UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-13-008, January, Other, IAEA DS458)

January 11, 2013

ALL AGREEMENT AND NON-AGREEMENT STATES STATE LIAISON OFFICERS

OPPORTUNITY TO REVIEW AND COMMENT ON INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA) DRAFT SAFETY GUIDE DS458, "RADIATION PROTECTION AND REGULATORY CONTROL FOR CONSUMER PRODUCTS" (FSME-13-008)

Purpose: To provide States with the opportunity to review and comment on the Draft Safety Guide DS458, "Radiation Protection and Regulatory Control for Consumer Products." We would appreciate receiving any comments[1,2,3] by February 28, 2013.

Background: The objective of Draft Safety Guide DS458 is to provide recommendations for the application of the requirements concerning the system of regulatory control for consumer products. The Draft Safety Guide considers how the principle of justification and the criteria for exemption should be applied to the regulatory control of consumer products.

1 This information request has been approved by OMB 3150-0029, expiration 11/30/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

2 This information request has been approved by OMB 3150-0200 expiration 09/30/2015. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

3 This information request has been approved by OMB 3150-0163, expiration 01/31/2013. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Discussion: NRC has been provided the Draft Safety Guide DS458, “Radiation Protection and Regulatory Control for Consumer Products” for Member State review and comment. Enclosed is: (1) communication from the IAEA concerning this document and its review, including an “Explanatory Note” regarding this document; (2) Draft Safety Guide, DS458, “Radiation Protection and Regulatory Control for Consumer Products;” and (3) a blank template for comment preparation.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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/RA PHenderson for /

Brian J. McDermott, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:
1. Explanatory Note from IAEA
2. DS458
3. IAEA Comments Template

IAEA

Atoms for Peace

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国际原子能机构
International Atomic Energy Agency
Agence internationale de l'énergie atomique
Международное агентство по атомной энергии
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In reply please refer to: J5.03.01
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The Secretariat of the International Atomic Energy Agency (IAEA) presents its compliments to the Ministries of Foreign Affairs of its Member States and has the honour to request that they draw the attention of the appropriate governmental authorities to the following draft safety standard:

Radiation Protection and Regulatory Control for Consumer Products
(DS458)

Member States and their experts are hereby provided with an opportunity to review and evaluate this draft safety standard, which is available online at:

http://www-ns.iaea.org/standards/documents/draft-ms-posted.asp

A hard copy of the document will be sent out upon request.

Any proposed changes to this document resulting from the review by Member States will be taken into account in the finalization of the safety standard.

Comments on the document should be provided in accordance with the guidance given in the attached Explanatory Note.

The Secretariat of the International Atomic Energy Agency avails itself of this opportunity to assure the Ministries of Foreign Affairs of its Member States of its highest consideration.

2012-12-27

Enclosures: Explanatory Note
Form for Comments
Statement by the Commission on Safety Standards
Process Flow

M-12/Rev. 8 (Sept 09)

Explanatory Note

Radiation Protection and Regulatory Control for Consumer Products (DS458)

The document for review, entitled ***Radiation Protection and Regulatory Control for Consumer Products***, was prepared as a draft Safety Guide to form part of the IAEA Safety Standards Series and has already been reviewed through consultants' meetings, as well as by the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC) and the Waste Safety Standards Committee (WASSC).

The objective of this document, as accepted by the Commission on Safety Standards (CSS), is to provide recommendations for the application of the requirements concerning the system of regulatory control for consumer products[1] laid down in ***Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards — Interim Edition*** (IAEA Safety Standards Series No. GSR Part 3 (Interim), Vienna, 2011).

The document considers how the principle of justification and the criteria for exemption should be applied to the regulatory control of consumer products. The approach adopted assigns these responsibilities to the regulatory body of the State in which these products are manufactured or into which they are to be imported. A harmonized approach, whereby consumer products that are authorized for supply to the public in one State are automatically authorized in other States, is advocated.

Comments are requested in relation to:

- Relevance and usefulness — Are the stated objectives appropriate, and are they met by the document?
- Scope and completeness — Is the stated scope appropriate, and is it adequately covered by the document?
- Quality and clarity — Do the requirements/guidance in the document represent the current consensus among specialists in the field, and are they expressed clearly and coherently?

Comments of an editorial nature will be considered; however, it should be noted that the document will be comprehensively edited by the IAEA Secretariat prior to its final submission to the CSS for endorsement.

Any comments made should be in English, should refer to the relevant paragraph number in the document being reviewed, and when appropriate should propose alternative text. Please use the attached Form for Comments to record all comments.

The responsible IAEA officer is Mr Tony Colgan of the Department of Nuclear Safety and Security. He may be contacted for further information in connection with this subject by telephone at: +43 1 2600 22744 or via email at: T.Colgan@iaea.org.

Any comments should be sent through the established official channels to the responsible IAEA officer by **30 April 2013**.

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[1] A consumer product is defined in the International Basic Safety Standards as "a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale".

Radiation Protection and Regulatory Control for Consumer Products (**DS458**)

COMMENTS BY REVIEWER Reviewer: Country/Organization:			Page.... of.... Date:	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

Statement by the Commission on Safety Standards

Publications in the IAEA Safety Standards Series are prepared and reviewed in accordance with a uniform process. To this end, the Commission on Safety Standards (CSS) and four committees with harmonized terms of reference — the Nuclear Safety Standards Committee (NUSSC), the Radiation Safety Standards Committee (RASSC), the Waste Safety Standards Committee (WASSC) and the Transport Safety Standards Committee (TRANSSC) — were established in 1996. The CSS has a special overview role with regard to the IAEA's safety standards and provides advice to the Director General on the IAEA's overall programme with regard to regulatory aspects of safety.

The uniform preparation and review process involves organizing expert group meetings; arranging at different stages of preparation for the internal review of draft texts; submitting documents to the relevant Committee(s) for review; submitting draft texts to the IAEA's Member States for comment; and submitting the approved final draft of the safety standard[1] for endorsement by the CSS before publication (see the flow diagram overleaf).

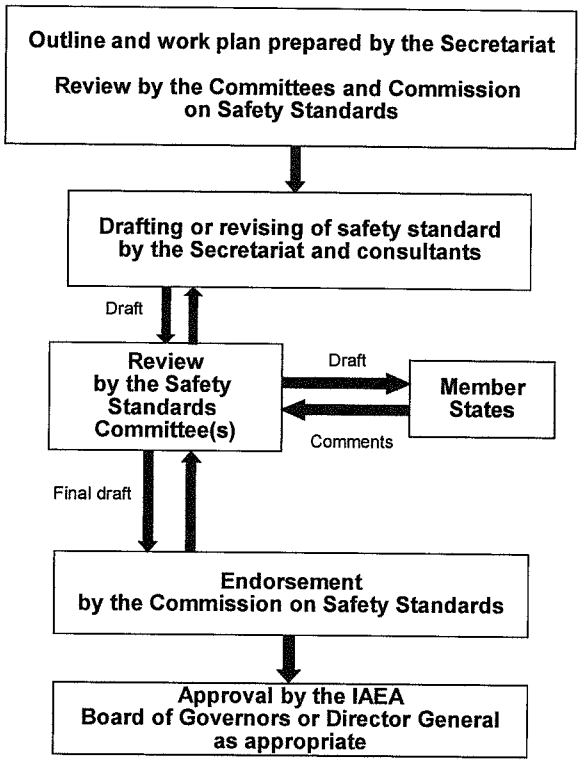
The CSS stresses the importance of Member States' comments to the preparation and review process for safety standards. Publications in the IAEA Safety Standards Series not only should be of the requisite quality but also should represent the consensus view of the Member States and should address the issues of importance to the Member States. While the CSS, the Committees and the Secretariat strive to provide safety standards that satisfy these criteria, the review of draft standards by experts in the Member States is an essential stage in obtaining the broadest possible technical consensus and the highest possible quality and relevance.

Member States are also encouraged to provide the IAEA with feedback on their use of the safety standards. The status of safety standards extant and in preparation can be seen on the IAEA's website, where there are also links to electronic files for existing publications, including those in other official languages.[2] The responsible IAEA officer is Mr Dominique Delattre, Head of the Safety Standards and Application Unit of the Department of Nuclear Safety and Security. He may be contacted for further information in connection with this subject by telephone at: + 43 1 2600 22696 or via email at: D.Delattre@iaea.org.

[1] Safety Guides are published under the authority of the Director General. Safety Fundamentals and Safety Requirements publications require the approval of the Board of Governors, after endorsement by the CSS.

[2] See http://www-ns.iaea.org/committees/files/CSS/205/status.pdf.

Process Flow for the Development of IAEA Safety Standards



DS458

Draft 3.6

IAEA SAFETY STANDARDS

for protecting people and the environment

Status: updated based on comments received from SSCs - November 2012

Sent to Member States for 120-day comment.
Deadline for comments: 30 April 2013

Radiation Protection and Regulatory Control for Consumer Products

DRAFT SAFETY GUIDE

No. DS458

New Safety Guide

IAEA
International Atomic Energy Agency

FOREWORD

by

Director General

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. In the IAEA safety standard on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (Interim Edition) [1], a consumer product is defined as "a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing 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 radioactive material have been added either for functional reasons or because of its physical or chemical properties;

(2) Equipment capable of generating ionizing radiation;

(3) Products which, as a result of being intentionally exposed to ionizing radiation, contain activation products.

1.2. A number of different products to which small amounts of radioactive material 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 (ICSDs) in which the air between the electrodes is ionized by a radioactive source. In the modern ICSD, the radionuclide ^{241}Am is used exclusively. Some old ICSDs that incorporate ^{85}Kr, ^{226}Ra, ^{238}Pu or ^{239}Pu may still be in use, although these radionuclides have not been incorporated in ICSDs for many years;

(b) Radioluminous products using luminous paint or containing gaseous tritium light sources (GTLSs). These include items such as timepieces, navigational instruments (e.g. compasses), torches, fishing floats and some novelty items (e.g. key-rings). Some specialist devices such as weapons sights may also contain tritium light sources. The use of small, low activity GTLSs in consumer products is an expanding market;

(c) ^{232}Th, ^{85}Kr and tritium are all used by the lamp industry either to improve electrode metallurgical properties, to optimize the light spectrum or to provide a starter aid function either 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 radioactive material have been added are less widely available but are still manufactured and sold in some Member States. These include:

(a) Some electronic components such as voltage regulators, current surge protectors, spark gap irradiators and indicator lights, which contain small quantities of radioactive material, usually to cause ionization and promote current flow;

(b) Gas mantles containing thorium, normally 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 (TIG) welding techniques;

(d) Glassware and tableware that may contain uranium compounds incorporated into the glass for the purpose of fluorescence; and

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

1.4. Some historical consumer products incorporating radioactive material are no longer manufactured but may still be in use or available for purchase in second hand shops. 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 are also used in surface coatings to reduce glare; and

(c) Miscellaneous products such as vending machine coins luminized with ^{14}C and identity cards luminized with ^{147}Pm.

1.5. Cathode ray tubes used in televisions and computer monitors have the capability to produce X radiation and are constructed in accordance with an international standard to ensure that external X ray emissions are negligible. In recent years the use of cathode ray tubes has been almost completely superseded by LCD, LED and plasma screens, and no X ray generating devices are currently 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 or neutron irradiation in a nuclear (research) reactor. With electron beam and neutron irradiation, radioactive material in the form of activation products can be produced within the gemstone structure. The half-life of these activation products is normally short, i.e. of the order of a few weeks, but some activation products have longer half-lives.

1.7. Neutron transmutation doping (NTD) of single crystal silicon involves the irradiation of bulk amounts of high purity silicon in a thermal neutron flux and is carried out in many nuclear research reactors [2]. The dopant, phosphorous, 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 and the doped silicon is used in a variety of electronic devices, such as transistors, diodes, and integrated circuit (IC) chips. NTD 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 normally not available for supply directly to the public.

1.8. Some consumer products may be supplied 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, ICSDs are on sale in many hardware stores worldwide and irradiated

gemstones can be purchased from many jewellers. On the other hand, weapons sights are normally only sold under controlled conditions for military purposes in some Member States, but may be freely purchased in others. Discharge lamps containing added radioactive material are routinely used in private cars while others have a specialist application as floodlights in sports arenas and projection lamps in cinemas. Thus, members of the public may be exposed to ionizing radiation as a consequence of the personal or professional use of these products or activities[1] such as their transport, storage, recycling and disposal.

1.9. The IAEA safety standards provide the basic requirements for regulatory control of such products. The most relevant documents are the Governmental, Legal and Regulatory Framework for Safety [4] and Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (hereafter referred to as the BSS) [1]. These requirements include notification of a practice to the regulatory body and authorization of the practice by the regulatory body. Provision is made for the exemption of practices from these and other regulatory requirements based on general criteria given in the BSS or any exemption levels specified by the regulatory body on the basis of these criteria. The BSS, which is jointly sponsored by the IAEA and several other international organizations, apply to all facilities and all activities that give rise to radiation risks.

1.10. In the interest of harmonization of approaches among Member States, some guidance on justification and the application of the criteria for exemption from regulatory control of consumer products has been provided in a number of IAEA Safety Guides e.g. Regulatory Control of Radiation Sources [5], Application of the Concepts of Exclusion, Exemption and Clearance, [6] and Application of the Principle of Justification to Practices, including Non-Medical Human Imaging [7]. Nevertheless, the process of justification and the application of the provisions for exemption to consumer products are not straightforward and have resulted in different approaches being adopted by Member States. This potential difficulty is a particular issue with regard to some very common consumer products, whose supply to the public is considered justified in some Member States but is

[1] The term ‘activities’ includes: 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 [3].

prohibited in others. Inconsistencies of approach may be a cause of confusion since the reasons for the different approaches will not be clear to the manufacturers and suppliers of products and the public who might use them.

1.11. Further harmonization of the regulatory approaches in Member States in the application of the justification principle [8] and the use of the exemption provisions in the BSS in relation to the supply of consumer products to the public is desirable. Such consumer products may be marketed globally, and lack of harmonization can be a cause of confusion among the public and others regarding the risks posed by their use. In addition, more consistent regulatory approaches can assist regulatory bodies with the efficient and effective use of their limited resources, leaving them more time to devote to those 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 suppliers[2] of consumer products containing small amounts of radioactive material, either deliberately added or produced by activation, or equipment capable of generating ionizing radiation. Its principal objective is to provide guidance on the application of the principles of justification and optimization [8] and on authorization to the supply of consumer products to the public. It also outlines how the provisions for exemption given in the BSS [1] should be applied to products containing small amounts of radioactive material, radiation generators and products containing activation products. The Safety Guide considers both the administrative and the radiation protection requirements outlined in the BSS. 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 supply of a consumer product containing radioactive material. Account is also taken of the approach to the application of the concepts of exemption and clearance given in ICRP Publication 104, Scope of Radiological Protection Control Measures [9].

[2] The term ‘supplier’ includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, exporters or importers of a source [3].

1.13. The guide also provides information on the construction and testing standards for certain consumer products.

SCOPE

1.14. The scope of the Safety Guide is restricted to finished products (i.e. not components produced for further assembly) that contain small amounts of radioactive material 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 various stages of the lifecycle of these items following manufacture, including transport, storage, supply, use, recycling and disposal. The Safety Guide also covers items in which radioactive material is produced by activation (such as irradiated gemstones), which may also be supplied to the public. Equipment that generates ionizing radiation and may be purchased by the public is also covered, although no such items are currently available.

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

(a) Occupational exposure, such as exposure of workers involved in the manufacture or assembly of consumer products or the irradiation of gemstones in a licensed facility where such exposure is already subject to regulatory control;

(b) Products and appliances installed in public places (e.g. exit signs and lightning preventers) 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 explosive and chemical detectors containing tritium, ^{63}Ni or ^{133}Ba, receiver protection devices (TR limiters) containing tritium used in radar communications and dust monitors containing ^{14}C, all of which are normally not available for supply to the public;

(d) Practices involving the frivolous use of radiation or radioactive substances in products such as toys and personal jewellery or adornments, as well as human imaging using radiation used as a form of art or for publicity purposes, which are deemed to be not justified;

(e) Un-irradiated gemstones containing naturally occurring radionuclides, as these are not covered by the definition of consumer products in which “radionuclides have deliberately been incorporated or produced by activation”; and

(f) Doped gallium, germanium, selenium and silicon as these are not supplied directly to the public. After incorporation into electronic components, the doped materials no longer contain measurable amounts of activity.

