part 3 [1] relating to planned exposure situations would apply.

2.6. The approach to radiation safety for consumer products outlined in this Safety Guide should also be applied to certain goods that are intended for use in places such as cinemas or sports arenas to which the public may have access but which are not consumer products in the sense given to the term in GSR Part 3 [1]. Those workers who handle, install and maintain such products are required to have the same level of protection against such exposure as members of the public, unless the regulatory body decides otherwise (GSR Part 3 [1], para. 3.78).

2.7. Requirements for protection and safety specific to occupational exposure in planned exposure situations are established in paras 3.68–3.116 of GSR Part 3 [1]. Occupational exposure in planned exposure situations is outside the scope of this Safety Guide (see para. 1.15) and is not considered here. Recommendations and guidance are provided on meeting the requirements in GSR Part 3 [1] on applying the graded approach (para. 3.6), on notification and authorization (paras 3.7–3.9), on exemption (paras 3.10 and 3.11), on justification of practices (paras 3.16–3.21), on optimization of protection and safety (paras 3.22–3.25) and on safety assessment (paras 3.29–3.36), as they all apply to consumer products, as well as the responsibilities of the government, the regulatory body and relevant parties specific to public exposure due to consumer products (paras 3.118, 3.125 and 3.138–3.144).

JUSTIFICATION

2.8. The principle of justification is one of the fundamental safety principles [8]. Paragraph 1.13 of GSR Part 3 [1] states that “The operation of facilities or the conduct of activities that introduce a new source of radiation, that change exposures or that change the likelihood of exposures has to be justified in the sense that the detriments that may be caused are outweighed by the individual and societal benefits that are expected”. This concept is not unique to radiation safety. Decisions concerning the adoption of a particular human activity involve a balancing of costs (including detriments) and benefits. Often, this balancing is done implicitly. GSR Part 3 [1], however, explicitly requires a demonstration of a positive net benefit before a practice can be authorized by the regulatory body. Recommendations and guidance on meeting the requirements for justification are provided in a separate Safety Guide [7].

2.9. GSR Part 3 [1] requires that only justified practices be authorized. Paragraph 3.16 [1] 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.” The government or regulatory body should first determine whether a particular practice is justified. Consideration should be given to authorization only if the practice is justified.

2.10. The criteria for exemption should be applied only to those practices that are deemed to be justified. This means that although provision is made in GSR Part 3 [1] for exemption from the regulatory requirements of practices

that pose a trivial level of risk, justification for such practices should first be demonstrated.

2.11. It is recognized that States may arrive at different outcomes on applying the requirements for justification. For example, as part of the decision making process, the availability and affordability of alternative materials and devices should be considered, which may differ between States. Such economic factors, as well as the need to make value judgements as part of any decision on justification, mean that certain practices may be deemed to be justified in some States but not in others.

GRADED APPROACH

2.12. The IAEA safety standards emphasize the importance of a graded approach in the regulation of facilities and activities. In particular, the general safety requirements in para. 4.5 of GSR Part 1 (Rev. 1) [3] require that “The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach”, adding that “for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control”.

2.13. Not all practices represent the same level of risk and, as stated in Requirement 6 of GSR Part 3 [1], the application of requirements in planned exposure situations is required to be “commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.” There is a further requirement to “ensure that a graded approach is taken to the regulatory control of radiation exposure” (GSR Part 3 [1], para. 2.18) and the regulatory body is specifically required to “adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation” (GSR Part 3 [1], para. 2.31).

2.14. The requirement on using a graded approach should be applied for both occupational exposure and public exposure. A graded approach represents an effective use of the often limited resources of the regulatory body in that greater attention and resources are focused on those practices that represent the more significant risks. Registrants and licensees should also apply a graded approach to those activities for which they are authorized.

NOTIFICATION AND AUTHORIZATION

2.15. The requirement to apply a graded approach is reflected in the requirements in GSR Part 3 [1] relating to regulatory infrastructure. These are, in decreasing order of rigour of regulatory control, authorization⁴ by licensing, authorization by registration, notification and exemption.

