DS458

IAEA SAFETY STANDARDS

for protecting people and the environment

Status

Text endorsed by the CSS and established as Safety Standards by the Publications Committee

Radiation Safety for Consumer Products

SPECIFIC SAFETY GUIDE SSG-36

DS458

New Safety Guide

IAEA
International Atomic Energy Agency

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1. INTRODUCTION

BACKGROUND

1.1. In the IAEA Safety Requirements publication on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3, Interim Edition) (hereinafter referred to as the BSS) [1], a 'consumer product' is defined for the purposes of the IAEA safety standards as "a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation (hereinafter referred to as 'radiation'), and which can be sold or made available to members of the public without special surveillance or regulatory control after sale". Three distinct categories of consumer product can be identified:

(1) Products to which small amounts of radionuclides have been added, either for functional reasons or because of their physical or chemical properties;

(2) Equipment capable of generating radiation;

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

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

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

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(b) Radioluminous products using luminous paint or containing gaseous tritium light sources. These include items such as timepieces[1], navigational instruments (e.g. compasses), torches, fishing floats and novelty items (e.g. key rings). Some specialist devices such as weapon sights may also contain gaseous tritium light sources. The use of small, low activity gaseous tritium light sources in consumer products is expanding.

(c) Thorium, ^{85}Kr and tritium are all used by the lamp industry, to improve the metallurgical properties of electrodes, to optimize the light spectrum or to provide a starter aid in high intensity lamps or in older fluorescent lamps. High intensity lamps have applications as xenon car lighting and low wattage specialist lamps.

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

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

(b) Gas mantles containing thorium, usually in the form of thorium nitrate. Although only thorium is initially present in a newly manufactured mantle, the amount of thorium progeny increases with time. In the last 20 years, gas mantle manufacturers have been switching to non-radioactive alternatives to thorium and as a result the availability of thoriated gas mantles has greatly declined, although some may still be available;

(c) Thoriated tungsten welding electrodes used in tungsten inert gas welding techniques;

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[1] Nowadays, watches and clocks with non-radioactive luminous dials are available for supply to the public. The coating material most commonly used is a phosphorescent pigment on the basis of strontium aluminate doped with traces of europium and dysprosium ($SrAl_2O_4$:Eu,Dy). In contrast to radioluminescent paints, this material needs to be activated through exposure to sunlight or artificial light for just a few minutes. Following activation, its luminosity gradually fades and reaches the threshold of visibility to the eye after several hours. Watches with phosphorescent paints are therefore not a direct replacement for watches with radioluminescent paints in certain specialist applications.

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

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

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

(a) Static eliminators incorporating ^{210}Po or ^{241}Am used for removing dust from photographic negatives, vinyl records, camera lenses and spectacles;

(b) Glass lenses containing uranium and thorium compounds, added at the time of manufacture to improve certain optical properties. Thorium compounds may also be used in surface coatings to reduce glare or increase reflectivity;

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

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

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

1.7. Neutron transmutation doping of single crystal silicon involves the irradiation of bulk amounts of high purity silicon in a thermal neutron flux and this is carried out in many nuclear research reactors [2]. The dopant, phosphorus, is produced by thermal neutron capture in ^{30}Si, transmuting it to the unstable radioisotope ^{31}Si which subsequently decays to the stable isotope ^{31}P by beta decay with a half-life of 2.62 h. The thermal neutrons also interact with the ^{31}P to produce ^{32}P,

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

1.8. Some consumer products may be sold directly to the public through commercial outlets, while others are intended for specialist use by professionals but may still be purchased by members of the public. For example, ionization chamber smoke detectors are sold in hardware stores and irradiated gemstones can be purchased from jewellers. Weapon sights are usually sold only under controlled conditions for military purposes in some States, but they may be freely purchased in others. Discharge lamps containing added radionuclides are routinely fitted in private cars while other such discharge lamps have a specialist application as floodlights in sports arenas and projection lamps in cinemas. Members of the public may thus be exposed to radiation as a consequence of the personal or professional use of these products or as a consequence of activities[2] such as their transport, storage, recycling and disposal.

1.9. Exemption from regulatory control is an essential prerequisite for authorization of the provision of consumer products to the public. The relevant IAEA safety standards addressing this issue are Governmental, Legal and Regulatory Framework for Safety [4] and Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1]. These requirements include requirements for notification of a practice to the regulatory body and requirements for the authorization of practice by the regulatory body. Provision is made for the exemption of practices from these and other regulatory requirements on the basis of general criteria given in the BSS or any exemption levels specified by the regulatory body on the basis of these criteria. The BSS apply to all facilities and all activities [3] that give rise to radiation risks.