1.16. This Safety Guide will also be appropriate for application to any novel products for supply 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 radiation protection framework for protection of the public while the application of this framework to consumer products is discussed in Chapter 3. Special considerations related to consumer products to which small amounts of radioactive material have been added either for functional reasons or because of their physical or chemical properties are dealt with in Section 4. Special considerations in relation to irradiated gemstones and other products containing activation products are addressed in Section 5. International approaches to improved harmonization of the justification, authorization and exemption from regulatory control of consumer products supplied to the public are considered in Section 6.

1.18. A number of annexes are included in the Safety Guide. The first three of these provide examples of how justification decisions can be reached in relation to different consumer products. Annex IV contains a design, construction and performance standard for ionization chamber smoke detectors (ICSDs) that can be used as input to a decision on the exemption of their supply to the public from regulatory control. Annex V provides information on the radiation doses that might typically be received by the public from normal use, misuse and disposal of ICSDs. Annex VI contains a national standard for consumer products that contain gaseous tritium light sources that can be used when considering their exemption from regulatory control. In Annex VII, information on the safety-related aspects of gemstone irradiation technologies is provided in support of the guidance in Section 5.

2. THE FRAMEWORK FOR RADIATION PROTECTION OF THE PUBLIC

GENERAL

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

(a) Radioactive material may be added for functional reasons or because of particular physical or chemical properties as part of the manufacturing process of particular items. The radioactive material will normally have a relatively long half-life that allows the item in question to continue to function throughout its expected lifetime. Exposure of the public may therefore take place throughout the operational lifetime of the product and also after disposal;

(b) Radiation generators or electronic tubes may be incorporated in more complex equipment or devices at the time of manufacture. However, exposure of the public is normally possible only when the device is energized;

(c) Electron beam or neutron irradiation can result in the production of radioactive material in the form of activation products. Presently, the only consumer products known to undergo such irradiation are gemstones. Depending on the chemical composition of the gemstone, different activation products with different half-lives will be produced. The associated dose rate, and therefore the potential for exposure of the public, will decrease with time following irradiation.

2.2. The manufacture of consumer products involving the addition of radioactive material is a planned exposure situation[3] that requires authorization from the regulatory body. Such practices are subject to the three fundamental safety principles of justification, optimization of protection and safety, and limitation of doses [8]. Dose limits apply to the occupational exposure of workers involved in the manufacturing process and to members of the public who may be exposed either as a result of activities at the facilities in question or from authorized discharges.

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

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

2.4. The irradiation of gemstones either by electron beams or 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 also be used for the production of radiopharmaceuticals 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 ionizing 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 three basic principles of justification of practices, optimization of protection and safety, and compliance with dose limits, apply [8].

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

2.5. The approach to regulatory control of consumer products outlined in this Safety Guide should also be applied to certain goods that are intended for use in particular types of market such as cinemas, sports arenas or other places to which the public may have access but which are not consumer products in the sense given to the term in the BSS. Those who handle, install and maintain such products are regarded as members of the public from the viewpoint of radiation protection, unless the regulatory body decides otherwise.

2.6. Requirements for protection and safety specific to occupational exposure in planned exposure situations can be found in paras 3.68 to 3.116 of the BSS [1]. These are not relevant to the scope of this Safety Guide and for that reason are not considered further here. Requirements in the BSS on applying the graded approach (para 3.6), notification and authorization (paras 3.7 to 3.9), exemption (paras 3.10 to 3.11), justification (paras 3.16 to 3.21), optimization (paras 3.22 to 3.25) and safety assessments (paras 3.29 to 3.36), as they apply to consumer products, as well as specific requirements relating to public exposure to consumer products (paras 3.125 to 3.127 and 3.138 to 3.143) are discussed in greater detail throughout the text.

JUSTIFICATION

2.7. The principle of justification is one of the basic principles of radiation protection [8]. Justification requires that any practice produces a positive net benefit to the exposed individuals or to society. This concept 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. The BSS however explicitly requires a demonstration of a positive net benefit before a practice can be authorized by the regulatory body. Application of the principle of justification is discussed in detail in a separate Safety Guide [7].

2.8. The BSS requires that only justified practices be authorized and para. 3.16 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 if a particular practice is justified and, only if that is indeed the case, should consideration be given to authorization.

2.9. 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 the BSS for the exemption from the regulatory requirements of practices that pose a trivial level of risk, justification for such practices should first to be demonstrated.

GRADED APPROACH

2.10. The IAEA safety standards emphasize the importance of a graded approach in the regulation of activities and practices. In particular, the General Safety Requirements on Governmental, Legal and Regulatory Framework for Safety [4] requires 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".

2.11. The philosophy behind the use of a graded approach is straightforward. Not all practices represent the same degree of risk and, as stated in Requirement 6 of the BSS [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 magnitude and likelihood of the exposures." There is a further requirement "to ensure that a graded approach is taken to the regulatory

control of radiation exposure" (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" (para. 2.31).

2.12. The requirement on using a graded approach should be applied to both occupational and public exposure. Such an approach also 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 highest risks. It is implicit that registrants and licensees should also apply a graded approach to those activities for which they are authorized.

NOTIFICATION AND AUTHORIZATION

2.13. The requirement to apply a graded approach is reflected in requirements relating to regulatory infrastructure outlined the BSS. These are authorization[4] by licensing, authorization by registration, notification and exemption: these are listed in decreasing order of rigour as far as regulatory control is concerned.

2.14. Practices that pose or are likely to pose a relatively high radiation risk should be subject to a system of authorization by means of licensing. This requires a detailed safety assessment (see paras 2.34 to 2.37 below) to be carried out prior to the issuance of a license by the regulatory body. In addition, the license should contain 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.

2.15. Authorization by means of registration should be applied to practices of low to moderate radiation risks. The requirements for safety assessment should be less severe 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 severe as those contained in licenses. Typical practices that are amenable to registration are those for which

[4] Authorization is defined as "the granting by a regulatory body or other governmental body of written permission for a person or organization to conduct specific activities" [3].

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

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.

2.16. Notification of the regulatory body by a person or organization intending to undertake a practice is required by the BSS. The regulatory body may decide that notification alone is sufficient (i.e. authorization is not required) if "the exposures expected to be associated with the practice 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" (Ref. [1], para. 3.7).

2.17. The BSS also states that notification is required for consumer products "only with respect to manufacture, assembly, maintenance, import, 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 that no notification of use is required. However, any person or organization intending to carry out any of these practices specified in the statement 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 individual doses identified by the safety assessment.

2.18. Decisions by the regulatory body in relation to authorization should be consistent with the graded approach. For example, the irradiation of gemstones can involve the use of very high dose rates and, immediately after irradiation, the activity concentrations of many radionuclides are likely to exceed, by a large amount, the exemption values in the BSS [1]. In such circumstances, authorization by license would clearly be appropriate. On the other hand, the assembly of ionization chamber smoke detectors may only involve the fitting of pre-constructed 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 members of the public is small and the regulatory body may decide only to require authorization by registration in line with application of the graded approach.

2.19. The regulatory approach in many Member 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 Member 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, it is not essential that all three possibilities should all be used. What is however essential is that the regulatory body should use a graded approach in order to ensure that it assigns its limited resources in an appropriate way, focusing its efforts on those practices that present the highest risks. The requlatory body should also ensure that a graded approach is applied by principal parties.

EXEMPTION

2.20. 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 as part of the graded approach to regulation in that it is less restrictive than either authorization or notification, but still requires a decision to be made by the regulatory body.

2.21. The general criteria for exemption are laid down in Schedule I of the BSS (Ref. [1], para. I-1), namely that

(a) Radiation risks arising from the practice or a source within a practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations 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 control measures would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

2.22. These criteria are subjective in nature and, taken on their own, require value judgements to be made by the regulatory body. The BSS [1] further clarify what is meant by the term "radiation risks…..are sufficiently low" by stating (para. I-2) that "a practice or a source within a practice may be exempted under the terms of para. I-1(a) without further consideration provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any member of the public (normally evaluated on the basis of a safety assessment) owing to the exempted practice or the exempted 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 member of the public for such low probability scenarios does not exceed 1 mSv in a year."

2.23. 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 in protecting workers and the public from radiation risks. By applying the same dose criteria on a global basis, greater consistency between individual Member States is to be expected. If the dose criteria defined in para. I-2 of the BSS are met, then the associated practice, or the source within that practice, should be exempted without further consideration i.e. exemption should be automatic.

2.24. Para. I-2 of the BSS also states that the evaluation of doses likely to be received from a given practice should be based on the outcome of a safety assessment. The carrying out of a safety assessment can be expensive and time-consuming and, in situations where the expected doses 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 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", then the individual effective dose in a year will not exceed 10 μSv and the practice should be exempted without further consideration (Ref. [1], para. I-3).

2.25. Many Member 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 above, 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 need 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 normally will be the case, and only in exceptional circumstances should the regulatory body require additional scenarios to be considered.

2.26. From a regulatory viewpoint, the existence and application of pre-defined numbers to be used for taking decisions on exemption has obvious benefits in that it is easy to apply. It also increases the likelihood of consistency by the regulatory body and between regulatory bodies in different Member

States. However, to rely on numerical values alone removes the need for the regulatory body to use its own judgement in taking such decisions and undermines the considerable flexibility afforded to regulatory bodies in the BSS. 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 doses or 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 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 but, on their own, they may provide an insufficient basis for a final decision.

2.27. The BSS also provide for automatic exemption without further consideration of "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

(a) they do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; or

(b) the maximum energy of the radiation generated is no greater than 5 keV.

2.28. Paragraph I-6 of the BSS allows for the granting of exemptions "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 exempted 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 μSv/h at a distance of 0.1 m from any accessible surface of the apparatus;

"(d) Necessary conditions for disposal of the equipment have been specified by the regulatory body."

2.29. 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 Standards Organization (ISO). While the exemption can be based on the external dose rate at a distance of 0.1 m from the surface of the apparatus, 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 readily be accessible in the event of, for example, dismantling of the device or incineration, then exemption from regulatory control may not be appropriate.

2.30. This provision in the BSS that provides 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 containing higher levels of activity than those defined 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.

2.31. There is no specific reference in the BSS 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 radioactive material has been added during 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 greater detail in Section 5.

OPTIMIZATION OF PROTECTION AND SAFETY

2.32. Demonstration of net benefit is not in itself sufficient for a practice to be authorized. The BSS also require the government or regulatory body to "establish and enforce requirements for the optimization of protection and safety" (para. 3.22) while "registrants and licensees shall ensure that protection and safety is optimized." (para. 3.23).

2.33. Optimization of protection and safety is the process of deciding on the level of protection that is required to be applied in order to obtain the maximum net benefit. Thus, both justification of a practice and optimization of the protection and safety measures 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 should be the best possible under the prevailing circumstances. Optimization is especially important, and should be fully taken into account, in the design and construction of consumer products, particularly with regard to the choice of radioactive source that is to be used.

SAFETY AND ASSESSMENT

2.34. Requirements in relation to the carrying out of safety assessments 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 responsible for establishing the requirement for a safety assessment to be carried out and should 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" (Ref. [1], para. 3.30).

2.35. 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 high degree of risk should require a more detailed safety assessment than those with a much lower level of risk. Even if the level of risk 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 justification of a particular practice is being considered and the decision of the regulatory body should not be automatically reviewed for subsequent applications, except as described in para. 2.37 below. However, as discussed in paras 2.24 and 2.25, in situations where the derived values of activity or activity concentration are not exceeded, a safety assessment should not be required; provided the practice is deemed to be justified, such sources should be exempted from regulatory control without further consideration.

2.36. The safety assessment should “determine the expected magnitudes and expected exposures in normal operation” and “to the extent reasonable and practicable, make an assessment of potential exposures” (Ref. [1], para. 3.31). This has a particular relevance to consumer products where an individual dose of 10μSv is one of the criteria to be used in deciding on the exemption of practices from regulatory control.

2.37. Registrants and licensees are required to perform additional reviews of the safety assessment if “significant modifications are envisaged to the facility or to its operating conditions” or if any “significant changes in activities are envisaged” (Ref. [1], para. 3.35). In the case of consumer products, a review of the safety assessment could result in the regulatory body deciding that supply to the public no longer meets the criteria for exemption and, as such, the manufacture of such products is no longer justified.

3. APPLYING THE RADIATION PROTECTION FRAMEWORK TO CONSUMER PRODUCTS

INTRODUCTION

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 below.

JUSTIFICATION

3.2. Prior to initiating the manufacture and supply to the public of a new type of consumer product incorporating radioactive material, the manufacturer should inform the regulatory body of its intention and seek a decision on the justification of the proposed practice.

3.3. While the BSS requires that the government or regulatory body ensures that provision is made for the justification of any type of practice (Ref. [1], para. 3.16), 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 which consumer products are likely to represent and, as such, decisions on their justification do not represent high level decisions more appropriate for the government to take.

3.4. Determination of the justification of the manufacture and supply 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. That should be the end of the matter, although the BSS does make provision for the "review of justification". This should be taken to mean both the review of decisions that a particular practice in not justified as well as decisions that it is.

3.5. The justification procedure should consider all aspects of the practice, including manufacture, assembly, transportation, supply, use by members of the public and ultimate disposal. It follows that when addressing the justification of a specific consumer product, one component of the practice should not be considered in isolation from the end use of the product by members of the

public i.e. it makes little sense to justify the manufacture of a given consumer product and, at a later stage, decide that its supply to the public is not justified.

3.6. 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 technique 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 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.

3.7. In some circumstances the justification of the manufacture of the source may already have been addressed in another State. The regulatory body should then only consider the justification of the supply of the consumer product to the public. In practice, the most critical consideration for most consumer products is likely to be the potential doses to members of the public and hence the regulatory body should pay particular attention to this aspect during the justification process.

3.8. If the use of a particular consumer product is considered not to be justified, then it follows that the other stages — manufacture, importation, transport, etc. — are also not justified. This is essential in order to ensure that clarity is maintained over how the requirement for justification is to be applied to consumer products. In particular, the importance of maintaining the focus, first and foremost, on the intended use and benefit from that use is critical. On the other hand, if the use of a particular consumer product is considered to be justified, then it should normally follow that the other stages, such manufacture, importation and transport, are also justified.

3.9. While every effort should be made to guarantee objectivity in the evaluation of justification, this may not always be easy to achieve. One of the reasons is that it is often not possible to quantify both costs and benefits in units that are directly comparable, such as lives or money. For this reason, determination of benefit normally involves making a judgement on behalf of society. To try to overcome these difficulties, the regulatory body should establish a mechanism for obtaining input from individuals or bodies reflecting societal interests. As stated elsewhere in the IAEA safety standards (Ref. [7], para. 3.16), “in the case of consumer products, such a group might comprise individuals from consumer interest groups, manufacturers or providers of such products, academics and government officials. As an input to the group, the regulatory body should provide its own

assessment of the radiological risks associated with the proposed practice." Such a mechanism helps to avoid decisions being made based on the subjective judgement of the regulatory body alone.

3.10. The fact that the level of risk is trivial is not, in itself, sufficient grounds for justification. For practices that pose a trivial level of risk, such as the supply and use of consumer products, justification for such practices is still required to be demonstrated. If the risk is indeed trivial then the benefit need not be substantial in order for the practice to be shown to be justified.

3.11. Although radiation safety is concerned with protection against risks to health, the regulatory body should not justify only those consumer products that are potentially life-saving or prevent injury or illness. The benefits to be considered could be of many different types, not just possible saving of life or prevention of injury or illness, but also technical benefits, prevention of property damage, improvements in security or simply improvements in the quality of life.

3.12. Justification decisions are normally taken with respect to a type of practice and therefore should not be applied to each and every notification for authorization. Thus, for example, if the manufacture of a certain type of smoke detector is deemed justified, the manufacture of an identical smoke detector should be regarded as justified automatically. The regulatory body should consider the national and international technical standards that are in existence for a particular type of practice and decide if this is sufficient to indicate that the practice in question is justified. This is discussed further in relation to certain specific types of consumer product in section 4.

3.13. In some instances, a decision on the justification of a particular type of consumer product may already have been taken by the regulatory body in another State. Nevertheless, the regulatory body in a State in which the consumer product in question is to be supplied to the public should reach its own decision on justification. In reaching its decision, the regulatory body should take into account the previous decision to justify, or not to justify, the practice and the basis on which this decision was reached. While different regulatory bodies may reach different decisions, it is desirable that regulatory bodies should, as much as possible, cooperate with each other so that a uniform approach is taken to the justifying the supply of consumer products to the public. International harmonization is considered further in section 6.

3.14. The regulatory body should review all justification decisions at regular intervals. In particular, justification decisions should be reviewed whenever new and important evidence becomes available about the efficacy or safety of a particular practice. In reviewing the justification of the supply to the public of a given consumer product, the availability of a new technology not involving

the use of ionizing radiation should not, in itself, be the determining factor in deciding whether or not to continue to justify the practice.