2.16. Practices that pose or are likely to pose relatively high radiation risks should be subject to a system of authorization by means of licensing. This requires a detailed safety assessment (see paras 2.36–2.39 in this Safety Guide) to be carried out prior to the issuing of a licence by the regulatory body. In addition, the licence should state the detailed conditions that the operator (the licensee) is required to meet and the practice should be subject to relatively frequent inspections by the regulatory body.

2.17. Authorization by means of registration should be applied to practices of low to moderate radiation risk. The requirements for safety assessment should be less stringent than those for authorization by licensing. Such authorizations should be accompanied by conditions or limitations with which the operator (the registrant) is required to comply, but again they are unlikely to be as stringent as the conditions stated in licences. Typical practices that are amenable to registration are those for which:

- (a) Safety can largely be ensured by the design of the facilities and equipment;
- (b) The operating procedures are simple to follow;
- (c) The requirements for training in safety are minimal;
- (d) There is a history of few problems with safety in operations.

Authorization by means of registration is best suited to those practices for which operations do not vary significantly. Normally, registration should only be considered if the operating conditions for the practice are laid down in general legislative or administrative provisions.

⁴ Authorization is defined as “The granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities” [1].

2.18. Notification of the regulatory body by a person or organization intending to undertake a practice is required in GSR Part 3 [1]. The regulatory body may decide that notification alone is sufficient (i.e. authorization is not required) provided that “the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible” (GSR Part 3 [1], para. 3.7).

2.19. Paragraph 3.7 of GSR Part 3 [1] also states that “Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal”. This requirement recognizes that the use of consumer products by members of the public is effectively beyond regulatory control and no notification of use is required. However, any person or organization intending to carry out any of the practices specified in the requirement should notify the regulatory body of their intention to do so. The regulatory body should then consider whether authorization of any of these practices is necessary, taking into account the nature of the product, the associated risks and the prospective individual doses identified in the safety assessment.

2.20. Decisions by the regulatory body in relation to authorization should be consistent with the graded approach. For example, the irradiation of gemstones can involve very high dose rates and, immediately after the irradiation, the activity concentrations of many radionuclides are likely to exceed, by a large margin, the exemption values in GSR Part 3 [1]. In such circumstances, authorization by licensing would clearly be appropriate. However, the assembly of ionization chamber smoke detectors may only involve the fitting of preconstructed ionization chambers into the circuitry and plastic structure of the detectors. In this situation, the potential for large radiation doses to be received either by workers or by members of the public is small and the regulatory body may decide only to require authorization by registration in line with the application of the graded approach.

2.21. The regulatory approach in many States does not always make a distinction between authorization by licensing and authorization by registration and often there is no provision for notification alone. In fact, in some States ‘licensing’ may be the only term that is used. While the use of the separate terms — authorization by licensing, authorization by registration and notification — provides clarity, the three possibilities should not necessarily all be used. The regulatory body should use a graded approach to ensure that it assigns its limited resources in an

appropriate way, focusing its efforts on those practices that pose the highest radiation risks. The regulatory body should also ensure that a graded approach is applied by the principal parties⁵.

EXEMPTION

2.22. Once the regulatory body is notified of the intention to carry out a practice that is deemed to be justified, it may decide to exempt the practice or sources within the practice from some or all aspects of regulatory control. Exemption should be considered part of the graded approach to regulation in that exemption is less restrictive than either authorization or notification, but it still requires a decision to be made by the regulatory body.

2.23. The general criteria for exemption are stated in para. I.1 in Schedule I of GSR Part 3 [1], namely that:

- “(a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or
- (b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.”

2.24. These criteria are subjective in nature and, taken on their own, require value judgements to be made by the regulatory body. Paragraph I.2 of GSR Part 3 [1] clarifies what is meant by radiation risks being sufficiently low by stating that “A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Standards under the terms of para. I.1(a) provided that under all reasonably foreseeable circumstances

⁵ As stated in para. 2.40 of GSR Part 3 [1]:

“The principal parties responsible for protection and safety are:

- (a) Registrants or licensees, or the person or organization responsible for facilities and activities for which notification only is required;
- (b) Employers, in relation to occupational exposure;
- (c) Radiological medical practitioners, in relation to medical exposure;
- (d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.”

the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.” The individual dose criterion for low probability scenarios is based on the assumption that the probability of occurrence does not exceed 0.01 per year [10].