[2] The term 'facilities and 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].

1.10. In the interest of harmonization of approaches among States, some guidance on justification and application of the criteria for exemption from regulatory control for consumer products has been provided in a number of IAEA Safety Guides: Regulatory Control of Radiation Sources [5], Application of the Concepts of Exclusion, Exemption and Clearance [6] and Justification of Practices, including Non-Medical Human Imaging [7]. The process of justification and the application of the provisions for exemption to consumer products are not straightforward and this has resulted in different approaches being adopted in different States. This potential difficulty is a particular issue with regard to some very common consumer products, whose provision to the public is considered to be justified in some States but is prohibited in others. Inconsistencies in approaches may be a cause of confusion since the reasons for the differences between approaches would not be clear to the manufacturers and providers of products or to the public who might use them.

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

OBJECTIVE

1.12. This Safety Guide is directed at regulatory bodies as well as at providers of consumer products containing small amounts of radionuclides, either deliberately added or produced by activation, or suppliers of equipment available to the public that is capable of generating radiation. Its principal objective is to provide recommendations and guidance on meeting the requirements for justification and optimization [1, 8] and for authorization of the provision of consumer products to the public. It also recommends how the provisions for exemption given in the BSS [1] are to be applied to products containing small amounts of radionuclides, radiation generators and products containing radionuclides as activation products. The Safety Guide considers both the administrative requirements and the radiation protection requirements established 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 provision of a consumer product containing radionuclides. Account is also taken of the approach to the application of the concepts of exemption and clearance given in ICRP Publication 104 [9].

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

SCOPE

1.14. The scope of this Safety Guide is restricted to finished products (i.e. not to components produced solely for further assembly)[3] that contain small amounts of radionuclides and for which exemption from regulatory control may be appropriate. These items may be destined either for individual or for professional use. The Safety Guide addresses the decision making process to allow the manufacture or import of consumer products as well as the various stages of the life cycle of these items following manufacture, including transport, storage, provision, use, recycling and disposal. The Safety Guide also covers items (such as irradiated gemstones) in which radionuclides are produced by activation, which may also be provided to the public. Equipment that generates radiation and which may be purchased by the public is also covered, although no such items may currently be provided for sale to the public.

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

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

(b) Products and appliances installed in public places (e.g. exit signs and lightning conductors) and other items such as building materials, ceramic tiles, spa waters, minerals and foodstuffs, which are excluded from the definition of consumer products;

(c) Products such as explosives and chemical detectors containing tritium, ^{63}Ni or ^{133}Ba, receiver protection devices (transmit/receive limiters) containing tritium used in radar communications and dust monitors containing ^{14}C, all of which are not normally available for provision to the public;

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

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

(e) Unirradiated gemstones containing naturally occurring radionuclides, as these are not covered by the definition of consumer products into which "radionuclides have deliberately been incorporated or produced by activation";

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

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

STRUCTURE

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

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

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2. THE SYSTEM FOR PROTECTION AND SAFETY OF THE PUBLIC

GENERAL

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

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

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

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

2.2. The manufacture of consumer products involving the addition of radionuclides is a planned exposure situation[4] which may require authorization by the regulatory body. In some instances, the repair and maintenance of consumer products may also require authorization. Such practices are subject to the requirements that apply the three fundamental safety principles of justification, optimization of protection and safety, and limitation of doses [1, 8]. Dose limits apply to the occupational exposure of workers involved in the manufacturing process and to members of the public who could be exposed as a result of either activities at the facilities in question or authorized discharges.

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

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

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

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

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

2.7. Requirements for protection and safety specific to occupational exposure in planned exposure situations are established in paras 3.68–3.116 of the BSS [1]. Occupational exposure in planned exposure situations is outside the scope of this Safety Guide (see para. 1.15) and are not considered here. Recommendations and guidance are provided on meeting the requirements in the BSS on applying the graded approach (Ref. [1], para. 3.6), on notification and authorization (paras 3.7 to 3.9), on exemption (paras 3.10 and 3.11), on justification (paras 3.16–3.21), on optimization (paras 3.22–3.25) and on safety assessments (paras 3.29–3.36), as they all apply to consumer products, as well as the responsibilities of government, the regulatory body and relevant parties specific to public exposure due to consumer products (Ref. [1], paras 3.118, 3.125 and 3.138–3.143).

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JUSTIFICATION

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

2.9. The BSS require that only justified practices be authorized. Paragraph 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 whether a particular practice is justified. Consideration should be given to authorization only if the practice is justified.

2.10. The criteria for exemption should be applied only to those practices that are deemed to be justified. This means that although provision is made in the BSS for exemption from the regulatory requirements of practices that pose a trivial level of risk, justification for such practices should first be demonstrated.