3.15. If a practice involving the supply to the public of a given consumer product is considered to be no longer justified, the regulatory should withdraw the authorization for continued manufacture and supply of the consumer product in question. The basis for the decision should be made available to all interested parties.

3.16. The role of the regulatory body in these matters is limited. The regulatory body does not have any responsibility in setting societal standards with regard to what may or may not be supplied to and used by the public. Its primary role should be to ensure that any products destined for sale to the public that contain small amounts of radioactive material are inherently safe; consumer decisions will subsequently determine whether the product is competitively priced and useful.

3.17. The specific considerations in relation to justification of the practice of the irradiation of gemstones to enhance their colour are addressed in paras 5.1 to 5.5.

3.18. Examples of justification decisions are given in Annexes I–III.

NOTIFICATION AND AUTHORIZATION

3.19. As discussed in section 2, a person or organization is required to notify the regulatory body of its intention to manufacture, assemble, maintain, import, distribute or dispose of consumer products (Ref. [1], para. 3.5). As noted in paras 2.13 to 2.19, regulatory bodies take different approaches to notification and authorization, and use different terminologies, depending on the structure of their national legislation.

3.20. As part of any notification, the person or organization should provide to the regulatory body all the necessary information, including a safety assessment, in support of its request for authorization. Ideally, the information required should be specified in advance by the regulatory body in written procedures that are easily and readily available. The notification should also provide evidence that the practice has previously been justified.

3.21. The information that should be made available to the regulatory body will vary, depending on the practice(s) covered by the notification. However, the information provided should be sufficient to allow to regulatory body to review and assess the proposed product. Specifically the information

made available to the regulatory body should be sufficient to allow it to reach a decision on whether or not the proposed practice is a candidate for exemption from regulatory control.

3.22. The documentation to be provided to the regulatory body is discussed in greater detail in Ref. [7] but normally should include the following:

(a) A description of the consumer product, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive material fulfils its function also should be provided;

(b) The activity of the radionuclide(s) to be used in the consumer product;

(c) Justification of the choice of a radionuclide, particularly relative to the hazard associated with and the half-lives of other radionuclide(s);

(d) The chemical and physical forms of the radionuclide(s) contained in the consumer product;

(e) Details of the configuration and design of the consumer product, particularly as related to the containment and shielding of the radionuclide in normal and adverse conditions of use and disposal, and the degree of accessibility to the radioactive material;

(f) The quality testing and verification procedures to be applied to radioactive sources, components and finished products to ensure that the maximum specified quantities of radioactive material or the maximum specified radiation levels are not exceeded, and that consumer products are constructed according to the design specifications;

(g) A description of the prototype tests for demonstrating the integrity of the consumer product in normal use and for possible misuse and accidental damage, and the results of these tests;

(h) External radiation levels arising from the consumer product and the method of measurement;

(i) Safety assessments arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing and repair;

(j) The anticipated useful lifetime of the consumer product and the total number expected to be distributed annually;

(k) Information about any advice to be provided on the correct use, installation, maintenance, servicing and repair of the consumer product;

(l) An analysis to demonstrate that the consumer product is inherently safe (i.e. will not result in significant doses to individuals in the event of reasonably foreseeable accidents); and

(m) Information on how the consumer product is intended to be labeled.

3.23. The regulatory body should critically evaluate the information, particularly the safety assessment, and seek any additional information it considers necessary as input to the decision on whether exemption from some or all the requirements of regulatory control can be granted. Exemption from regulatory control is an essential pre-requisite for the authorization of the supply of consumer products to the public.

3.24. In the case of a notification relating only to the distribution and/or supply of consumer products to the public, the documentation provided should include evidence that the consumer product in question has been authorized for supply to the public in the State in which it is manufactured. The regulatory body should carefully evaluate and assess the documentation provided and, unless it has concerns about the basis for the decision, authorization in the State of manufacture should normally be a sufficient basis for granting the authorization.

OPTIMIZATION OF PROTECTION AND SAFETY

3.25. Optimization of protection and safety should be implemented through attention to the design and configuration of the consumer product. It can also be applied through the use of procedural controls. However, if procedural controls are necessary in order for protection to be optimized, then the practice is unlikely to be a candidate for exemption.

3.26. Important factors that should be taken into account in the optimization of protection and safety for consumer products into which radionuclides have deliberately been incorporated include the following:

(a) Selection of the most appropriate radionuclide with respect to the half-life, radiation type, energy and activity necessary for the product to function effectively;

(b) Selection of the chemical and physical forms of the radionuclide that provide the highest degree of intrinsic safety under both normal and accident conditions and for disposal;

(c) Configuration of the consumer product;

(d) Prevention of access to the radioactive material without the use of special tools;

(e) Use of experience with other products, particularly similar products, that have previously been assessed; and

(f) Verification of quality.

3.27. Optimization is about selecting the best option, taking into account the technical, economic, legal and social contexts that apply. The best option is always specific to the exposure pathways and represents the best level of protection that can be achieved under the given circumstances. In the case of consumer products, whether or not exemption values are exceeded, protection should be optimized. The regulatory body should ensure that the principle of optimization is applied, even below the exemption value.

3.28. Well established standards for the construction of some of the more common consumer products are available and applied internationally. These are discussed and referenced in Section 4.

3.29. In the case of the irradiated gemstones, the short half-life of many of the activation products means that the dose rate decreases measurably with time after supply to the public. Protection should be optimized by designing the radiation exposure conditions to minimize the production of those radionuclides with longer half-lives and removing those stones with the highest activity concentrations. These issues are discussed further in Section 5.

SAFETY ASSESSMENT

3.30. The safety assessment is an essential input to the determination of the justification of a practice and in the optimization of protection. It covers the doses that are likely to be received from normal use, reasonably foreseeable accidents and disposal. The assessed doses should be compared with established dose criteria. In the case of consumer products, the dose criteria are those for exemption contained in the IAEA safety standards [1, 13] as discussed in Section 2.

3.31. Some consumer products are likely to be used singly or in small numbers. Other products, such as those installed in places of work to which the public may have access, may be used in greater quantities. For example, householders may install one or two ionization chamber smoke detectors

(ICSDs) in their home but a much larger number of similar ICSDs may be used to as part of a fire protection system in an office block, shopping mall or hotel. ICSDs installed as components of fire detection systems of this nature are not consumer products as defined in the BSS [1] since they are not supplied to members of the public. However, the criteria for construction and design are the same and a similar approach should be taken for dose assessment. Any dose assessments carried out should take account of the number of ICSDs deployed in a dwelling and hence the total potential exposure to an individual.

3.32. While the amount of radioactive material in an individual consumer product is normally small, much larger amounts of radioactive material are likely to be present during transport and storage in the warehouses of distributors. Separate safety assessments are necessary in dealing with the storage and transport of bulk quantities of consumer products containing individually small amounts of radioactive material. These stages should be assessed separately and should consider the doses that might be received during normal operations and in the event of an accident such as fire. Such assessments will indicate whether a limit should be placed on the numbers of products being stored or transported in order to ensure that the criteria for exemption are not exceeded. As indicated in para. 3.31 above, the starting point for the safety assessment should be the numbers of items typically transported or stored together; the analysis should then be expanded to calculate maximum allowable numbers of products in transport or storage.

3.33. While it is a pre-requisite that consumer products supplied directly to the public meet the criteria for exemption, it does not necessarily mean that other stages of the supply chain should be exempted automatically. On the basis of the safety assessment, the regulatory body should decide if authorization is necessary and, if so, apply a graded approach. Alternatively, the regulatory body may decide to exempt quantities of consumer products up to a maximum number provided it can be shown that the general criteria for exemption are met i.e. that the radiation risks are insufficient to warrant regulatory control or that regulatory control measures would achieve no worthwhile benefit. The regulatory body should avoid regulation for the sake of regulation: if the criteria for exemption are met for large numbers of consumer products under a range of normal usage and realistic accident scenarios, unless there are strong reasons not to do so, the practice should be exempted from regulatory control.

3.34. Once consumer products are supplied to the public, it is not realistic to control the manner in which they are disposed. Indeed, the basic premise of exemption is that such control is not warranted for radiation protection purposes. However, the regulatory body should take into account any waste management requirements applicable to the category of consumer product and ensure that the customers are informed thereof. The radioactivity content of the consumer product should not, in

general, be taken into consideration for this purpose in accordance with para. I-6(d) of the BSS [1] (see, for example, para. 4.34). The safety assessment should assume that individual consumer products supplied to the public are discarded with household waste at the end of their useful life. The safety assessment should consider a range of realistic scenarios following disposal, including combustion, handling by workers and retrieval by individuals.

3.35. If, after the end of their useful life, consumer products are to be collected for disposal they may need to be treated as radioactive waste. In such circumstances, the Safety Requirements on pre-disposal management of radioactive waste [14] and the Safety Requirements on disposal of radioactive waste [15] should be applied. If disused consumer products are to be recycled, this should be considered as a practice and regulated accordingly.

3.36. The regulatory processes for deciding on exemption from regulatory control are summarized in figs. 3.1 and 3.2

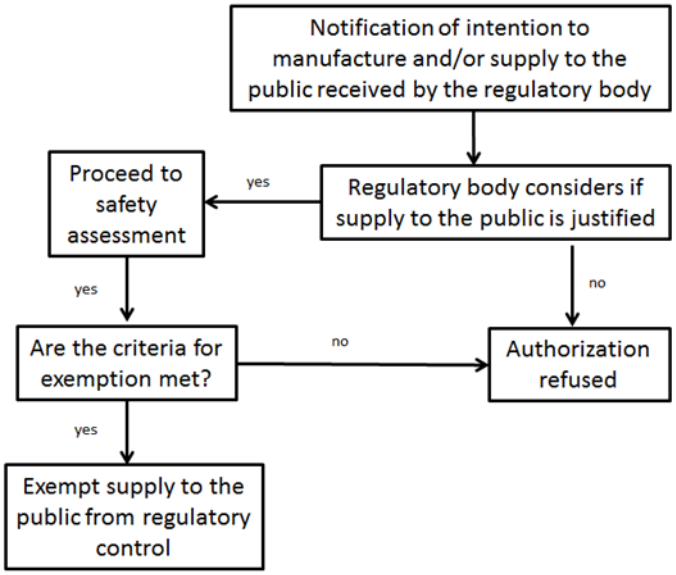


FIG. 3.1. Regulatory Control of Consumer Products.

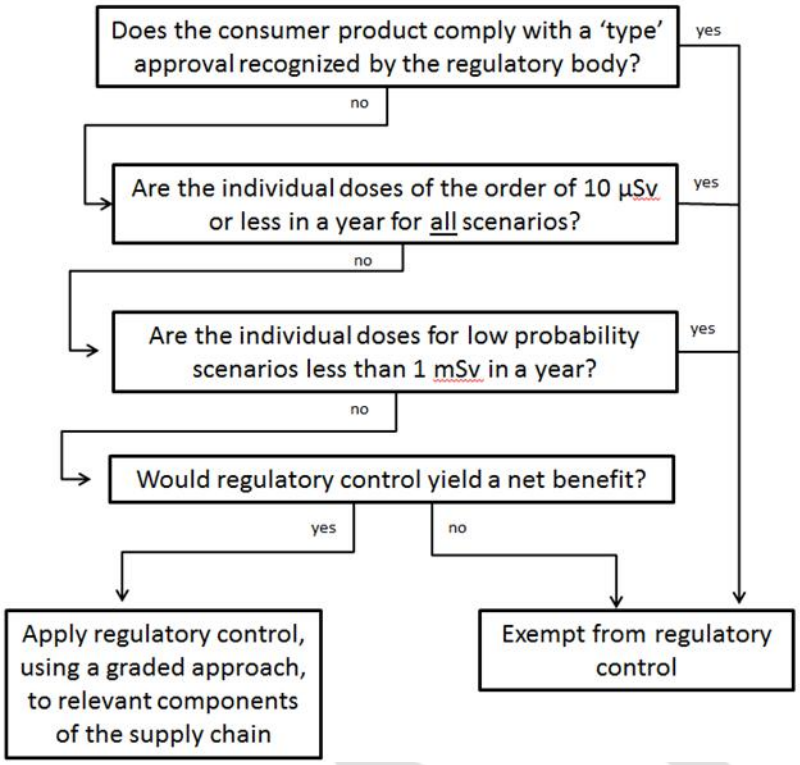


FIG. 3.2. Safety Assessment for Consumer Products.

4. SPECIAL CONSIDERATIONS FOR CONSUMER PRODUCTS INTO WHICH RADIONUCLIDES HAVE DELIBERATELY BEEN INCORPORATED

INTRODUCTION

4.1. This section considers those consumer products that are supplied to members of the public and into which small amounts of radioactive material have deliberately been incorporated either for functional reasons or because of particular physical or chemical characteristics i.e. the presence of the radioactive material is essential for the product to operate correctly. The majority of consumer products currently supplied to members of the public are of this type and most fit into the following categories:

(a) Ionization chamber smoke detectors;
(b) Gaseous tritium light devices;
(c) Luminous watches;
(d) Certain lamps and lamp starters.

4.2. These consumer products have been widely available for many years and safety assessments have been undertaken and published. In some cases, criteria have also been developed for their construction and testing. A number of publications are available on the general approach to the regulatory control of consumer products [16-22].

DETAILS OF THE PRACTICE

Ionization chamber smoke detectors

4.3. Ionization chamber smoke detectors (ICSDs) containing radioactive sources are widely available. Their use is important in saving lives and protecting property. Alternative detectors incorporating an optical detection mechanism rather than a radioactive source have been developed and are also available to the public as an alternative to the ICSD. However, the ICSD is considered to respond more rapidly to a fast burning fire, while the optical detector is more suited to the detection of smoldering fires [23]. Some detectors incorporate both an ionization chamber and an optical detector to detect both fast burning and smoldering fires. The regulatory body should take these issues into account when considering the justification of ICSDs.

4.4. Standards for the construction and prototype testing of ICSDs were published by Nuclear Energy Agency (NEA) in 1977 [24] and were subsequently revised and updated by UK National

Radiological Protection Board (NRPB) in 1992 [25]. This publication is still used as the accepted standard for the design, construction and performance of ICSDs and is summarized in Annex IV. An environmental assessment of ICSDs has also been undertaken in the United States [26].

4.5. The source activity within an ICSD is normally greater than the exemption values given in the BSS. As part of the work to develop standards for ICSDs, the NRPB carried out an assessment [25] of the potential radiation doses received by members of the public during normal operation and in reasonably foreseeable accidents from an ICSD that complied with the standards specified. This assessment indicated that potential doses satisfy the exemption criteria of 10 μSv/y for normal use and 1 mSv for low probability (accident) scenarios. This assessment is reproduced in Annex V.

4.6. Once the issue of justification has been addressed, the regulatory body should consider the exemption of ICSDs from regulatory control by giving type approval to ICSD models that satisfy the standards for construction and type testing. Such an approach does not prevent the regulatory body from specifying other conditions in the type approval e.g. disposal requirements and any additional labeling requirements. For many ICSDs currently available on the market, type testing information is readily available from the manufacturers.

Gaseous tritium light devices

4.7. Gaseous tritium light sources (GTLSs) consist of a sealed glass tube, internally coated with a phosphorescent material and filled with tritium gas. The beta particles from the tritium interact with the coating, creating radioluminescence. These tubes are installed in various products for illumination purposes. Such products are referred to as Gaseous Tritium Light Devices (GTLDs). GTLDs have been available for public use for many years, the most common product being compasses. Past applications of GTLSs have been limited by the difficulty in manufacturing small GTLSs with precise tritium activities although GTLD fishing floats and a limited number of GTLD digital watches have been marketed. Recent advances in technology now permit the manufacture of physically very small GTLSs with dimensions as low as 0.5 mm diameter and 1.3 mm length. These GTLSs are sometimes installed on the watch dials and hands of a range of modern watches. They are also used in key fobs, map lights and compasses.

4.8. The widespread use of GTLSs in a range of applications in the 1970s prompted the NEA to develop and publish construction standards for GTLDs [27]. The external radiation hazard from GTLSs is negligible, the primary pathway of exposure being the inhalation of tritiated water vapour from a GTLS when it is broken. Small amounts of tritium may also escape from intact devices and can

be inhaled or absorbed through the skin. For these reasons, the NEA standard focused on the GTLD construction, the tritium activity and the percentage of tritiated water in the GTLS. This standard was reviewed by the UK National Radiological Protection Board in 1992 and a national standard published [28]. The NRPB standard, which specifically addresses the use of GTLSs in watches and compasses, is summarized in Annex VI.