2.25. The establishment of dose criteria for reaching a decision on exemption of a practice from regulatory control assists the regulatory body in achieving a consistent approach to the protection of workers and the public from radiation risks. By applying the same dose criteria, greater consistency among States is to be expected. If the dose criteria defined in para. I.2 of GSR Part 3 [1] are met, then the associated practice, or the source within that practice, should be exempted without further consideration.

2.26. Paragraph I.2 of GSR Part 3 [1] also states that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the exempt practice or the exempt source within the practice is normally evaluated on the basis of a safety assessment. The carrying out of a safety assessment can be expensive and time consuming and, in situations where expected exposures are likely to be extremely low, it may be unnecessary. To further assist regulatory bodies, specific values of total activity and activity concentration for a wide range of radionuclides of both natural origin and artificial origin have been developed [1, 6, 10, 11]. Values have been derived for both moderate quantities and bulk amounts of material. The calculations are based on the evaluation of a set of typical exposure scenarios encompassing external irradiation, dust inhalation and ingestion [12]. Consequently, if “the total activity of an individual radionuclide present on the premises at any one time or the activity concentration as used in the practice does not exceed the applicable exemption level” (para. I.3(a) of GSR Part 3 [1]), then the individual effective dose in a year will not exceed 10 μSv and the practice may be exempted without further consideration from the requirements of GSR Part 3 [1].

2.27. Many States have found the derived values of total activity and activity concentration to be particularly useful and have adopted them in national legislation. As is the case for the dose criteria referred to in para. 2.24, these derived values should be used by the regulatory body to exempt a practice or a source within a practice from regulatory control without the requirement to conduct a safety assessment. While it is envisaged that such exemption

should be granted automatically, the regulatory body should satisfy itself that the exposure scenarios used to calculate the derived values of activity and activity concentration are representative of the practice within the State. This will usually be the case, and only in exceptional circumstances should the regulatory body require additional scenarios to be considered.

2.28. From a regulatory viewpoint, the existence and application of predefined numbers to be used for taking decisions on exemption has obvious benefits in that they are easy to apply. Applying predefined numbers also increases the likelihood of consistency on the part of the regulatory body and between regulatory bodies in different States. However, to rely on numerical values alone would remove the need for the regulatory body to use its own judgement in taking such decisions and would undermine the considerable flexibility afforded to regulatory bodies by GSR Part 3 [1]. For example, these numerical values relate only to the first general criterion dealing with radiation risks and do not address the second criterion of whether regulatory control would give rise to a net benefit in terms of reduction in individual exposures or in any health risks. The regulatory body should still consider this second criterion in situations where either the derived values of activity and activity concentration are exceeded or a safety assessment shows that the 10 μSv individual dose criterion may not be met in all scenarios. For this reason, the regulatory body should consider the derived values of total activity and activity concentration, as well as the 10 μSv individual dose criterion, as important contributors to a decision on exempting a given practice from regulatory control. However, these criteria alone may provide an insufficient basis for a final decision.

2.29. Paragraph I.3(c) of GSR Part 3 [1] also provides for automatic exemption without further consideration of:

- “(c) Radiation generators of a type approved by the regulatory body, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:
 - (i) They do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 $\mu\text{Sv/h}$ at a distance of 0.1 m from any accessible surface of the equipment; or
 - (ii) The maximum energy of the radiation generated is no greater than 5 keV.”