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

GRADED APPROACH

2.12. The IAEA safety standards emphasize the importance of a graded approach in the regulation of facilities and activities. In particular, the General Safety Requirements on Governmental, Legal and Regulatory Framework for Safety (Ref. [4], para. 4.5) require that "The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance

with a graded approach", adding that "for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control".

2.13. Not all practices represent the same level of risk and, as stated in Requirement 6 of 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).

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

NOTIFICATION AND AUTHORIZATION

2.15. The requirement to apply a graded approach is reflected in requirements in the BSS relating to regulatory infrastructure. These are, in decreasing order of rigour of regulatory control, authorization[5] by licensing, authorization by registration, notification and exemption.

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

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

[5] 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].

stringent as the conditions stated in licences. Typical practices that are amenable to registration are those for which:

(a) safety can largely be ensured by the design of the facilities and equipment;

(b) the operating procedures are simple to follow;

(c) the requirements for training in safety are minimal;

(d) there is a history of few problems with safety in operations.

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

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

2.19. 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" (Ref. [1], para. 3.7). This requirement recognizes that the use of consumer products by members of the public is effectively beyond regulatory control and no notification of use is required. However, any person or organization intending to carry out any of the practices specified in the requirement should notify the regulatory body of their intention to do so. The regulatory body should then consider whether authorization of any of these practices is necessary, taking into account the nature of the product, the associated risks and the prospective individual doses identified in the safety assessment.

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

2.21. The regulatory approach in many States does not always make a distinction between authorization by licensing and authorization by registration and often there is no provision for notification alone. In fact, in some States 'licensing' may be the only term that is used. While the use of the separate terms — authorization by licensing, authorization by registration and notification — provides clarity, the three possibilities should not necessarily all be used. The regulatory body should use a graded approach to ensure that it assigns its limited resources in an appropriate way, focusing its efforts on those practices that pose the highest radiation risks. The regulatory body should also ensure that a graded approach is applied by principal parties[6] (Ref. [1], para. 2.40).

EXEMPTION

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

2.23. The general criteria for exemption are stated in 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."

2.24. These criteria are subjective in nature and, taken on their own, require value judgements to be made by the regulatory body. The BSS [1] clarify what is meant by the term "radiation risks… are

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[6] The principal parties responsible for protection and safety are:
(a) Registrants or licensees, or the person or organization responsible for facilities and activities for which notification only is required;
(b) Employers, in relation to occupational exposure;
(c) Radiological medical practitioners, in relation to medical exposure;
(d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

sufficiently low" by stating 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[7], 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" (Ref. [1], para. I-2).

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

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

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[7] The individual dose criterion for low probability scenarios is based on the assumption that the probability of occurrence does not exceed 10^{-2} per year [10].

2.27. Many States have found the derived values of total activity and activity concentration to be particularly useful and have adopted them in national legislation. As is the case for the dose criteria referred to in para. 2.24, these derived values should be used by the regulatory body to exempt a practice or a source within a practice from regulatory control without the requirement to conduct a safety assessment. While it is envisaged that such exemption should be granted automatically, the regulatory body should satisfy itself that the exposure scenarios used to calculate the derived values of activity and activity concentration are representative of the practice within the State. This will usually be the case, and only in exceptional circumstances should the regulatory body require additional scenarios to be considered.

2.28. From a regulatory viewpoint, the existence and application of predefined numbers to be used for taking decisions on exemption has obvious benefits in that it is easy to apply. It also increases the likelihood of consistency on the part of the regulatory body and between regulatory bodies in different States. However, to rely on numerical values alone would remove the need for the regulatory body to use its own judgement in taking such decisions and would undermine the considerable flexibility afforded to regulatory bodies by 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 exposures or in any health risks. The regulatory body should still consider this second criterion in situations where either the derived values of activity and activity concentration are exceeded or a safety assessment shows that the 10 μSv individual dose criterion may not be met in all scenarios. For this reason, the regulatory body should consider the derived values of total activity and activity concentration, as well as the 10 μSv individual dose criterion, as important contributors to a decision on exempting a given practice from regulatory control. However, these criteria alone may provide an insufficient basis for a final decision.

2.29. 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:

> "(i) 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
>
> "(ii) The maximum energy of the radiation generated is no greater than 5 keV." (Ref. [1], para. I-3(c).)

2.30. 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 equipment.

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

2.31. This is the so-called 'type approval', by which the regulatory body can exempt certain instruments or equipment from regulatory control under very specific conditions. Normally instruments or equipment exempted from regulatory control should comply with a national or international standard, for example those published by the International Organization for Standardization (ISO). While the exemption can be based on the external dose rate at a distance of 0.1 m from the surface of the 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 be possible in the event of, for example, dismantling of the device or its incineration, then exemption from regulatory control may not be appropriate.