4.9. The total activity for exemption of tritium without further consideration is given in the BSS as 1GBq. An assessment of the potential radiation doses to members of the public from a watch or compass that complied with the specified standards indicated that potential doses were well below the exemption criteria of 10 μSv/y for normal use and 1 mSv for low probability (accident) scenarios [28]. Consequently, on the basis of this assessment, the dose criteria for exemption can be met even for activities well above 1 GBq of tritium in watches and compasses.

4.10. Many modern GTLSs used in GTLDs have activities considerably less than 1 GBq. The individual activities of the very small GTLSs now manufactured for installation on watch hands and faces are in the order of 0.1 GBq, and the total activity in a watch is normally kept to below 1GBq. A similar approach is taken with regard to key fobs and compasses.

4.11. Provided the practice is considered justified, in order to comply with the exemption criteria BSS [1] the regulatory body should exempt the supply of such GTLDs to the public from regulatory control without further consideration provided the total activity is less than the exemption value of 1 GBq. In situations where the total activity in the GTLD exceeds 1 GBq, exemption from regulatory control should still be granted provided the safety assessment demonstrates that the individual dose criteria of 10 μSv/y for normal use and 1 mSv for low probability (accident) scenarios are met.

Luminous watches

4.12. The combination of radioactive material with a phosphor to produce a luminescent paint was one of the earliest uses of radioactive material. The radioactive material originally used for luminescing purposes was ^{226}Ra, but the use of this radionuclide was gradually phased out in the second half of the twentieth century by the use of intrinsically safer radionuclides, primarily ^{147}Pm and tritium. Luminizing paints containing tritium or ^{147}Pm are still in use and many models of modern watch incorporate radioluminous markings in the watch face. ‘Divers’ style watches with a rotating bezel on the outside of the watch face sometimes incorporate a radioactive marking on the zero point of the bezel.

4.13. The ISO Standard 3157 “Radioluminescence for Time Measurement Instruments – Specifications” [29] gives requirements and test methods for the optical, mechanical and radioactive deposits fixed on watches and clocks. This ISO standard also specifies the maximum permitted activity of either tritium or ^{147}Pm that may be used in an individual item. These are 277 MBq for tritium and 5.5 MBq for ^{147}Pm, both of which are less than the respective exemption values of 1 GBq and 10 MBq in the BSS. The United States Nuclear Regulatory Commission has also published criteria for the exemption of timepieces containing either tritium or ^{147}Pm from regulatory control (see para. 30.15 entitled "certain items containing byproduct material" of Ref. [30]). A dose assessment [31] of potential doses from watches that comply with the ISO standard concluded that the exemption criteria of 10 μSv/y for normal use and 1 mSv for low probability (accident) scenarios are met.

4.14. The regulatory body should exempt the supply of radioluminous watches and clocks to the public from regulatory control by giving type approval to those models that satisfy the ISO Standard 3157. The regulatory body should also exempt without further consideration those watches and clocks that contain tritium or ^{147}Pm in amounts less than the exemption values given in the BSS [1]. Watches and clocks with higher activities should be exempted from regulatory control if a safety assessment demonstrates that they meet the dose criteria for exemption. Exemption from regulatory control should only be considered if the practice is firstly deemed to be justified.

Lamps and lamp starters

4.15. High intensity discharge (HID) lamps produce bright, white light with a high intensity in an energy efficient manner. These lamps are used in large numbers for street illumination and are also available to members of the public for car headlamps and other high intensity light applications. These lamps contain small amounts of ^{85}Kr or thorium, which aid the arcing process within the lamp. The total activity in a single lamp varies depending on the lamp model. In the case of lamps containing ^{85}Kr, neither the total activity nor activity concentration exemption values given in the BSS are exceeded. However, in certain lamps containing ^{232}Th, while the total activity in each item is below

the BSS exemption value, the activity concentration exceeds the BSS exemption value[5] of 10 Bq/g [32].

4.16. The starters in fluorescent lamps contain small amounts of tritium or ^{85}Kr to prompt the ignition of the lamp. The activities of tritium or ^{85}Kr in a starter normally do not exceed 500Bq, considerably lower than the BSS exemption values of 1 GBq and 10 kBq respectively.

4.17. The UK Health Protection Agency has carried out an assessment of the potential doses arising from the transport and use of HID lamps and fluorescent lamps [33] and a further report on their recycling and disposal [34]. IAEA has also considered the issue of safety assessment for lamps [32]. The HPA reports concluded that potential doses satisfy the exemption criteria of 10 μSv/y for normal use and 1 mSv for low probability (accident) scenarios.

4.18. For all lamps and starters that satisfy the BSS exemption criteria for total activity or activity concentration and are considered to be justified, the regulatory body should exempt their supply to the public from regulatory control without further consideration. In the case of multiple units, such as in storage in a warehouse prior to distribution, decisions on the degree of regulatory control that is necessary should be based on the results of a safety assessment as discussed in paras 3.30 to 3.36.

4.19. In view of the magnitude and international scope of this activity and the potential for higher activities and different radionuclides to be used in other models of lamps, the regulatory body should keep this practice under review and obtain further safety assessments, as appropriate. This is particularly important in circumstances where lamps have radionuclide activities or activity concentrations greater than the exemption values.

4.20. National and international standards of construction and testing for lamps and lamp starters should be developed, similar to those already in place for ICSDs, GTLDs and luminous watches.

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[5] The BSS allow for exemption without further consideration provided that either the derived values of total activity or the derived values of activity concentration are complied with; it is not necessary to comply with both.

RESPONSIBILITIES OF SUPPLIERS

4.21. The government or regulatory body is responsible for establishing the responsibilities of the supplier[6] of consumer products to members of the public [Ref. [1], para. 3.139(d)]. The nature of these responsibilities will depend on whether the supplier is the manufacturer/producer or an intermediary, such as a distributor or a retail outlet owner. The responsibilities laid down by the regulatory body should cover suitable storage of the products prior to supply, the labeling of the products, provision of instructions on use and disposal, and the provision of point-of-sale labeling. Additional responsibilities should be laid down by the regulatory body, as considered appropriate.

4.22. The manufacturer should be responsible for applying to the regulatory body for authorization for the manufacture and supply of the consumer product. In the case of a new type of consumer product the manufacturer should also apply to the relevant regulatory body for a justification decision for the product. This will involve the provision of a wide range of information including details of the proposed construction of the product, source radionuclide and activity, an assessment of doses to workers during manufacture and to members of the public during use, disposal options, assessments of doses as a consequence of disposal etc. as described in section 3.

4.23. The manufacturer should ensure that the consumer products are constructed in accordance with the relevant international design standards. The manufacturer should also be responsible for arranging any type testing that is specified in the standards.

4.24. Depending on the nature of the consumer product and the national legislation, the distributor and the supplier at the point of sale should obtain an authorization for the storage of the product. Consumer products containing amounts of activity less than the exemption values are likely to be viewed as being outside of regulatory control at the point of distribution and supply. However, in the case of certain consumer products, in particular those containing a radioactive source that exceeds the exemption value, the regulatory body should consider the need to restrict the number of items to be

[6] The term ‘supplier’ includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, exporters or importers of a source [3].

shipped as part of a single consignment or apply conditions on storage such as the maximum number that can be stored at one location.

4.25. National legislation may require the distributor and supplier at point of sale to hold documentation on storage requirements, emergency plans to deal with fires etc. The distributor and supplier should confirm with the regulatory body what information is required to be held.

4.26. The manufacturers of consumer products should ensure the products are adequately labeled, as required by the regulatory body. While some consumer products contain only very low activities of radionuclides and the individual doses during normal operation or misuse are trivial, others contain a radioactive source of significant size and should not be dismantled such that the source is directly accessible. Even with the latter consumer products, doses in the event of misuse or direct handling of the source should be relatively low (in order to comply with exemption criteria), but this does not remove the requirement to warn the user of the presence of a radioactive substance and advise against misuse or dismantling.

4.27. Consumer products that contain radioactive sources with activities greater than the exemption value activities specified in the BSS should always be labeled to warn users of the presence of a radioactive substance. This requirement is already incorporated into the relevant standards for the most common products. The NEA and NRPB standards [24, 25] for ICSDs require the ICSD to be labeled with the trefoil symbol and the wording 'radioactive' such that the label is clearly visible on opening the housing of the ICSD. The NEA and NRPB standards for GTLD watches and clocks [27, 28] require that the watches or clocks are clearly marked with the symbol ^{3}H or the wording 'tritium'.

4.28. The regulatory body should also consider requiring these consumer products to be labeled at the point of sale so that it is clear that the product contains a small radioactive source. While the regulatory body should not seek to influence customer decisions away from consumer products that are deemed to be justified and have been authorized for supply to the public, labeling on the outer box or on the display stand can be beneficial in informing customer choice in a manner similar to labeling on food products.

4.29. There is no safety benefit to be gained in labeling as radioactive those products that contain activities lower than the exemption values. Such labeling would also be problematic in some cases where the product is physically very small, such as lamp starters or small GTLSs. However, in the case of GTLDs that contain one or more small GTLSs, the regulatory body should consider requiring

the product to be labeled to indicate that it contains a radioactive source or to be clearly labeled as such at the point of sale. The purpose of such labeling is to inform customer choice.

4.30. Manufacturers should ensure that suitable instructions are provided with each unit in languages that are appropriate for the particular market into which the consumer product is to be supplied. Instructions should provide information on correct operation, safety considerations and acceptable methods of disposal. In the case of those products that must be recycled rather than disposed of as waste, information should be given on where the product should be taken or sent to for recycling. Where appropriate, instructions should also contain warnings on dismantling the product where this could result in access being gained to a radioactive source e.g. a warning not to dismantle the internal ionization chamber of an ICSD. While some consumer products are unlikely to need instructions on use and disposal, it may still be beneficial to provide the user with information on the radioactive content of the product and the low hazard from the source.

IMPORTATION OF CONSUMER PRODUCTS

4.31. In circumstances where consumer products are imported into a State from a manufacturer in another State, some of the responsibilities described above will transfer to the importer while others will remain with the manufacturer. The manufacturer should retain the responsibility for the construction of the product in accordance with the appropriate international standards. The manufacturer should also retain the responsibility for information on the safe use of the product. The importer should assume responsibility for any aspects of labeling and information provision that are a national rather than international requirement. These include the provision of information on any national requirements for disposal or recycling. The importer should also fulfil any authorization requirements for the storage, distribution and supply of the consumer products. In the case of products supplied via the internet direct to members of the public, the company selling the product should be responsible for satisfying the regulatory requirements in place in the Member States where the products are supplied.

TRANSPORT

4.32. As stated in para. 107 (e) of reference [13], the IAEA Transport Regulations do not apply to "radioactive material in consumer products that have received regulatory approval, following their sale to the end user". Consumer products are therefore outside the scope of the Transport Regulations only after supply to the end user. All other transport of consumer products, including the use of conveyances between manufacturers, distributors and retailers, as well as

the transport of large quantities of individually exempted consumer products, should be carried out in compliance with the IAEA Transport Regulations.

NUCLEAR SECURITY

4.33. Nuclear security measures should be implemented in line with IAEA nuclear security recommendations and guidance when the aggregated 1 “D” value for any particular radionuclide in a single location is exceeded. This is especially true for facilities which produce or store large quantities of consumer products which contain radioactive sources.

WASTE MANAGEMENT

4.34. Consumer products are effectively beyond regulatory control after supply to members of the public. The safety assessment should assume uncontrolled disposal and assesses the potential doses that could arise from the disposal pathways. This assessment should estimate the total numbers of the specific product that are likely to go to each landfill site per year and calculate the potential dose to the critical person living close to the landfill site from all of the disposals in the year. This assessed dose should be below the exemption dose criterion of 10 μSv/y. Such assessments require knowledge of the number of each product sold per year, the available disposal options for household waste, the number of waste disposal sites and the number of products likely to be disposed per year.

4.35. Although uncontrolled disposal is assumed for the purpose of dose assessment, in practice Member States may need to place restrictions on the disposal options for consumer products. These restrictions may be put in place to minimize the amount of uncontrolled radioactive material present in the environment, to encourage recycling or in response to regulatory controls. In the European Community, the Waste Electrical and Electronic Equipment Directive (WEEE Directive) [35] requires Member States to have legislation in place to control the disposal of electrical and electronic equipment and encourage recycling and recovery. In such circumstances, the regulatory body should ensure that arrangements are in place for the recovery and safe processing of radioactive sources that are being collected for recycling e.g. the sources used in ICSDs. The accumulation of such consumer products at a waste disposal or reclamation site may also present a potential radiological hazard and should be subject to a radiological assessment.

4.36. Information on any restrictions on disposal should be provided to members of the public at the point of sale of the consumer product.

5. SPECIAL CONSIDERATIONS FOR IRRADIATED GEMSTONES

JUSTIFICATION

5.1. The justification of the practice of the irradiation of gemstones to enhance their colour has been widely debated, and while some Member States prohibit the practice on the basis of it being not justified, other Member States have justified the practice and permit it to be carried out. Consequently, the practice is well established in many member States and irradiated gems are internationally traded and supplied to members of the public, even in those Member States where the practice is prohibited.

5.2. Paragraph 3.17 of the BSS specifies certain practices that are deemed not to be justified, including "practices involving the frivolous use of radiation or radioactive substances in commodities or in 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". A footnote to this requirement states that "this requirement is not intended to prohibit those practices that may involve short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as supplied".

5.3. It follows that, provided there is no increase in activity in irradiated gemstones that are released for supply to members of the public, there should be no prohibition, in principle, to the practice. However, reviews of the practice have shown that, while the majority of the activation products that arise in the gemstones have very short half-lives and decay to negligible levels very quickly, a limited number have longer half-lives e.g. ^{54}Mn (half-life 312 days) and ^{134}Cs (half-life 752 days). As is the case for all consumer products, irradiated gemstones should not be supplied to the public unless they comply with the exemption criteria in the BSS [1]. While this ensures that potential doses to end users of the gemstones are very low, it does mean that, at the time of supply, the gemstones do have an increase in activity compared to their state prior to irradiation. However, provided the exemption criteria are complied with, this increase in activity is small and the associated individual doses are low.

5.4. In view of these considerations, the practice of the irradiation of gemstones for subsequent supply to members of the public can be considered to fall within the context of para. 3.17 of the BSS and, as such, is deemed not to be justified. However, the statements in the BSS allow considerable flexibility and a final decision on justification should be made by the regulatory body of the State in which the practice is being considered for the first time.

5.5. As stated in para. 3.4, all justification decisions should be subject to review from time to time. This should involve a review of those practices that are deemed not to be justified as well as those deemed to be justified. In reviewing existing practices involving the irradiation of gemstones, the regulatory body should take all relevant factors into account including the relative size and value of the national and international markets in irradiated gemstones, the employment benefits to the community, potential doses to workers and to members of the public who wear the gemstones and the long-term effectiveness of the irradiation procedure.

DETAILS OF THE PRACTICE

5.6. The irradiation of gemstones is a widespread practice, carried out to enhance the colour of the gems and increase their market value. The irradiation process is usually carried out on cut gems, although the irradiation of gems prior to cutting is also sometimes carried out. The gemstone enhancement process may involve irradiation by neutrons, electron beams or gamma-emitting radionuclides to further enhance appearance and coloration. Additional information on irradiation techniques and the activation products generated is given in Annex VII.

5.7. The practice of gemstone irradiation can involve a number of organizations in the supply chain. The various steps in the supply chain, as illustrated in Figure 1 below, are as follows:

(a) Rough gems are mined within or outside the State of irradiation;

(b) Mined gems are sent to the wholesaler/distributor or through a buyer and gem cutter to be finished or partially finished before they are irradiated. Gemstones are irradiated in various stages of cut, from completely uncut to cut and polished ready for mounting;

(c) Irradiations are typically arranged by the gemstone wholesaler and are prepared for irradiation at the irradiation facility or at a processing facility and subsequently transferred to the irradiation facility;

(d) Gemstones are irradiated to achieve the desired colour enhancement and then held for a period of time at the irradiation facility to allow for the decay of short-lived activation products;

(e) Following this initial holding period, the gemstones are removed from the irradiation canister, cleaned to remove radioactive surface contamination and subsequently analyzed to identify the radioisotopes present and determine their activity concentrations. These activities may be

conducted at the irradiation facility or at a processing facility. In either case, the activity contained in the gemstones is almost always high enough to warrant regulatory controls;

(f) In some circumstances irradiated gemstones may undergo additional enhancements, for example neutron irradiation may be followed by electron beam irradiation. Additionally, at this stage in the supply chain regulatory controls associated with transport, and export/import if applicable, should be applied to gemstones transported between facilities;

(g) Irradiated gemstones are stored until the radioactivity has decayed below the activity concentrations for exemption [Ref [1], Schedule 1], or to activity concentrations authorized by the regulatory body;

(h) Irradiated gemstones are then transported from the irradiator or processor to the wholesaler/distributor. At this point in the supply chain the national regulatory bodyhas deemed that the activity associated with the irradiated gemstones is below a level requiring regulatory control. Some gemstones may require additional work, such as cutting and polishing, to prepare them for setting by the jeweller. These activities may be accomplished by one or more entities as defined by various business models; and

(i) The gemstones are sold to retailers, who in turn supply the finished jewellery to the consumer.