2.30. Paragraph I.6 of GSR Part 3 [1] allows for the granting of exemptions:

“Exemptions may be granted subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal. In particular, such an exemption may be granted for equipment containing radioactive material that is not otherwise automatically exempted without further consideration from some or all of the requirements of these Standards under para. I.3(a) provided that:

- (a) The equipment containing radioactive material is of a type approved by the regulatory body.
- (b) The radioactive material:
 - (i) Is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or
 - (ii) Is in the form of an unsealed source in a small amount such as sources used for radioimmunoassay.
- (c) In normal operating conditions, the equipment does not cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 $\mu\text{Sv/h}$ at a distance of 0.1 m from any accessible surface of the equipment.
- (d) Necessary conditions for disposal of the equipment have been specified by the regulatory body.”

2.31. This is the so-called ‘type approval’, by which the regulatory body can exempt certain instruments or equipment from regulatory control under very specific conditions. Normally instruments or equipment exempted from regulatory control should comply with a national or international standard, for example those published by the International Organization for Standardization (ISO). While the exemption can be based on the external dose rate at a distance of 0.1 m from the surface of the device, the regulatory body should also take fully into account the outcome of a safety assessment. If the safety assessment indicates that much higher dose rates would be possible in the event of, for example, dismantling of the device or its incineration, then exemption from regulatory control may not be appropriate.

2.32. This provision in GSR Part 3 [1] for the exemption of equipment containing sealed radioactive sources can be applied to consumer products. While there is a limit on dose rate outside the equipment, no limit applies to the activity of the sealed source. Thus, for example, ionization chamber smoke detectors with higher levels of activity than those specified for exemption without further

consideration can be exempted provided that the conditions stipulated by the regulatory body in respect of dose rate and other criteria are met and they are of a type approved by the regulatory body.

2.33. There is no specific reference in GSR Part 3 [1] to procedures for exemption of irradiated products containing radionuclides produced by activation. However, from a regulatory point of view, there is no reason to treat such products any differently from products to which radionuclides have been added in the manufacturing process. As such, the regulatory body should apply the general criteria for exemption, as well as the individual dose criterion and the derived values of total activity and activity concentration, in deciding whether or not to exempt such products from regulatory control. The application of these criteria to irradiated gemstones is discussed in Section 5.

OPTIMIZATION OF PROTECTION AND SAFETY

2.34. Demonstration of net benefit is not in itself sufficient for a practice to be authorized. Paragraph 3.22 of GSR Part 3 [1] also requires the government or regulatory body to “establish and enforce requirements for the optimization of protection and safety” while para. 3.23 states “Registrants and licensees shall ensure that protection and safety is optimized.”

2.35. Optimization of protection and safety is the process of deciding on the level of protection and safety that is required to be applied in order to obtain the maximum net benefit. Thus, both justification of a practice and optimization of the measures for protection and safety that should be applied in the practice involve the balancing of radiological detriment against benefit. The former, however, simply requires there to be a positive net benefit, while the latter requires that the net benefit should be maximized. This means that the level of protection and safety should be the best possible under the prevailing circumstances. Optimization is especially important, and should be fully taken into account, in the design and manufacture of consumer products, particularly with regard to the choice of radioactive source that is to be used and its activity.

SAFETY ASSESSMENT

2.36. Requirements in relation to safety assessment apply to the regulatory body, to persons or organizations intending to carry out activities that give rise to radiation risks and to registrants and licensees. The regulatory body is required

to be responsible for establishing the requirement for a safety assessment to be carried out and to review and assess the safety assessment prior to granting an authorization. Persons or organizations intending to carry out activities that give rise to radiation risks and registrants and licensees are required to “conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible” (see GSR Part 3 [1], para. 3.30).

2.37. The regulatory body should also apply the graded approach in establishing the requirement for a safety assessment to be carried out. Practices that represent a higher degree of radiation risks should require a more detailed safety assessment than those with a much lower level of radiation risks. Even if the level of radiation risks is thought to be trivial, a safety assessment should still be required to show that this is indeed the case. This applies only on the first occasion that the justification of a particular practice is being considered and the decision of the regulatory body should not necessarily be reviewed for subsequent applications, except as recommended in para. 2.39 in this Safety Guide. However, as described in paras 2.26 and 2.27, in situations where the derived values of activity or activity concentration are not exceeded, a safety assessment should not be required. Provided that the practice has previously been deemed to be justified, the sources should be exempted from regulatory control without further consideration.