2.32. This provision in the BSS for the exemption of equipment containing sealed radioactive sources can be applied to consumer products. While there is a limit on dose rate outside the equipment, no limit applies to the activity of the sealed source. Thus, for example, ionization chamber smoke detectors with higher levels of activity than those specified for exemption without further consideration can be exempted provided that the conditions stipulated by the regulatory body in respect of dose rate and other criteria are met and they are of a type approved by the regulatory body.

2.33. There is no specific reference in 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 radionuclides have been added in the manufacturing process. As such, the regulatory body should apply the general criteria for exemption, as well as the individual dose criterion and the derived values of total activity and activity

concentration, in deciding whether or not to exempt such products from regulatory control. The application of these criteria to irradiated gemstones is discussed in Section 5.

OPTIMIZATION OF PROTECTION AND SAFETY

2.34. Demonstration of net benefit is not in itself sufficient for a practice to be authorized. The BSS also require the government or regulatory body to "establish and enforce requirements for the optimization of protection and safety" (Ref. [1], para. 3.22) while "Registrants and licensees shall ensure that protection and safety is optimized." (Ref. [1], para. 3.23).

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

SAFETY ASSESSMENT

2.36. Requirements in relation to safety assessment apply to the regulatory body, to persons or organizations intending to carry out activities that give rise to radiation risks and to registrants and licensees. The regulatory body is required to be responsible for establishing the requirement for a safety assessment to be carried out and to review and assess the safety assessment prior to granting an authorization. Persons or organizations intending to carry out activities that give rise to radiation risks and registrants and licensees are required to "conduct a safety assessment that is either generic or specific to the practice or source for which they are responsible" (Ref. [1], para. 3.30).

2.37. The regulatory body should also apply the graded approach in establishing the requirement for a safety assessment to be carried out. Practices that represent a higher degree of radiation risks should require a more detailed safety assessment than those with a much lower level of radiation risks. Even if the level of radiation risks is thought to be trivial, a safety assessment should still be required to show that this is indeed the case. This applies only on the first occasion that the justification of a particular practice is being considered and the decision of the regulatory body should not necessarily be reviewed for subsequent applications, except as recommended in para. 2.39 below. However, as discussed in paras 2.26 and 2.27, in situations where the derived values of activity or activity concentration are not exceeded, a safety assessment should not be required; provided that the practice

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has previously been deemed to be justified, the sources should be exempted from regulatory control without further consideration.

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

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

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

GENERAL

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

JUSTIFICATION

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

3.3. While the BSS require the government or regulatory body to ensure 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 that consumer products are likely to present.

3.4. Determination of the justification of the manufacture and provision to the public of consumer products should be undertaken by the regulatory body prior to considering an application for authorization. If the practice is deemed to be not justified, the question of authorization does not arise and the person or organization submitting the notification should be so informed. The BSS do make

provision for the "review of justification", however. This should be taken to mean the review of decisions that a particular practice is not justified as well as the review of decisions that a particular practice is justified (see paras 3.13 and 3.14 in this Safety Guide).

3.5. The justification procedure should consider all aspects of the practice, including manufacture, assembly, transport, provision, use by members of the public and disposal. It follows that in addressing the justification of a particular consumer product, one stage of the practice should not be considered in isolation from the end use of the product by members of the public. For example, it makes no sense to decide that the manufacture of a given consumer product is justified and then, at a later stage, to decide that its provision to the public is not justified (see para. 3.7).

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

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

3.8. While every effort should be made to ensure objectivity in the evaluation of justification, this may not always be easy to achieve. One of the reasons is that it is often not possible to quantify both costs and benefits in terms of units that are directly comparable, such as in money terms. For this reason, the determination of benefits normally involves making a judgement on behalf of society. To try to overcome 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 justification of a practice involving consumer products, such an advisory body might comprise individuals from consumer interest groups, manufacturers or providers of such products, academics and government officials. As an input to the advisory body, the regulatory body should provide an assessment of the radiation risks associated with the proposed

practice. Such a mechanism will help to avoid decisions being made on the basis of the judgement of the regulatory body alone.

3.9. 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 provision and use of consumer products, justification for such practices is still required. If the risk is indeed trivial then the benefit need not be substantial in order for the practice to be shown to be justified.

3.10. Although radiation safety is concerned with protection against radiation risks to health, the regulatory body should not consider to be justified only those consumer products that are potentially lifesaving or that may prevent injury or illness. The benefits to be considered could be of many different types: not just the possible saving of lives or the prevention of injury or illness, but also practical benefits of the products, prevention of damage to property, improvements in security or improvements in the quality of life.