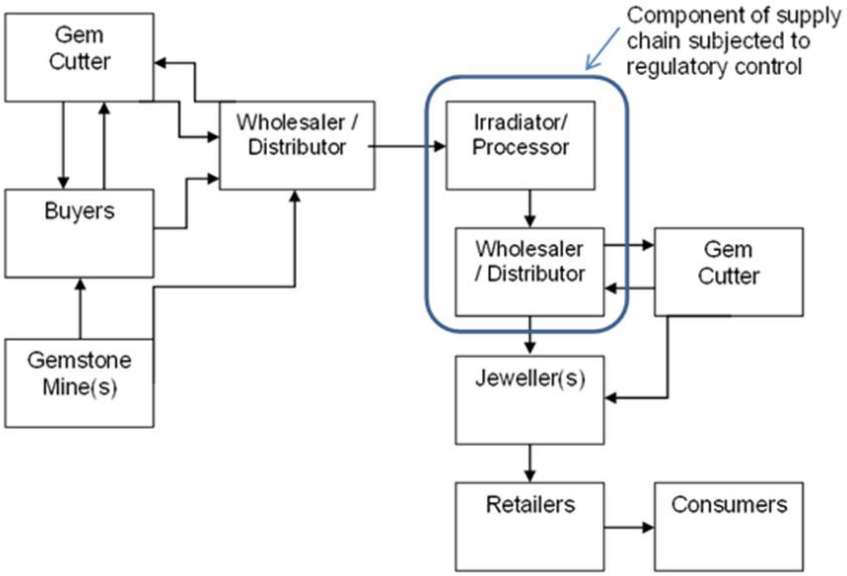

FIG 5.1. Example of irradiated gemstone supply chain.

5.8. The presence of radionuclides within irradiated gemstones is an unwanted by-product of the irradiation process resulting from the activation of impurities in the irradiated gem. Unlike most other consumer products where the added radioactive material provides an important function, the activation products induced in irradiated gemstones serve no useful purpose. However, appropriate storage of the gemstones after irradiation can ensure that most of the activation products quickly decay to insignificant levels.

5.9. The activities carried out during the irradiation and post irradiation process prior to the supply of irradiated gemstones to the public may involve occupational exposure to high radiation dose rates and should be subject to the appropriate regulatory control. While occupational exposure is outside the scope of this Safety Guide, occupational exposure may also occur if gemstones are released for further processing, such as sorting or cutting, before the activation products have decayed to trivial concentrations. Such exposures should also be subject to regulatory control.

5.10. Special attention should be given to manual operations with irradiated gemstones. Maximum use should be made of automatic sorting equipment and, if manual sorting is necessary, appropriate protection should be used and individual extremity doses should be measured and recorded. The management of occupational exposure is addressed elsewhere in the IAEA Safety Standards [36].

5.11. The international dimension of gemstone irradiation implies that different aspects of the practice are often carried out in different States e.g. the initial cutting of the gems may be carried out in State A, the irradiation process may be carried out in State B, and the final setting of the gemstones in items of jewellery and supply to members of the public may be carried out in State C. Intermediates, such as agents and brokers, may be located in a State different to those in which any of the practices are carried out and irradiated gemstones may be transported through third States. The regulatory bodies in each State involved in this practice should cooperate with each other in order to achieve a consistent approach to justification, authorization and regulatory control of all stages of the practice.

QUALITY TESTING AND VERIFICATION PROCEDURES

5.12. An effective testing and verification programme should be established and implemented by the irradiation facility. The purpose of such a programme is to ensure that gemstones with high activity concentrations are not supplied to the public after irradiation and that specific batches of gemstones are traceable. This programme should include:

(a) Effective batch labeling and processing, including methods for cataloguing, storing and tracking batches of gemstones;

(b) Assessment of activity concentration of specific radionuclides by gamma spectrometry by the use of appropriate detection equipment, normally a high purity germanium detector;

(c) Procedures and methods for the calculation of decay and release times;

(d) Record documentation and retention programme;

(e) Beta monitoring capability for ^{32}P and ^{35}S, if appropriate;

(f) Secure storage arrangements for radioactive materials commensurate with the level of activity associated with the irradiated gemstones; and

(g) Release criteria involving batch verification of radioactive decay to the activity concentration release value and the generation of release certification.

5.13. When considering the licensing of an irradiation and processing facility, the regulatory body should take account of the adequacy of the radiation protection programmes and quality assurance programmes in place. In some cases, it may be necessary to regulate the wholesaler/distributor if irradiated gemstones exceeding the exemption criteria will be processed or stored by the wholesaler/distributor prior to being transferred to the retailer. The programme described in para. 5.12 above should be considered the minimum necessary to ensure effective control.

5.14. The quality assurance programme for the irradiation facility should include validation and verification protocols to ensure that the irradiation of gemstones achieves the desired colour enhancement and that the activity concentrations of the induced radionuclides are such that the gemstones can be sold commercially.

5.15. The irradiation of some gemstones and other minerals (e.g. beryl) that may have been included in a gemstone batch can result in highly activated items that do not rapidly decay with time. Such items may remain highly radioactive for many months and sometimes years. The quality testing and verification programme should incorporate procedures to identify, retain and securely store such "rogue" gemstones until they are below the exemption values or can disposed of in accordance with an authorized disposal route. These storage and disposal considerations should be discussed and agreed

between the irradiation facility operators and the gemstone owners to determine responsibilities for management and disposal of radioactive wastes generated from the gemstone irradiation process. 5.16.

Direct supply of irradiated gemstones to the public should normally only be permitted when the activity concentrations fall below the exemption values given in the BSS. As discussed in Annex VII, the regulatory body may approve release at higher activity concentrations provided the more general exemption criteria are met.

5.17. Irradiated gemstones may require further processing prior to being supplied to the public. The regulatory body should ensure that

(a) the activity concentrations of the irradiated gemstones are below the exemption values in the BSS; or

(b) if the exemption values in the BSS are exceeded, that the person or organization who will undertake the processing is authorized to do so, or has been exempted from regulatory control.

In determining the activity concentration criteria for the release of gemstones to a customer for further processing (i.e. cutting), the irradiation facility should take into account whether the receiving customer is suitably authorized for the receipt of radioactive materials and the processing of the gemstones. The irradiation facility should also confirm and agree the release criteria with the customer.

5.18. The IAEA has produced nuclear security recommendations and guidance that may apply to licensed gemstone irradiation facilities such as nuclear research reactors and cobalt irradiators. Nuclear security measures should be implemented in line with this guidance, as well as corporate security requirements for the gemstones themselves. This will ensure that, in most cases, no additional security measures will be necessary due to the relatively low activities involved. Exceptions requiring additional nuclear security considerations occur when the aggregated 1 “D” value for any particular radionuclide in a single location is exceeded.

TRANSPORT

5.19. The regulatory requirements for the transport of irradiated gemstones will depend on the activity concentration and total activity of the consignment. In circumstances where the gemstones are retained by the facility until the activation products have decayed to below the exemption values specified in the BSS, they also meet the exemption values specified in the IAEA Transport Regulations [13] and

hence may be transported without control. However, in circumstances where the irradiation facility is releasing gemstones for further processing before decay to the exemption levels, all transport activities must be carried out in accordance with the requirements in [13]. Any handling or inspection of transport-labeled packages of irradiated gemstones during transportation e.g. during customs procedures at ports of entry, should be carried out in accordance with the established procedures for the handling of packaged radioactive materials.

OTHER CONSIDERATIONS

5.20. Gemstone irradiation is part of an international trade, and consignments of irradiated gemstones are routinely transported from the State where they have been irradiated to other States for setting, distribution and supply. Importers have general responsibilities to ensure that products that they import are safe and that they satisfy regulatory requirements. An importer of gemstones should be aware of the activity concentrations of the gems. The importer should know whether the activity concentrations are below the exemption values and hence whether or not the gemstones can be supplied to the public. In circumstances where the gemstones do not satisfy the exemption criteria, the importer should be aware of any restrictions on their use, and the potential occupational exposure requirements associated with any cutting or processing operations. The importer should obtain information on the activity concentrations of the irradiated gemstones from the irradiation facility and pass this information on to any organization that will be processing or retailing the gemstones.

5.21. When gemstones that satisfy the exemption criteria are supplied to members of the public, it is not necessary to provide information on the retail packaging or to affix a label to the item indicating that it has been irradiated, unless this is part of a general requirement of national legislation relating to consumer choice. According to existing legislation of labeling in some States (e.g. European Union), the individual package of item containing irradiated gemstone should have the indication that it contains “treated material”, without special indication as to the nature of such treatment.

5.22. The regulatory body should be kept aware of the numbers and activity concentrations of irradiated gemstones that are exported to other States. If the State into which irradiated gemstones are to be exported has reached the view that the practice of gemstone irradiation is not justified, the exportation of irradiated gemstones to that State may need to be prevented. Decisions on such matters, including the means of their implementation, should be decided through joint discussions between the regulatory bodies in the States concerned.

5.23. The regulatory body in a State into which irradiated gemstones are imported should ensure that irradiated gemstones are only being supplied to members of the public when the activity concentrations are below the appropriate exemption values.

OTHER IRRADIATED ITEMS

5.24. While currently several different types of gemstones are colour-enhanced though irradiation, it is possible that new products that have been irradiated may be introduced onto the market. For example, gamma irradiation of golf balls has been shown to increase the toughness of the ball's cover and strengthens the materials used in their core, allowing the golf ball to last longer and fly further on impact [37]. The regulator should justify and authorize future products in line with the requirements in the BSS and the supporting Safety Guides.

6. INTERNATIONAL HARMONIZATION

INTRODUCTION

6.1. The supply of consumer products to the public is a common practice with a significant international dimension. For example, ICSDs are constructed in several States and exported for distribution and supply around the world. Modern small GTLSs are manufactured and then sold to watch manufacturers and other producers for incorporation into watches, key fobs and weapon sights. These products are then exported for supply to members of the public in many States. In the case of small, easily transportable products like GTLD key fobs, a primary route of supply is via internet sales directly to the consumer. Irradiated gemstones are also traded internationally and have a high intrinsic value. It follows that a consistent approach by regulatory bodies to the justification and authorization of such products is beneficial in maintaining an adequate level of control and preventing the supply of products of practices that are not justified, while not unnecessarily obstructing the supply of products of justified practices.

6.2. The provisions in the BSS already indicate that consensus among Member States has been achieved regarding:

(a) A common understanding on the application of the principle of justification;

(b) The level of individual dose that may be used for the purpose of exemption from regulatory control without further consideration;

(c) The total activities and activity concentrations of many radionuclides that may be used in exempting moderate and bulk quantities of radioactive material from regulatory control without further consideration;

(d) The criteria for exempting devices containing sealed radioactive sources; and

(e) The criteria for exempting radiation generators.

6.3. Harmonization of regulatory approaches relies on the implementation of these provisions. Many States have already adopted the BSS exemption criteria in national legislation. States who have not done so should consider the formal adoption of these provisions. However, even if these criteria

are not fully met, the BSS still provides considerable flexibility by allowing the regulatory body to decide whether or not to exempt certain sources or practices from some or all aspects of regulatory control.

6.4. In the case of individual dose criteria that are assessed using safety assessments, this flexibility is provided for by allowing the regulatory body to take into account "low probability scenarios…..[for which] the effective dose expected to be incurred by a member of the public…….does not exceed 1 mSv in a year" (Ref. [1], para. I-2). Thus, the regulatory body should not apply rigidly the 10 μSv individual dose requirement but take fully into consideration the range of doses that may be received under different scenarios, and also the likelihood of each of these scenarios occurring.

6.5. Further flexibility is afforded to the regulatory body by para. I-1 of the BSS [1], which allows for exemption if, in the opinion of the regulatory body, "no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or of health risks." The intent of this requirement is clear: the regulatory body should not impose regulation for its own sake and any regulation that is deemed necessary must be effective in improving protection and safety. As mentioned throughout the IAEA safety standards, any such regulation should be applied using a graded approach.

6.6. While numerical values of activity, activity concentration, individual dose and dose rate are appropriate for inclusion in national legislation, the flexibility that exists in the BSS ultimately demands some subjective decision-making by the regulatory body. The guidance outlined in this Safety Guide specifies how such decisions should be reached and, if applied, should assist on reducing this subjectivity.

INTERNATIONAL CONSENSUS

6.7. Although the BSS and other IAEA safety standards reflect the consensus of Member States and are intended to lead to harmonization of approaches, this has not happened with consumer products. Whatever the reason for the differences, further harmonization is both possible and desirable.

6.8. For example, consideration should be given to whether type approval of consumer products in one State should be accepted in other States, or, at least, whether the safety assessment that has been used as the basis of type approval in one State should be used for the purpose of granting type

approval in another. This would necessitate international consensus on the approaches to be used in determining the benefit associated with the use of products and in undertaking the safety assessment.

6.9. A further argument in support of greater harmonization relates to the increasing use of the internet for the marketing of products. If a particular consumer product is authorized for supply to the public in one State, it will be extremely difficult, if not impossible, to prevent it being sold online and purchased by consumers in an adjacent State. While it may be possible to intercept and impound such products during transport to a State in which supply to the public is not authorized, this is likely to involve significant resources in terms of both manpower and training. It is clearly in the interest of all States and all regulatory bodies to adopt a harmonized approach to ensure that consumer products authorized for supply to the public in one State are similarly authorized in another.

6.10. To this end, regulatory bodies should establish contact with their counterparts in neighboring States to agree the procedures and criteria for undertaking safety assessments and for exempting the supply of radiation generators and other products to the public from regulatory control. Formal agreements should be entered into on either a bilateral basis or, ideally, throughout a region. As part of the process leading to the establishment of such agreements, discussions should take place with interested parties such as manufacturers and suppliers.

6.11. In June 2011, the Heads of the European Radiological Protection Competent Authorities (HERCA) issued an interim statement on lamps used in various public and professional environments and to which small amounts of radioactive substances have been added for functional reasons [38]. The statement committed national regulatory bodies to ensuring that the "results of national assessments and regulatory decisions will be shared in Europe through HERCA to promote a consistent European approach to the process" and noted that "as consumer goods are introduced in open markets in Europe, HERCA recognizes more generally the need for harmonization of the radiation safety regulation of goods containing small quantities of radioactive material." This initiative provides a good model that should be followed by the regulatory bodies of other regions.

6.12. Regional fora provide a convenient forum for the discussion of national approaches and the sharing of information on the benefits and detriments associated with particular products. It is recommended that regulatory bodies should initiate discussions at the national and regional level on consumer product issues with the intention of achieving regional agreement on the following:

(1) A common approach to the justification process, and the sharing of the supporting information that was the basis for a justification decision;

(2) The development of a common agreement on the justification of specific products, where practicable;
(3) A common view on the information required as part of the authorization process;
(4) The acceptance by one State of the safety assessments carried out for other States;
(5) Common agreement on the exemption from regulatory control of the supply of specific consumer products; and
(6) A common view on the justification of the most widespread consumer products: ICSDs, GTLD watches and key fobs, lamps containing radioactive materials and irradiated gemstones.

The development and implementation of such an understanding would represent a significant saving of regulatory resources that could be more usefully deployed elsewhere, and would also provide clarity and guidance to manufacturers and suppliers of consumer products.

6.13. While regulatory bodies have a shared interest in adopting a harmonized approach to regulating radiation safety, this harmonization is also in the interest of the public. Different approaches can lead to a situation where products are freely available for purchase in one State but not in another. This can create confusion over the significance of radiological hazards in the minds of the public who may not understand why products regarded as inherently safe in one State are not on sale in another. Different approaches to regulation can also lead to individuals inadvertently being out of compliance with national requirements when moving from one State to another. The regulatory body should recognize that harmonized approaches to regulation support international trade and should take steps to facilitate national and international agreements in this regard.