2.38. Safety assessments are required to be conducted so as “To determine the expected likelihood and magnitudes of exposures in normal operation and, to the extent reasonable and practicable, to make an assessment of potential exposures” (see GSR Part 3 [1], para. 3.31(b)). This has a particular relevance to consumer products, for which an individual dose of 10 μSv is one of the criteria to be used in deciding on the exemption of practices from regulatory control.

2.39. Registrants and licensees are required to perform additional reviews of the safety assessment as necessary under certain circumstances (see GSR Part 3 [1], para. 3.35). In the case of consumer products, a review of the safety assessment could result in a decision by the regulatory body that their provision to the public no longer meets the criteria for exemption and, as such, that the manufacture of such products is no longer justified.

3. APPLYING THE SYSTEM FOR PROTECTION AND SAFETY TO CONSUMER PRODUCTS

GENERAL

3.1. Although the processes of justification and authorization are separate and distinct, some regulatory bodies may decide to combine the two subjects into one application process, while others may treat them as two completely separate processes, possibly dealt with by different national authorities. For clarity, the two processes, as they apply to consumer products, are described separately here.

JUSTIFICATION

3.2. Prior to initiating the manufacture and provision to the public of a new type of consumer product that incorporates radionuclides, the manufacturer should notify the regulatory body of its intention and should seek a decision on the justification of the proposed practice.

3.3. While para. 3.16 of GSR Part 3 [1] requires the government or regulatory body to ensure that provision is made for the justification of any type of practice, decisions on justification in relation to consumer products should normally be deferred to the regulatory body. This is because of the relatively low level of risk to the public that consumer products are likely to present.

3.4. Determination of the justification of the manufacture and provision to the public of consumer products should be undertaken by the regulatory body prior to considering an application for authorization. If the practice is deemed to be not justified, the question of authorization does not arise and the person or organization submitting the notification should be so informed. GSR Part 3 [1] does make provision for the review of justification, however. This should be taken to mean the review of decisions that a particular practice is not justified as well as the review of decisions that a particular practice is justified (see paras 3.13 and 3.14 in this Safety Guide).

3.5. The justification procedure should consider all aspects of the practice, including manufacture, assembly, transport, provision, use by members of the public and disposal. It follows that in addressing the justification of a particular consumer product, one stage of the practice should not be considered in isolation from the end use of the product by members of the public. For example, it makes

no sense to decide that the manufacture of a given consumer product is justified and then, at a later stage, to decide that its provision to the public is not justified (see para. 3.7 in this Safety Guide).

3.6. Alternative methods that do not involve the use of radiation, but that achieve the same or similar objectives for consumer products may exist. If so, the alternative methods should be taken into account in reaching a decision on justification. The mere existence of an alternative technique should not be taken as a reason for deciding that the type of practice involving the use of radiation is not justified. Nevertheless, if comparisons with such alternative methods are necessary, they should be undertaken with appropriate caution. Alternative methods are unlikely to be without detriment and may not achieve entirely the same benefit.

3.7. If the use of a particular consumer product is considered to be not justified, then it follows that the other stages — manufacture, import, transport, etc. — are also not justified (see para. 3.5 in this Safety Guide). This is essential to ensure that clarity is maintained about how the requirement for justification is to be applied for consumer products. In particular, it is important to maintain the focus, first and foremost, on the intended use of the consumer product and the benefit from that use. If the use of a particular consumer product is considered to be justified, then it should normally follow that the other stages, such as manufacture, import and transport, are also justified.

3.8. While every effort should be made to ensure objectivity in the evaluation of justification, this may not always be easy to achieve. One of the reasons for this is that it is often not possible to quantify both costs and benefits in terms of units that are directly comparable, such as in money terms. For this reason, the determination of benefits normally involves making a judgement on behalf of society. To try to overcome difficulties associated with making such judgements, the regulatory body should establish a mechanism for obtaining input from individuals or bodies reflecting societal interests. As stated in para. 3.16 of GSG-5 [7]:

“...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.”