3.11. Decisions on justification are normally taken with respect to a particular type of practice and should not need to be repeated for each and every notification for authorization. Thus, for example, if the manufacture of a certain type of smoke detector is deemed to be justified, then the manufacture of a similar smoke detector should be considered to be justified automatically. The regulatory body should consider the national and international technical standards that apply for a particular type of practice and should decide whether these are sufficient to indicate that the practice in question is justified. This issue is discussed further in relation to certain specific types of consumer product in Section 4.

3.12. 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 made available 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 made. While different regulatory bodies may reach different decisions, it is desirable that regulatory bodies should, as far as possible, cooperate with each other so that a uniform approach is taken to the justification of the provision of consumer products to the public. International harmonization is considered further in Section 6.

3.13. The regulatory body should review all decisions on justification at regular intervals. In particular, decisions on justification 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 provision to the public of a given consumer product, the availability of a new technology not

involving the use of radiation should not, of itself, be the determining factor in deciding whether or not the practice continues to be justified.

3.14. If a practice involving the provision to the public of a given consumer product is no longer considered to be justified, the regulatory body should withdraw the authorization for the manufacture and provision of the consumer product in question. The basis for the decision should be made available to all interested parties. The regulatory body should also decide on and communicate on the steps to be taken to manage existing consumer products properly (including their disposal) in the interim.

3.15. The regulatory body may become aware of consumer products having been provided to the public without such provision having previously being justified. In such cases, the regulatory body should review, as best it can, the justification for the provision of these consumer products to the public. It is possible that the consumer products in question may no longer be manufactured and as such, the necessary information on which to base a safety assessment may not be readily available. If the decision by the regulatory body is that their provision to the public is not justified, the regulatory body should publish advice on radiation protection for those who own and use such consumer products, putting the associated risks into perspective. In considering the option of collecting and disposing of such consumer products and making its decision, the regulatory body should take into account the associated radiation risks.

3.16. The role of the regulatory body in such matters is limited. The regulatory body does not have any responsibility for setting societal norms with regard to what may or may not be provided 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 radionuclides are inherently safe; consumer decisions will subsequently determine whether such products are competitively priced and useful.

3.17. Considerations in relation to justification of the practice of irradiation of gemstones to enhance their colour are addressed in paras 5.1–5.5.

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

NOTIFICATION AND AUTHORIZATION

3.19. As discussed in section 2, a person or organization is required to "submit a notification to the regulatory body" of its intention to manufacture, assemble, maintain, import, distribute or dispose of consumer products (Ref. [1], para. 3.7). As noted in paras 2.15 to 2.21, regulatory bodies take different approaches to notification and authorization, and use different terminologies, depending on their national legislation.

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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 any available evidence that the practice had 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 the 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 functions served by the radionuclide(s). Documentary evidence that the radionuclide 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 radionuclide, particularly with regard 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 conditions and adverse conditions of use and disposal, and the degree of accessibility to the radionuclides;

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

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

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

(i) Safety assessments with regard to normal use, possible misuse and accidental damage and disposal and, if applicable, servicing, maintenance and repair;

(j) The anticipated useful lifetime of the consumer product and the total numbers expected to be distributed and/or made available annually;

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

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

(m) Information on how the consumer product is intended to be labelled;

(n) The provisions foreseen for recycling or disposal of consumer products at the end of their useful lifetimes.

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.

3.24. In the case of a notification relating only to the distribution and/or provision of consumer products to the public, the documentation provided should include evidence that the consumer product in question has been authorized for provision 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 to make the consumer product in question available in other States.

OPTIMIZATION OF PROTECTION AND SAFETY

3.25. Protection and safety should be optimized through attention to the design and configuration of the consumer product. Optimization can also be applied through the use of procedural controls. However, if procedural controls are necessary for protection and safety 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(s) with respect to the half-life, radiation type, energy and activity necessary for the product to function effectively;

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

(c) Configuration of the consumer product;

(d) Prevention of access to the radionuclide(s) without the use of special tools;

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

(f) Quality management.

3.27. Optimization is about selection of the best option for protection and safety, with account taken of technical, economic, legal and societal contexts that apply. The best option is always specific to the relevant exposure pathways and represents the best level of protection and safety that can be achieved under the given circumstances. In the case of consumer products, whether or not exemption values are exceeded, protection and safety should be optimized. The regulatory body should ensure that the requirements for optimization are met, even below the exemption value.

3.28. Established international standards for the construction of some of the more common consumer products are available and applied in a number of States. These are discussed and referenced in Section 4.