6.14. A coordinated regional approach should be used to facilitate the development of international technical standards for new types of product that had been justified and authorized for supply to members of the public. Such technical standards are indicative of the fact that the products in question have been accepted as justified in a number of States and therefore provide confidence regarding their justification and that protection is optimized in products complying with the standard.

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ANNEX I.
CASE STUDY ON JUSTIFICATION:
DOMESTIC IONIZATION CHAMBER SMOKE DETECTORS [I-1]

INTRODUCTION

I-1. The justification for the use of ionization chamber smoke detectors (ICSDs) by members of the public was considered by an expert group of the Nuclear Energy Agency (NEA) of the OECD during the 1970s [I-1]. This is a rather old example and although the data may now be out of date, the approach is still valid. The foreword to the group's recommendations state "Currently available information indicated that the best protection for a home would be a combination of properly functioning ionization-type and optical-type detectors. Accordingly and because the individual radiological risk resulting from the use, misuse, disposal etc. of ICSDs and the collective radiological risk are estimated to be very low, the Expert Group has concluded that ICSDs should not be excluded from use because of the availability of the optical type but rather both should be available to the public. When controlled in accordance with the provisions of this document, the benefits associated with ICSDs are significantly greater than the risks".

I-2. The NEA review covered ICSDs containing ^{63}Ni, ^{85}Kr, ^{226}Ra, ^{239}Pu or ^{241}Am for use in multi-station fire detection or alarm systems. For single, self-contained units in which the alarm is incorporated in the ICSD (i.e. those units designed for domestic use), only units containing ^{226}Ra or ^{241}Am were considered. More recently, the use of ^{226}Ra in individual ICSDs has been discontinued as its use is no longer considered justified.

BENEFITS

I-3. The main benefit is the potential saving of lives especially in domestic fires. Figures for 1972 showed a range of 3 to 57 fire deaths per million persons in a range of States, of which almost half were due to the victim being overcome by gas or smoke. The NEA document quotes the results of a number of studies which indicated that between a third and a half of the fatalities might not have occurred if fire detection systems were universally installed. An average figure for the preventable fatalities of 20 deaths per million per year was therefore assumed. Any savings in terms of prevention of loss of property would have been an additional benefit.

DETRIMENTS

I-4. The safety assessment was carried out for ICSDs containing 40 kBq ^{241}Am under a range of normal use and accident scenarios. The annual effective dose to an individual householder as a result of normal use was estimated to be about 1μSv. The potential committed equivalent dose to bone from deliberate misuse was estimated to be about 1 mSv, which corresponds to a committed effective dose of 10 μSv.

I-5. The disposal of the ICSD as household waste was also considered, including scenarios whereby the waste was subsequently incinerated. It was concluded that the maximum annual effective dose to an individual would be substantially less than 0.1 μSv.

DECISION

I-6. The overall conclusion of the NEA Expert Group, which covered both detector systems used in industrial and other commercial premises and single-station detectors used in homes was that "the benefit which can be obtained from ICSDs, both in terms of reducing property damage and saving lives, significantly outweighs any radiological risks involved in their use, misuse, disposal etc."

REFERENCES TO ANNEX 1

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ANNEX II.
CASE STUDY ON JUSTIFICATION:
HIGH INTENSITY DISCHARGE LAMPS

INTRODUCTION

II-1. High intensity discharge (HID) lamps produce bright white light with a high intensity in an energy efficient manner. These lamps are typically used in large numbers in public and professional environments such as shops, warehouses, hotels and offices. They are also used in outdoor applications to illuminate streets, buildings, statues, flags, gardens and further as architecture lighting. They also have applications associated with film projection in cinemas, manufacture of semiconductors, fluorescence endoscopy and microscopy, schlieren photography, hologram projection, UV-curing, sky beamers and car headlights. Some types of HID-lamps, as well as certain other lighting products, contain radioactive material for functional reasons. The radionuclides that are typically incorporated into HID-lamps are ^{85}Kr and ^{232}Th. Given the wide range of uses, specific justification decisions may be required for different applications.

II-2. A small number of safety assessments for HID lamps have been carried out and published [II-1 - II-3]. No published national decisions addressing specifically the justification of the use of HID lamps have been identified.

BENEFITS

II-3. A major benefit of this technology is that light of a desired spectral quality and high intensity is produced in a very energy efficient manner. The light yield of HID-lamps is typically 90–100 lumen per watt and is substantially higher compared to the performance of that of halogen lamps (20–30 lumen per watt). As this energy-saving technology is ubiquitously available in society, the utilization of this lamp technology makes an important contribution to a reduction of CO_2-emission and helps society towards achieving the objectives of the Kyoto Protocol [II-4].

II-4. Energy-saving is an important characteristic of HID-lamps and the associated economic and environmental considerations need to be taken into account as a benefit in the justification process. When alternative lamps are used, more lamps as well as more energy would be needed to produce the equal amount of required light. The use of HID lamps is also economical as the average lifetime of up to 20 000 hours is considerably longer compared to the average life expectancy of halogen lamps (2 000 hours).

II-5. Other energy efficient alternatives, such as fluorescent lamps, produce more diffuse light rather than focused high intensity light and do not provide the same ambience compared to HID-lamps. Fluorescent lamps are therefore not a direct replacement for HID-lamps in certain specialist applications. Also the compactness of HID-lamps is in many instances an advantage or even an essential requirement.

DETRIMENTS

II-6. For the radiological assessment of lamps containing ^{85}Kr, each lamp is assumed to contain 10 kBq of ^{85}Kr. The dose to members of the public is estimated to not exceed 1 μSv per year for normal use and for accident scenarios when the lamp may lose its integrity. At the end of the life, lamps may be recycled or disposed to landfill. It is estimated that the dose to members of the public will increase by 2 pSv per year when the ^{85}Kr activity of 1 million light products is released to the atmosphere during waste processing [II-5]. The radiological consequences of landfill disposal are considered to be insignificant [II-2].

II-7. For the radiological assessment of lamps with ^{232}Th, each lamp is assumed to contain 4.5 kBq (corresponding to about 1 g) of ^{232}Th. The dose to members of the public for normal use and from accident scenarios is estimated to not exceed 1 μSv per year. When end-of-life lamps are sent to a municipal waste landfill, the resulting annual doses are estimated to be below 0.1 μSv [II-6]. In the unlikely case that someone swallows a thoriated lamp electrode (intake by ingestion) taken from a landfill site, the resulting dose is estimated to be 0.4 μSv [II-7]. In the event that lamps are disposed of by incineration, the resulting dose to members of the public was estimated to be 0.0002 μSv by incineration of 20 MBq of ^{232}Th [II-8].

EVALUATION

II-8. Studies also demonstrated that the scenarios and exposure pathways used to derive the exemption levels specified in the Basic Safety Standards, are not directly relevant to the evaluation of the radiological consequences for members of the public when exposed to lamps under normal as well as accident scenarios. When more realistic scenarios are used, the radiological consequences for members of the public were shown to be insignificant during the entire life cycle of the lamps, including following disposal.

II-9. The benefits of the use of such lamps is from savings in terms of energy and cost (due to their energy efficiency), and to help States to meet the Kyoto Protocol targets on CO_2 emission reductions.

HID-lamps have certain characteristics that cannot be duplicated by other types of lamp and therefore are the only option for certain specialist applications.

II-10. Direct comparison of benefit and detriment is not straightforward as the benefit is in terms of energy- and cost-saving, functionality and environmental protection while the detriment is expressed in terms of individual dose. Regulatory bodies therefore need to make subjective decisions on the basis of perceived benefit to society and the inherent safety of the products. However, provided the regulatory body deems that the criteria for justification have been met, the available safety assessments indicate that HID lamps can be exempted from regulatory control.

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ANNEX III.
CASE STUDY ON JUSTIFICATION – DECISION TO NO LONGER JUSTIFY THE SUPPLY OF IONIZING CHAMBER SMOKE DETECTORS TO THE PUBLIC

INTRODUCTION

III-1. Ionizing chamber smoke detectors generally contain a low-level (less than 40 kBq) sealed source of americium ^{241}Am. Older models can also contain other radionuclides, such as ^{238}Pu or ^{226}Ra. In France, these detectors have been extensively used in fire detection systems since the early 1940s (however their use in private homes has been prohibited since 1966). Today, nearly seven million of these detectors are still in use throughout France on more than 300,000 sites (companies and public buildings).

BENEFITS

III-2. At the time when these detectors were being installed on a large scale, they were able to offer a better response time than the other non-ionizing technologies until then available. The use of ionizing radiation was thus fully justified in order to comply with fire-related security standards in force and to protect people against the risk of fire.

DETRIMENTS

III-3. Due to their design, the ionization chamber smoke detectors do not constitute a radiological risk for the people frequenting the premises in which this type of detector is fitted. However, their removal (when incorrectly performed) and their disposal using conventional waste management chains are liable to present a risk.

EVALUATION

III-4. Since the large-scale installation of these detectors, their efficiency compared with other non-ionizing technologies, efficiency has been progressively reassessed with the successive technological developments of non-ionizing detectors (particularly optical and thermal ones) which enable smoke detection as early as ionization chamber smoke detectors. International standards (in particular Council Directive 89/106/EEC [III-1] relating to consumer products) now recognize the performance of these new technologies.

III-5. The use of these ionization chamber smoke detectors is thus no longer justified, because the radiological risk (however slight) presented by these devices is no longer offset by the superior performance of the ionizing technology. This is consistent with the approach of keeping exposures as low as reasonably achievable (ALARA).

DECISION

III-6. Given the large number of these detectors still in use and the low radiological risk that they present, their immediate and systematic replacement throughout France was not considered to be pertinent by the French Nuclear Safety Authority (ASN).

III-7. However, their installation in any new fire detection systems has been prohibited and, after consultation with the fire detection stakeholders, the gradual withdrawal over a 10-year period of these 7 million ionizing smoke detectors was introduced into the French regulation at the request of ASN.

III-8. Specific regulations [III-2 – III-4] now allow

- to ban all manufacture and import of new detectors;
- to prohibit the installation of ionizing smoke detectors in new fire detection systems;
- to guarantee the availability of disposal chains (disassembly, collection, storage, etc.), limiting the duration of the removal operations;
- to implement a staggered replacement programme for the detectors still in use;
- to monitor the progress of the withdrawal plan;
- to regulate (via notification or licensing) the companies in charge of the removal operations; and
- to avoid illegal dumping of these devices in conventional waste management chains.

III-9. These provisions specific to ionizing smoke detectors are part of a more global approach

resulting from the transposition of Council Directive 96/29 into national legislation [Ref. III-5]. Since 2002, French regulations have prohibited the intentional addition of radionuclides into consumer goods, foodstuffs and construction materials (which include ionization chamber smoke detectors).

REFERENCES TO ANNEX III

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[III-2] Order of 18 November 2011 derogating from article R. 1333-2 of the Public Health Code for ionising smoke detectors

[III-3] ASN resolution 2011-DC-0252 of 21 December 2011 requiring the notification of certain nuclear activities pursuant to 2° of article R. 1333-19 of the Public Health Code (confirmed by the order of 6 March 2012)

[III-4] ASN resolution 2011-DC-0253 of 21 December 2011, implementing the Public Health Code, defining the particular conditions of use as well as the registration procedures and the rules for the monitoring, the recovery and the disposal of ionising smoke detectors (confirmed by the order of 6 March 2012)

[III-5] EUROPEAN COMMISSION Communication from the Commission concerning the implementation of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of the workers and the general public against the dangers arising from ionising radiation, EC, Luxembourg (1998)
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ANNEX IV.

SUMMARY OF NRPB STANDARD FOR DESIGN, CONSTRUCTION AND PERFORMANCE FOR IONIZATION CHAMBER SMOKE DETECTORS (ICSDS) [IV-1]

SCOPE

IV-1. This standard details the radiation protection requirements for ionization chamber smoke detectors (ICSDs). The standards relate to those ICSDs intended for use by the general public in their own homes. These devices are frequently referred to as single station ICSDs.

IV-2. The standard does not cover the protection of persons normally handling ICSDs as a result of their occupation (manufacturers, distributors, maintenance engineers etc.), nor does it specify requirements for the storage and transport of ICSDs.

IV-3. The standard only relates to ICSDs containing ^{241}Am.

DEFINITIONS

IV-4. An *ionization chamber smoke detector* (ICSD) is a device intended for the detection of combustion products. It contains an ionization chamber and a radioactive source. Entry of the combustion products into the ionisation chamber affects the ionization current and this in turn triggers an alarm.

IV-5. A *single-station ICSD* is a self-contained device (mains and/or battery operated) in which the alarm is incorporated in the ICSD and the ICSD does not need to be linked to any other external fire detection or alarm system in order to function.

IV-6. A *sealed source* is a radioactive source sealed in a capsule or having a bonded cover, the capsule or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which the sealed source was designed. This includes cut foil sources where the radioactive material is sandwiched between inactive layers.

IV-7. A *source holder* is the mechanical support for the sealed source.

PRINCIPAL SPECIFICATIONS

IV-8. The radioactive source(s) used in an ICSD shall be ^{241}Am sealed source(s) conforming to the relevant requirements of ISO standard 9978 [Ref. IV-2]. The tests specified in the ISO standard shall be applied to the sealed source mounted in its source holder.

IV-9. The total activity of the source(s) shall be as low as reasonably achievable consistent with the reliable function of the ICSD and shall not exceed 40 kBq.

IV-10. Under normal conditions of use, direct contact with the radioactive source shall be impossible. The design of the device shall also discourage persons from attempting to gain access to the radioactive source and should be tamper-proof.

IV-11. ICSD (or parts of ICSD where permitted) shall satisfy the prototype tests specified below.

PROTOTYPE TESTS

IV-12. The following tests shall be carried out on a prototype of each ICSD submitted for approval. A separate ICSD may be submitted for each test. The source shall not become detached or suffer loss of integrity as a result of each test.

Temperature

IV-13. The ICSD shall be cooled to -25ºC, kept at this temperature for one hour and then allowed to return to ambient temperature. It shall then be heated to 100ºC, kept at this temperature for one hour and then allowed to return to ambient temperature.

Impact

IV-14. The equipment and procedure for the impact test shall be those described in ISO 2919 [Ref. IV-3]. A steel hammer of mass 0.5 kg shall be dropped from a height of 0.5 m on to the ICSD, which should be positioned on a steel anvil.

Drop

IV-15. The ICSD shall be dropped from a minimum height of 4 m on to a hard, unyielding surface.

Vibration

IV-16. The ICSD shall be vibrated sinusoidally in a direction perpendicular to its normal plane of fixation; the frequency of vibration being swept from 5 to 60 Hz at a rate of 4 octaves per hour. The peak acceleration shall be 2.4 m s-2 for the range 5 to 20 Hz, 4 m s^{-2} for the range 20 to 40 Hz and 5.1 m s-2 for the range 40 to 60 Hz. Two sweeps through the range shall be made and the ICSD shall then be vibrated for one hour at any resonant frequencies found, the peak acceleration being $0.7\sqrt{f}$ m s-2, where f is the resonant frequency.

Evaluation

IV-17. Following each of the above four tests, wipe or immersion tests shall be carried out. The wipe test shall be carried out over each source and the inactive surfaces of the detector, paying particular attention to the source holder. The immersion test shall be carried out using the complete detector. If the removed activity is less than 200 Bq from each source, then the source shall be considered to have retained its integrity.

Tests for the effects of fire

IV-18. A fire test shall be carried out on the complete ICSD or on the source mounted in its source holder in the presence of parts of the ICSD which are sufficiently representative of the whole device. Air shall be passed through the furnace for the duration of the test at a flow rate of 1 to 5 litres per minute, and condensed and filtered before release to atmosphere. The ICSD (or its parts) shall be heated from room temperature to 600ºC and retained at this temperature for one hour. If the sum of the activity remote from the source (i.e. that which is in the condenser, on the filters and in the debris) and that removed from the source and holder (either by wipe or immersion testing) is less than 200 Bq, then the ICSD shall be considered to have passed the test.

Incineration test

IV-19. A high temperature fire and incineration test shall be carried out on the complete ICSD or on the source mounted in its source holder in the presence of parts of the ICSD which are sufficiently representative of the whole device. The procedure shall be the same as that described in Tests for the effects of fire, except that the ICSD (or its parts) shall be heated to 1200ºC and retained at this temperature for one hour. If the activity detected in the condenser and on the filter is less than 1% of the activity of the ICSD, then the ICSD shall be considered to have passed the test.