3.29. In the case of irradiated gemstones, the short half-life of many of the activation product radionuclides means that the dose rate decreases measurably with time after they are made available to the public. Protection and safety should be optimized by planning the conditions for their irradiation to minimize the production of those radionuclides with longer half-lives and by retaining those gemstones with the highest activity concentrations. These issues are discussed further in Section 5.

SAFETY ASSESSMENT

3.30. A safety assessment is an essential input to the decision on the justification of a practice and in the optimization of protection and safety. The safety assessment covers the doses that are likely to be received in normal use, in foreseeable accidents and in disposal. The assessed doses should be compared with established dose criteria. In the case of consumer products, the dose criteria are those criteria for exemption established in 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 consumer products, such as those installed in places of work to which the public may have access, could be used in greater quantities. For example, householders may install one or two ionization chamber smoke detectors in their homes, but a much larger number of ionization chamber smoke detectors may be used as part of a fire protection system in an office block, shopping mall or hotel. Ionization chamber smoke detectors installed as components of fire detection systems of this nature are not consumer products as defined in the BSS [1] since they are not made available to members of the public. However, the criteria for construction and design of such consumer products are the same, and a similar approach should be taken to dose assessment in both cases. In any dose assessments carried

out, account should be taken of the number of ionization chamber smoke detectors typically deployed in a dwelling or other building and hence the total exposure and the potential exposure of an individual.

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

3.33. While it is a prerequisite that consumer products made available directly to the public meet the criteria for exemption, this does not necessarily mean that other stages of the chain should be exempted automatically. On the basis of the safety assessment, the regulatory body should decide whether authorization is necessary and, if so, should apply a graded approach. Alternatively, the regulatory body may decide to exempt numbers of consumer products up to a maximum, provided that it can be shown that the general criteria for exemption are met. This can be shown by demonstrating that the radiation risks are insufficient to warrant regulatory control or that measures for purposes of regulatory control 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 scenarios for normal usage and realistic accidents, unless there are strong reasons not to do so, the practice should be exempted from regulatory control.

3.34. Once consumer products are provided to the public, it is not realistic to control the manner in which they are disposed of. Indeed, the basic premise of exemption is that such control is not warranted for purposes of radiation protection. However, the regulatory body should take into account any requirements for waste management that are applicable to the category of consumer product and should ensure that customers are informed thereof. The activity content of the consumer products should not, in general, be taken into consideration for this purpose in accordance with para. 3.141(a) and (b) of the BSS [1] (see para. 4.39). It should be assumed in the safety assessment that individual consumer products provided to the public will be discarded with household waste at the end of their

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useful lifetimes. A range of realistic scenarios following disposal, including combustion, handling by workers and retrieval, should be considered the safety assessment.

3.35. The regulatory processes for deciding on exemption from regulatory control are summarized in Figs 1 and 2.

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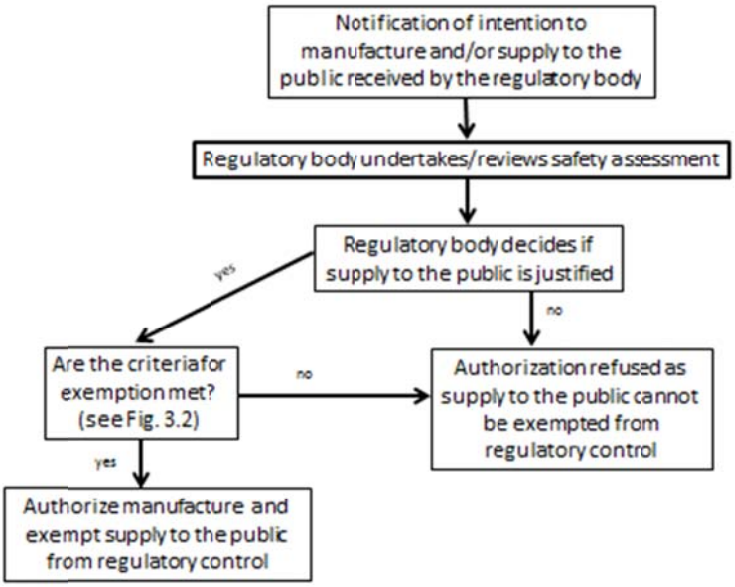


FIG. 1. Regulatory control for consumer products.

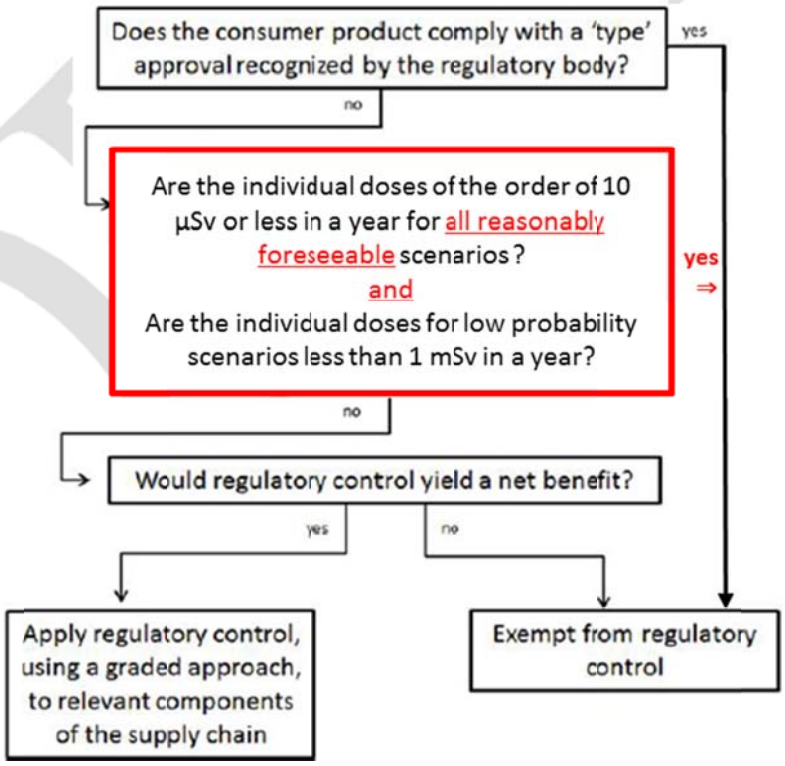


FIG. 2. Safety assessment for consumer products.

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

GENERAL

4.1. This section covers considerations for those consumer products that are provided to members of the public and into which small amounts of radionuclides have deliberately been incorporated, either for functional reasons or because of particular physical or chemical characteristics; i.e. the presence of the radionuclides is essential for the product to function correctly. The majority of consumer products currently made available to members of the public are of this type and most of these fit into the following categories:

(a) Ionization chamber smoke detectors;

(b) Gaseous tritium light devices;

(c) Luminous clocks and watches;

(d) Certain lamps and lamp starters;

(e) Thoriated tungsten welding electrodes.

4.2. These consumer products have been widely available to the public for many years and safety assessments have been undertaken and findings published. In some cases, criteria have also been developed for the construction and testing of such consumer products. A number of publications are available on the general approach to regulatory control for consumer products [14–20].

DESCRIPTION OF PARTICULAR PRACTICES

Ionization chamber smoke detectors

4.3. Ionization chamber smoke detectors containing radioactive sources are widely available to the public. Their use is important in saving lives and warning of fires. Detectors incorporating an optical smoke detection mechanism rather than a radioactive source have been developed and are also available to the public as an alternative to ionization chamber smoke detectors. Historically ionization chamber smoke detectors are considered to respond more rapidly to a fast burning fire, whereas optical smoke detectors are more suited to the detection of smouldering fires [21]. Some detectors incorporate both an ionization chamber smoke detectors and an optical smoke detector to detect both fast burning and smouldering fires. The regulatory body should take these issues into account in considering the justification of ionization chamber smoke detectors.

4.4. Standards for the construction and prototype testing of ionization chamber smoke detectors were published by the OECD Nuclear Energy Agency in 1977 [22] and were subsequently revised and

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updated by the United Kingdom National Radiological Protection Board in 1992 [23]. This publication, which is summarized in Annex IV, is still used as the accepted standard for the design, construction and performance of ionization chamber smoke detectors. An environmental assessment of ionization chamber smoke detectors has also been undertaken in the United States of America [24].

4.5. The source activity in an ionization chamber smoke detector is normally greater than the exemption values given in the BSS. As part of the work to develop standards for ionization chamber smoke detectors, the United Kingdom National Radiological Protection Board carried out an assessment [25] of the doses that could be received by members of the public in normal use and in foreseeable accidents from an ionization chamber smoke detector that complied with the standards specified. This assessment indicated that the possible doses would satisfy the exemption criteria of 10 μSv/a 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 ionization chamber smoke detectors from regulatory control by giving type approval to models of ionization chamber smoke detector that satisfy the standards for construction and type testing. Such an approach does not preclude the regulatory body from specifying other conditions in the type approval, e.g. disposal requirements and any additional labelling requirements. For many ionization chamber smoke detectors currently available on the market, type testing information is readily available from the manufacturers.