MARKING AND LABELING OF ICSDs

IV-20. The ionization chamber of each ICSD shall bear a label with the trefoil symbol and the word "radioactive". This label shall be clearly visible on removing any cover or housing of the ICSD. The outer housing of the ICSD should be marked in the same way.

IV-21. The packaging of the product should include a warning label and instructions for safe use and disposal.

QUALITY CONTROL

IV-22. The production of an ICSD shall be subject to adequate quality control procedures. Applicants for authorisation will be expected to provide descriptions of such procedures, indicating the methods employed to ensure that each ICSD manufactured is within the specification of the prototype.

REFERENCES FOR ANNEX IV

[IV-1] NATIONAL RADIOLOGICAL PROTECTION BOARD, Radiological Protection Standards for Ionisation Chamber Smoke Detectors (ICSDs) Documents of the NRPB, vol. 3 no.2, pages 9-20, HMSO (1992).

[IV-2] INTERNATIONAL STANDARDS ORGANIZATION, Radiation protection – Sealed radioactive sources – Leakage test methods, ISO 9978, Geneva (2002).

[IV-3] INTERNATIONAL STANDARDS ORGANIZATION, Radiation protection – Sealed radioactive sources – General requirements and classification, ISO 2919, Geneva (2012).

ANNEX V.
RADIATION DOSES FROM IONIZATION CHAMBER SMOKE DETECTORS [V-1][7]

INTRODUCTION

V-1. Ionization chamber smoke detectors (ICSDs) are designed to give early warning of fire and as such are considered to be Category I (safety) products. The appropriate dose criteria for the approval of consumer goods containing radioactive substances are given in Ref. [V-2].

V-2. The estimated doses arising from normal use, incidents, misuse and disposal of ICSDs are given below. Where internal doses are reported, only the most restrictive of the doses to an adult, a child or an infant is given.

NORMAL USE AND DISPOSAL

V-3. During normal use of ICSDs the doses to members of the public are limited to those resulting from external radiation. The dose equivalent rate in air, *D*, at a distance *d* (m) from the surface of an ICSD, is given by

$$D = \frac{t \times A}{d^2}$$

where t is the dose equivalent rate given in terms of Sv h^{-1} at 1 m from 1 GBq and *A* is the activity of the source in GBq. The value of t for ^{241}Am is 2.4×10^{-6}.

The NRPB standard for ICSDs (see Annex IV) requires that the activity of the sealed source shall not exceed 40 kBq of ^{241}Am. From the equation it can be concluded that the maximum dose equivalent rate at a distance of 2 m from the source of an ICSD that satisfies this requirement will be 24 pSv h^{-1}.

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[7] Dose coefficients and associated calculations have been updated in line with ICRP Publication 72 [V-5]

Normal use

V-4. Most ICSDs will be installed on staircases or in hallways and an individual will spend very little time in these areas. Some, however, may be installed in bedrooms. In estimating the doses, the following assumptions have been made.

(i) The ICSD is installed in a bedroom, irradiating the individual for 8 h each day.

(ii) The body to source distance is 2 m.

The maximum effective dose equivalent to the individual is therefore 70 nSv each year.

Maintenance

V-5. ICSDs installed in homes will be handled during installation, cleaning and battery changes. The maximum dose equivalent rate at the surface of a detector that satisfies the NRPB standard (see Annex IV) can be calculated to be approximately 1 μSv h^{-1}, assuming that the source is 1 cm below the detector surface, and the maximum dose equivalent rate at 0.5 m from the source can be calculated to be 400 pSv h^{-1}. In estimating the potential doses the following assumptions have been made:

(i) The ICSD is handled by the individual for a total of 3 h per year.

(ii) The body to source distance during handling is 0.5 m.

The maximum dose equivalent to the hands of an individual is therefore 3 μSv each year and the maximum effective dose equivalent to an individual is 1 nSv each year.

Disposal

V-6. ICSDs may be disposed of with normal household waste. In practice, this means that some may be sent to a landfill site and some may be incinerated. In estimating the potential effective doses from disposal, the following assumptions have been made:

(i) There are 20 million homes in the UK;

(ii) Each household in the UK has one ICSD;

(iii) 20% of these ICSDs are disposed of each year;

(iv) 80% of those disposed of are distributed between 500 landfill sites, i.e. a maximum of 6400 ICSDs per site each year;

(v) 20% of those disposed of are distributed between 200 incinerators, i.e. a maximum of 4000 ICSDs per incinerator each year.

Disposal to a landfill site

V-7. The two main pathways for exposure associated with this method of disposal are ingestion of drinking water contaminated with leachate from the site, and inhalation of airborne contamination caused by a waste fire. The NRPB standard for ICSDs (see Annex IV) states that an ICSD which passes the test for the effects of fire will release no more than 200 Bq during a fire. In estimating the doses arising from a waste fire, the following assumptions have been made:

(i) 1% of the ICSDs disposed of at a single landfill site are involved in waste fires during the year;

(ii) 200 Bq are released from each ICSD involved in a fire;

(iii) Each fire is of short duration. This is taken to be 30 min;

(iv) The most exposed individual lives 200 m from the tip;

(v) The ground-level time integrated concentration for unit release (1 Bq) in normal weather conditions (Pasquill category D) at 200 m from the tip[2] is 2.5×10^{-4} Bq s m^{-3} [V-3];

(vi) The breathing rate of an adult is 3.33×10^{-4} m^3 s^{-1} [V-4];

(vii) The committed effective dose equivalent per unit intake to an adult via inhalation is 9.6×10^{-5} Sv Bq^{-1} [V-5].

The maximum committed effective dose equivalent to an adult from one year's intake is therefore 104 nSv.

V-8. The committed effective dose equivalent to an adult drinking contaminated water during one year was estimated in NRPB-R205 as 1.2 nSv from a shallow inland burial of 1 TBq [V-6]. If 6 400 detectors of the maximum activity allowed by the NRPB standard are disposed of, the total activity disposed of at a single landfill per year would be 260 MBq. This would give a maximum committed effective dose equivalent to an adult of 0.3 pSv from one year's intake.

Disposal via incineration

V-9. The NRPB standard for ICSDs (see Annex IV) states that an ICSD which passes the incineration test will release no more than 1% of its activity during incineration. In estimating the doses arising from incineration, the following assumptions have been made:

(i) 1% of the radioactivity in the ICSDs is released during incineration;

(ii) The release is constant throughout the year;

(iii) The stack height is 50 m;

(iv) The maximum ground-level time integrated concentration for unit release (1 Bq) in normal weather conditions (Pasquill category D) is 3×10^{-6} Bq s m^{-3}[V-3];

(v) The breathing rate of an adult is 3.33×10^{-4} m^3 s^{-1} [V-4];

(vi) The committed effective dose equivalent per unit intake to an adult via inhalation is 9.6×10^{-5} Sv Bq^{-1} [V-5].

V-10. The maximum committed effective dose equivalent to an adult from one year's release is therefore 160 nSv. It can be assumed that the activity remaining in the slag will be disposed of to a landfill resulting in doses similar to those given above.

INCIDENTS AND MISUSE

V-11. Potential incidents involving ICSDs can be categorised as follows:

(i) fire;

(ii) misuse and mutilation.

Fire

V-12. In a survey of known incidents involving smoke detectors in the UK, fire was found to be the most common occurrence [V-7]. The NRPB standard for ICSDs (see Annex IV) states that an ICSD which passes the test for the effects of fire will release no more than 200 Bq during a fire. In estimating the doses during and after a fire the following assumptions have been made:

During fire:

(i) the ICSD contains 40 kBq americium-241;

(ii) 200 Bq becomes airborne;

(iii) 10^{-5} of the airborne activity is inhaled by a firefighter;

(iv) the firefighter attends 20 fires involving ICSDs each year.

After fire:

(i) the ICSD contains 40 kBq americium-241;

(ii) the ICSD was protecting 30 m^2;

(iii) the activity is mixed with the rubble and dust – 1% of the activity is resuspendable and respirable;

(iv) the resuspension factor is 2×10^{-6} m^{-1};

(v) the clear-up takes 8 h;

(vi) the breathing rate of an adult is 3.33×10^{-4} m^3 s^{-1}.

The maximum annual committed effective doses to an adult are therefore 4 μSv during fires and 24 nSv after fires.

Misuse and mutilation

V-13. The most significant possible misuse is dismantling of the ICSD by a member of the public. However, the probability of such an occurrence is small because the ionization chamber must be made tamper-proof in order for the ICSD to comply with the NRPB standard. An estimate of the potential dose to an infant who manages to break open the chamber and damage the source has been made using the following assumptions.

(i) 1% of the source activity is released due to damage;

(ii) 10% of this activity is transferred to the fingers and ingested;

(iii) The committed effective dose equivalent per unit intake to a three-month infant via ingestion is 3.7×10^{-6} Sv Bq^{-1} [V-8].

The resulting committed effective dose equivalent to an infant would be 140 μSv.

CONCLUSION

V-14. The potential doses arising from normal use, incidents, misuse and disposal of ICSDs which comply with the NRPB Standard do not exceed the appropriate dose criteria.

REFERENCES FOR ANNEX V

[V-1] NATIONAL RADIOLOGICAL PROTECTION BOARD, Radiological Protection Standards for Ionisation Chamber Smoke Detectors (ICSDs) Documents of the NRPB, vol. 3 no.2, pages 9-20, HMSO (1992)

[V-2] NATIONAL RADIOLOGICAL PROTECTION BOARD, Criteria of acceptability relating to the approval of consumer goods containing radioactive substances. *Doc. NRPB*, **3**, No. 2 (1992).

[V-3] CLARKE, R H., A model for short and medium range dispersion of radionuclides released to the atmosphere, Report NRPB-R91, Chilton (1979)

[V-4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Report of the Task Group on Reference Man, ICRP Publication 23 (1975).

[V-5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Age-dependent Doses to Members of the Public from Intake of Radionuclides Part 5, Compilation of Ingestion and Inhalation Coefficients, ICRP Publication 72, Annals of the ICRP, v. 26 no. 1 (1996).

[V-6] SMITH, G M, FEARN, H S, DELOW, C E, LAWSON, G AND DAVIS, J P., Calculations of the radiological impact of disposal of unit activity of selected radionuclides, Report NRPB-R205, Chilton (1987).

[V-7] NUCLEAR ENERGY AGENCY, Recommendations for ionisation chamber smoke detectors in implementation of radiation protection standards. Paris, NEA, OECD (1977).

[V-8] NATIONAL RADIOLOGICAL PROTECTION BOARD, Committed doses to selected organs and committed effective doses from intakes of radionuclides. Chilton, NRPB-GS7 (1987) (London, HMSO).

ANNEX VI.
NRPB STANDARD FOR WATCHES AND COMPASSES INCORPORATING GASEOUS TRITIUM LIGHT SOURCES (GTLSS) [VI-1]

SCOPE

VI-1. This standard details the radiological protection requirements for time measurement instruments containing gaseous tritium light sources (GTLSs). They relate to those instruments intended for use by the general public.

VI-2. The standard does not cover the protection of persons normally handling time measurement instruments as a result of their occupation (manufacturers, distributors, repairers etc.), nor does it specify requirements for the storage and transport of time measurement instruments containing GTLSs.

VI-3. The standard does not relate to time measurement instruments with some other form of illumination provided by radioactive materials, in particular radioactive deposits.

DEFINITIONS

VI-4. *Gaseous tritium light source (GTLS)* is a sealed glass tube internally coated with a phosphor and filled with tritium gas.

VI-5. *Time measurement instrument* is a watch or a clock.

VI-6. *Total activity* is the total activity of tritium present in all the GTLSs contained in a single Gaseous Tritium Light Device (GTLD).

VI-7. *Gaseous tritium light device (GTLD)* is a time measurement instrument or compass containing one or more GTLSs.

PRINCIPAL CONSIDERATIONS

VI-8. Watches and compasses shall satisfy the tests described below.

VI-9. Under normal conditions of use, direct contact with the GTLS shall be impossible. In addition, access to the GTLS shall only be possible by means of a special tool.

GTLS SPECIFICATION

VI-10. The GTLD total activity shall be as low as reasonably achievable, consistent with effective illumination and shall not exceed 7.4 GBq for watches/clocks and 10 GBq for compasses.

VI-11. The percentage of the activity of a single GTLS that is in the form of tritiated water or water soluble tritium shall be as low as practicable and shall not exceed 2% of the activity of that GTLS, except for a GTLS containing less than 2 GBq in which case the activity in this form shall not exceed 40 MBq.

VI-12. The rate at which tritium leaks from all the GTLSs in the GTLD shall not exceed a total of 2kBq per day.

INSTRUMENT SPECIFICATION

VI-13. The equivalent dose rate shall not exceed 0.1μSv/h at the surface of the GTLD.

VI-14. The GTLSs shall be fixed in a suitable metal or plastic support that will provide secure and shock-absorbing attachment during the lifetime of the GTLD.

MARKING AND LABELING

VI-15. The GTLD shall be marked externally with the symbol ^{3}H or the word ‘tritium’ in such a manner that the marking is visible.

QUALITY CONTROL

VI-16. The production of the GTLD shall be subject to adequate quality control procedures.

VI-17. Applicants for approval will be expected to provide descriptions of such procedures, indicating the methods employed to ensure that each timepiece manufactured is within the specification of the prototype.

PROTOTYPE TESTS

VI-18. The following tests shall be carried out on prototype time measurement instructions; a separate instrument may be used for each test. The GTLSs shall not become detached or suffer loss of integrity as a result of each test.

Temperature

VI-19. The GTLD shall be heated to +60 °C within 5 min, kept at this temperature for 1 h, then cooled to –20 °C in less than 45 min and kept at this temperature for 1 h.

Thermal shock

VI-20. The GTLD shall be heated in air to +60 °C and held at this temperature for at least 15 min. It shall be transferred in 15 s or less to water at 0 °C and held at this temperature for at least 15 min. The volume of water shall be at least twenty times that of the GTLD.

Vibration

VI-21. The GTLD shall be subjected to three complete test cycles in the range 25500 Hz at an acceleration of 50 m s^{-2}. The test shall be conducted by sweeping through the range at a uniform rate from the minimum to the maximum frequency and back to the minimum frequency in 10 min or longer. Each axis of the GTLD shall be tested. The GTLD shall then be vibrated for 30 min at any resonant frequencies found.

Pressure

VI-22. The GTLD shall be put into a test chamber and exposed to 25 and 200 kPa for four periods of 15 min each. The pressure shall be returned to atmospheric between each period and the test shall be conducted in air.

Impact (drop)

VI-23. The GTLD shall be dropped from a height of 1 m on to a hard, unyielding surface. The test shall be performed three times with the GTLD in a different orientation each time.

Crushing

VI-24. The GTLD shall be subjected to a crushing pressure of 1 kg cm^{-2} for 5 min. Each axis of the GTLD shall be tested.

Puncture

VI-25. A hammer of mass 10 g with a small pin fixed to its lower surface shall be dropped on to the face of the GTLD from a height of 1 m. The equipment and procedure used in this test shall be those specified in the British Standard for sealed radioactive sources [VI-2].

Evaluation

VI-26. After each test, determination of compliance with the performance requirements shall be carried out according to the following procedure.

(i) The GTLD shall be examined visually; there shall be no evidence of loss of integrity of the GTLSs or that the GTLSs have been dislodged from their support or have become readily accessible.

(ii) The GTLD shall be totally immersed in water at 20 ± 2 °C for 24 h, then removed and the activity in the water measured; the activity in the solution shall not exceed 2 kBq.

REFERENCES FOR ANNEX VI

[VI-1] NATIONAL RADIOLOGICAL PROTECTION BOARD, Radiological Protection Standards for Compasses containing Gaseous Tritium Light Sources, Documents of the NRPB, vol. 3 no.2, pages 47-59, HMSO (1992).

[VI-2] BRITISH STANDARDS INSTITUTION, Specification – sealed radioactive sources, British Standard 5288, BSI, London, (1976).

ANNEX VII.
SAFETY RELATED ASPECTS OF GEMSTONE IRRADIATION TECHNOLOGIES

INTRODUCTION

VII-1. Terrestrial background radiation in the host rock of a gem deposit can alter the colour of the gem material if the radiation dose is high enough and the ambient temperature low enough. For example, tourmalines from gem pegmatite become pink or red from exposure to high energy (1.46 MeV) gamma rays from ^{40}K over periods of millions of years. The natural blue colour of some topaz is thought to be produced by natural irradiation, as is the deep blue colour of Maxixe beryl. The surface coloration of yellow and yellow-green diamonds has also been attributed to natural radiation [VII-1].

VII-2. The natural processes of gem coloration induced by background radiation can be accelerated by artificial means, with a number of irradiation technologies used around the world to enhance the colour and beauty of many different gemstones. This can produce gemstones in colours not found in nature as well as significantly increase their commercial value. For example, the value of irradiated topaz can be increased up to ten times [VII-2]. There is also evidence of increased hardness of irradiated gemstones, another factor that adds to their commercial success [VII-3, VII-4].

VII-3. Today, a wide variety of gemstones are colour-enhanced by irradiation [VII-5 - VII-8]. The irradiation allows the creation of certain gemstone colours that do not exist or are extremely rare in nature. The colour changes that can be induced are given in Table VII-1.

TABLE VII-1: EFFECTS OF IRRADIATION TREATMENT ON VARIOUS GEM MATERIALS

Material	Starting colour	End colour
Beryl	Colourless	Yellow
	Blue	Green
Maxixe type	Pale or colourless	Blue
Cats-eye chrysoberyl	Pale yellowish-green or colourless	Intensifies colour or green
Corundum	Colourless	Yellow
	Pink	Padparadscha (bright pinkish-orange)
Diamond	Colourless or pale to yellow and brown	Green, black or blue. In combination with heating, the colour turns to yellow, orange, brown, pink or red.
Fluorite	Colourless	Various colours
Pearl	Light colours	Gray, brown, blue or black
Quartz	Colourless to yellow or pale green	Brown, amethyst, "smoky" or rose
Scapolite	Colourless, "straw," pink, or light blue	Blue, lavender, amethyst or red
Spodumene	Colourless to pink	Orange, yellow, green or pink
Topaz	Yellow, orange, colourless, pale blue	Colours are intensified
	Colourless, pale blue	Brown, blue (may require heat) or green
Tourmaline	Colourless to pale colours	Yellow, brown, pink, red or green-red
	Blue	Purple
Zircon	Colourless	Brown to red

TYPES OF RADIATION, TECHNOLOGIES AND DOSES APPLIED FOR TREATMENT

VII-4. Three different processes are routinely used in the irradiation of gemstones to enhance their appearance and colour. These processes involve irradiation by neutrons (in a nuclear research reactor), electron beams (using a linear accelerator) or gamma-emitting radionuclides [VII-8]. In some instances, more than one process (e.g. irradiation by neutrons followed by electron beam irradiation) may be applied.

Gamma-Ray Irradiation Facilities

VII-5. Many types of gemstones are currently irradiated with gamma rays to produce or enhance their colour. The most commonly used irradiation source is ^{60}Co. Gamma irradiation is sometimes also

used to screen out unwanted material, such as beryl or quartz, or to prepare certain gemstones for subsequent treatments, e.g. topaz turns light blue following gamma irradiation and a much darker blue can be induced following additional radiation treatment with high-energy electrons. The advantage of gamma irradiation processing is that it does not have sufficient energy to activate impurities within the gemstones and hence radioactive material is not introduced or activated. The disadvantage of gamma irradiation is that the colour enhancement is not as permanent as with other irradiation technologies.

Electron Beam Accelerators

VII-6. Beams of electrons generated by electron beam accelerators (of different design schemes including linear and non-linear geometries of electron acceleration) at energies up to 12 MeV and at currents of several hundred microamperes are used to irradiate gemstones at dose rates up to and exceeding several MGy per hour. At these dose rates, the gem materials must be water cooled to prevent elevated temperatures and thermal shock. High temperatures will anneal or destroy the colour centres in the gem materials, while thermal shock will crack or shatter them. For instance, topaz receiving a typical dose rate of 2.5 to 5 MGy per hour will increase in temperature at the rate of 50C° to 100C° per minute if it is not properly cooled.

VII-7. The accelerator beam energy dictates the irradiation time and therefore the penetration rate and level of induced radioactivity. Beam energies below 10 MeV have relatively low penetration depths but induce little to no radioactivity in the gemstone. By contrast, beam energies above 12 MeV have higher penetration depths but are not generally used for gem materials because such high energies can induce significant radioactivity within the material with the level of radioactivity depending on the quantity and nature of impurities present in the gemstone [VII-9]. According to the ISO standard 11137 [VII-10], the application of electron beam energies above 12 MeV is not permitted for industrial irradiators (e.g. for medical supplies sterilization by electron beam). The induced activity is of relatively short half-life requiring a cooling off period from a few days to a few weeks until the radioactivity decays to below the exemption values specified in GSR Part 3 [VII-11]. For example, after electron beam irradiation of topaz the only radionuclides normally detected are ^{69}Ge ($T_{1/2}$= 1.63 days) and ^{24}Na ($T_{1/2}$= 0.6 days) [VII-8].

Nuclear reactors

VII-8. The most significant radiation safety issues arise with neutron exposure of gemstones which results in radioactivity in the form of activation products within the gemstone. The irradiation is

almost exclusively carried out at nuclear research reactors, which are often also used for other industrial and non-industrial applications.

VII-9. Topaz is the gemstone most commonly irradiated in research reactors [VII-12] and the colour is induced by the interaction of fast neutrons. The intensity of colour is related to the size of the gemstone, the neutron flux and the irradiation time: the larger the gemstone the shorter is the exposure required to achieve a desired colour (see Figure VII-1). The presence of thermal neutrons is primarily responsible for the generation of activation products in the stone impurities and therefore steps are normally taken to minimize the thermal neutron component.

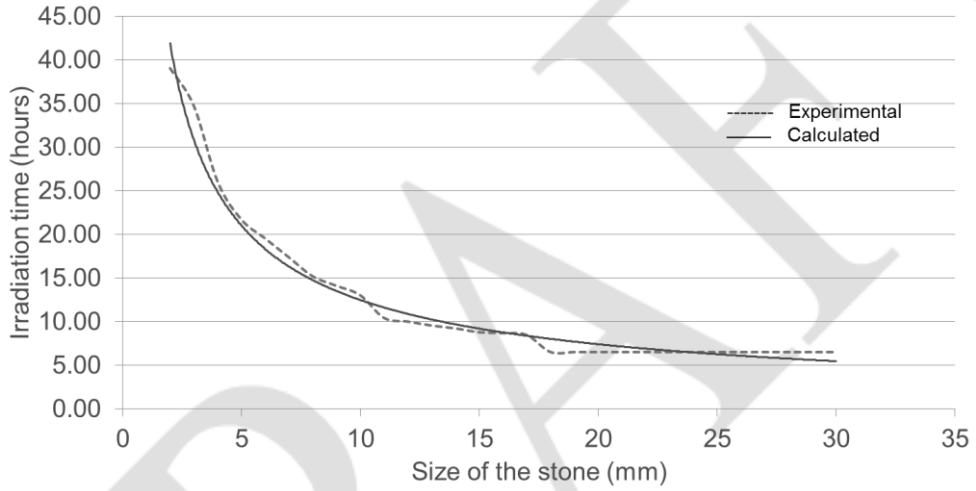

FIG. VII-1: Dependence of irradiation time versus topaz gemstone size [VII-5]

VII-10. Normally, gemstones are cleaned to remove any dirt and surface contamination prior to irradiation. Radionuclides such as ^{24}Na, ^{64}Zn, ^{140}La, ^{187}W and ^{198}Au can be produced due to the presence of human sweat and oils as well as chipping of tungsten carbide drill bits used for gem cutting [VII-12]. The cleaning minimizes the production of activation products that would otherwise need to be removed following irradiation and could potentially need to be managed as radioactive waste. In some instances, further cleaning and decontamination takes place following irradiation.

VII-11. Gemstones are typically irradiated in batches using irradiation canisters that are compatible with the reactor design. After irradiation, the canisters containing the irradiated gemstones are held for a period of time to allow for the decay of short-lived activation products; a large fraction of the short-lived activation products are induced in the irradiation canister itself. Irradiated gemstones are removed from the irradiation canister after the short-lived radionuclides have decayed to levels that

allow controlled handling of the irradiated gemstones. Subsequent processing of the irradiated gemstones includes analysis of radioactive concentrations to determine additional holding period required to achieve the exemption levels. The decay time necessary to reach the exemption criteria for supply to the public may range from a few months to a few years.

Other types of radiation treatment

VII-12. Ion implantation has been shown to be an effective method of enhancing the quality of Thai local natural corundum, including sapphire and ruby [VII-6, VII-13]. Oxygen and nitrogen ions at low and medium energies were implanted into the natural gemstones. Depending on the flux, the implantation modifies the colour and improves the colour distribution, transmission and lustre. This technology is still at the developmental stage and is not applied commercially.

WORLDWIDE PRODUCTION OF IRRADIATED GEMSTONES

VII-13. Large amounts of topaz, and to a lesser extent diamonds, are irradiated annually. Topaz irradiation in this context has proved to be a commercial success [VII-5]. The quantity of gemstones irradiated on an annual basis fluctuates with economic conditions and consumer demand. The technical abilities of research reactors allow for the irradiation of 2000 to 4000 kg (10-20 million carats) per reactor per year.

RESIDUAL RADIOACTIVITY AFTER IRRADIATION

Neutron induced activation products

VII-14. The type and quantities of impurities found in gemstones depends on the type and origin of the gemstone. These impurities are activated during the irradiation process resulting, in most cases, in relatively short-lived activation products. In the case of topaz, the predominant activation product is ^{182}Ta, with ^{22}Na, ^{46}Sc, ^{54}Mn, ^{65}Zn and ^{134}Cs also commonly present (see Table VII-2). Activity concentrations of these predominant radionuclides may be several hundred Bq/g shortly after irradiation. Pure beta emitters, ^{32}P and ^{35}S may also be present; these isotopes pose less of a regulatory concern due to their relatively short half-lives and low energy (in the case of ^{35}S) and their much higher exemption values compared with the gamma-emitting activation products.

VII-15. Several less predominant radionuclides may also be present (in the case of topaz, see Table VII-2); activity concentrations of these radionuclides are typically less than 10 Bq/g. Activation

products produced in surface impurities on the gemstone, such as residual cutting and polishing oils, are reduced or eliminated by cleaning the gemstones in nitric acid prior to irradiation. Further decontamination of the gemstones after irradiation may be warranted if surface contamination is present.

TABLE VII-2: RADIONUCLIDES FOUND IN IRRADIATED TOPAZ [VII-8]

Predominant Radionuclides	Half-life (days)	Less Predominant Radionuclides	Half-life (days)	Less Predominant Radionuclides	Half-life (days)
Ta-182	114.50	As-74	17.78	Pa-233	27.00
Na-22	949.00	Ba-133	3905.50	Pm-151	1.18
Sc-46	83.85	Ce-139	137.50	Rb-86	18.60
Mn-54	312.50	Ce-141	32.50	Re-183	70.00
Zn-65	243.80	Co-58	70.78	Sb-122	2.72
Cs-134	751.90	Co-60	1923.55	Sb-124	60.20
P-32	14.28	Cr-51	27.70	Sb-125	1011.05
S-35	87.90	Fe-59	44.50	Sn-113	115.10
		Hf-181	42.39	Sr-85	64.84
		Hg-203	46.59	Tb-160	72.30
		Ir-192	74.02	Y-91	58.50
		Nb-95	34.97	Zr-95	64.02

VII-16. As the various radionuclides present and their corresponding activity concentrations can show large variations, even for the same gemstone type, detailed analytical techniques such as gamma spectroscopy are required to determine the necessary decay-storage period. In some cases, neutron irradiation of different gemstones, for instance topaz and diamonds, can result in very similar radionuclide spectra.

Electron induced radionuclides

VII-17. High-energy electrons may induce radioactivity in a gemstone through photo-neutron reactions. For instance, a photon interacts with a ^{23}Na nuclide and transform it into ^{22}Na. The free neutron released during this nuclear reaction can produce another radionuclide , transforming, for example, ^{133}Cs into ^{134}Cs.

VII-18. These photo-neutron reactions occur only above certain energies and are therefore referred to as threshold reactions. Several radionuclides can be produced and generally occur with photons of energies from 7 to 18 MeV. As a general rule, the lower the atomic weight, the higher the photon energy needed to cause the reaction, the fewer the number of neutrons released, and the shorter the half-life of the produced radionuclide[VII-12]. For most gem materials, if the electron-beam energy is kept below 12 MeV, the half-lives of the induced radionuclides are short enough that the radioactivity decays to background levels within a few weeks. The radionuclides produced by high-energy electron treatment include ^{18}F, ^{24}Na, ^{49}Cr, ^{58}Ga, ^{64}Cu and ^{69}Ge but positive identification may not always be possible because of their relatively short half-lives ($\leq$ 1 day).

RADIATION DOSES AND HEALTH RISKS

VII-19. Radiation exposure received by the irradiator and processing facility personnel working with and handling irradiated gemstones prior to their release to the public should be considered as occupational radiation exposures to which the normal dose limits apply. Particular attention may need to be given to those workers who handle irradiated gemstones as, in some circumstances, it may be required to control the dose to the lens of the eye. Retailers and consumers should be regarded as the members of the public as they should only come in contact with irradiated gemstones whose activity concentrations satisfy the criteria for exemption.

VII-20. The principal exposure pathway for members of the public is external radiation exposure from wearing items of jewellery containing irradiated gemstones [VII-14, VII-15]. Much lower doses have been shown to be received during transportation and distribution of gemstones containing exempt concentrations of radionuclides [VII-15]. Additional supporting material has been published in the United States [VII-16, VII-17].

VII-21. A study in the United Kingdom [VII-14] analyzed over 5 000 samples of gemstones collected from dealers supplying directly to the public. No residual activation products were identified in any of the samples. As part of the same study, a number of so-called “rogue” gemstones from electron beam irradiated batches of topaz were also analyzed to determine the possible impact of the uncontrolled release of irradiated gemstones. The annual equivalent dose to the skin was calculated for two scenarios: a worst case scenario whereby the gemstone (for example in a ring) is worn continuously throughout the year and a second scenario in which the gemstone is worn for three hours a day, 30 days a year (as might be the case with a bracelet or pendant).

VII-22. The effective dose (to the whole body), E, can be calculated using the equation:

$$\mathbf{E = A_{skin} \times W_T \times D_{skin} / A_{body}}$$

where A_{skin} = Surface area irradiated

W_T = Tissue weighting factor for skin (10^{-2})

D_{skin} = Skin equivalent dose

A_{body} = Total body skin area ($1.8\ 10^4$ cm^2 for adults)

The highest estimated dose to 1 cm^2 of skin was found to be 3 Sv/y, corresponding to an annual effective dose of approximately 2 μSv. For occasional wear, the range of annual effective doses for "rogue" gemstones was calculated as <0.01 μSv up to 0.02 μSv.

VII-23. Analysis by the USNRC [VII-12, VII-15] assessed the external doses likely to be received by an individual from irradiated topaz containing exempt concentrations of by-product material as specified in national regulations [VII-18]. The US exemption activity concentrations are given in Table VII-3 for the five activation products most commonly found in irradiated gemstones, along with the corresponding exemption values from the BSS. The study noted that approximately 60% of the individual annual dose could be attributed to the presence of ^{182}Ta, with the remaining 40% equally divided between ^{46}Sc and ^{134}Cs – the contributions from ^{54}Mn and ^{65}Zn were negligible.

TABLE VII-3: COMPARISON OF EXEMPTION CONCENTRATION VALUES (Bq/g)

Radionuclide	10 CFR 30	BSS (GSR Part 3)
Sc-46	14.8	10
Mn-54	37	10
Zn-65	37	10
Cs-134	3.3	10
Ta-182	14.8	10

VII-24. The dose equivalent to an irradiated skin area of 1 cm^2 while wearing a 30-carat (6 g) gemstone continuously (24 hours per day for 365 days) was estimated to be approximately 15 mSv.[8] The corresponding annual effective dose is of the order of 0.01 µSv. This is the estimated dose for the first year, and because of the short half-lives of the radionuclides, the individual doses in subsequent years will be considerably lower. The calculation is likely to overestimate the doses for two reasons: firstly, no account is taken of the shielding afforded by the gemstone mounting and, secondly, the actual concentrations of activation products observed in gemstones supplied to the public are usually lower by at least a factor of two compared with the exemption values.

VII-25. A similar calculation has been carried out using the Microshield software [VII-19] for a combination of the five radionuclides of interest as listed in Table VII-3. Calculations were made for a 30 carat (6 g) unmounted gemstone and a number of different exposure scenarios involving exposure of the skin, breast and lens of the eye. It was assumed that the activity concentration of each activation product was at the maximum exemption value quoted in Table VII-3 for the BSS i.e. 10 Bq/g for each radionuclide. The highest annual effective doses calculated were similar to those reported elsewhere i.e. less than 0.01 µSv. Doses to the breast and lens of the eye were lower by at least an order of magnitude.

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