Gaseous tritium light devices

4.7. Gaseous tritium light sources 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, producing radioluminescence. These tubes are installed in various products for illumination purposes. Such products are referred to as gaseous tritium light devices. Gaseous tritium light devices have been available for public use for many years, the most common products being compasses. Past applications of gaseous tritium light sources have been limited by the difficulty in manufacturing small gaseous tritium light sources with precise tritium activities. Fishing floats using gaseous tritium light device and a limited number of digital wristwatches using gaseous tritium light devices have been marketed, however. Recent advances in technology now permit the manufacture of gaseous tritium light sources that are physically very small with dimensions as low as 0.5 mm diameter and 1.3 mm in length. These gaseous tritium light sources are mounted on the watch dials and the hands of a range of modern wristwatches. They are also used in key fobs, map lights and compasses.

4.8. The widespread use of gaseous tritium light sources in a range of applications in the 1970s prompted the OECD Nuclear Energy Agency to develop and publish construction standards for gaseous tritium light devices [26]. The hazard due to external exposure to radiation from gaseous tritium light sources is negligible, the primary pathway of exposure being the inhalation of tritiated water vapour from a gaseous tritium light source 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 OECD Nuclear Energy Agency standard focused on the construction of gaseous tritium light devices, the activity of tritium and the percentage of tritiated water in the gaseous tritium light source. This standard was reviewed by the United Kingdom National Radiological Protection Board in 1992 and a national standard was published [25]. The National Radiological Protection Board standard, which specifically addresses the use of gaseous tritium light sources in watches and compasses, is summarized in Annex VI.

4.9. The total activity for exemption of tritium from regulatory control without further consideration is given in the BSS as 1 GBq. An assessment of the possible radiation doses to members of the public from a watch or a compass that complied with the specified requirements indicated that possible doses were well below the exemption criteria of 10 μSv/a for normal use and 1 mSv for low probability (accident) scenarios [25]. 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 gaseous tritium light sources used in gaseous tritium light devices have activities of considerably less than 1 GBq. The individual activities of the very small gaseous tritium light sources now manufactured for use on watch hands and faces are of the order of 0.1 GBq, and the total activity in a watch is normally kept to below 1 GBq. A similar approach is taken with regard to key fobs and compasses.

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

Luminous watches

4.12. The combination of radioactive substances with a phosphor to produce a luminescent paint was one of the earliest uses of radioactive substances. The radioactive substance 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 (promethium) and tritium. Luminizing paints containing tritium or ^{147}Pm are still in use and many modern models of watch incorporate radioluminous markings on the watch face. 'Diver's' style watches with a rotating bezel on the outside of the watch face sometimes have a radioactive marking on the zero point of the bezel.

4.13. The ISO standard 3157 on Radioluminescence for Time Measurement Instruments — Specifications [27] gives requirements and test methods for the 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 (for tritium) and 10 MBq (for ^{147}Pm) 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 of Ref. [28] on "certain items containing by-product material"). A dose assessment [29] of possible doses from watches that comply with the ISO standard concluded that the exemption criteria of 10 μSv/a for normal use and 1 mSv for low probability (accident) scenarios are met.

4.14. Exemption from regulatory control should only be considered if the practice is first deemed to be justified. The regulatory body should exempt the provision of radioluminous watches and clocks to the public from regulatory control by giving type approval to those models that satisfy the ISO standard 3157 [27], or that comply with other standards recognized by the regulatory body. 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.

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Lamps and lamp starters

4.15. High intensity discharge 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 in car headlamps and other high intensity light applications. These lamps contain small amounts of ^{85}Kr or thorium, which aid the process of producing an arc within the lamp. The total activity in a single lamp varies depending on the model of lamp. In the case of lamps containing ^{85}Kr, neither the exemption value for total activity nor that for activity concentration given in the BSS are exceeded. However, in certain lamps containing ^{232}Th, while the total activity in each item is below the exemption value, the activity concentration exceeds the exemption value[8] of 10 Bq/g [30].

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

4.17. The United Kingdom Health Protection Agency has carried out an assessment [31] of the possible doses arising from the transport and use of high intensity discharge lamps and fluorescent lamps and has issued a further report on their recycling and disposal [32]. The IAEA has considered the issue of safety assessment for lamps [30]. The Health Protection Agency reports concluded that the possible doses satisfy the exemption criteria of 10 μSv/a for normal use and 1 mSv for low probability (accident) scenarios.

4.18. For all lamps and starters that satisfy the exemption criteria for total activity or activity concentration and whose use is considered to be justified, the regulatory body should exempt their provision to the public from regulatory control without further consideration. In the case of multiple units, such as units 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 3.29–3.34.

4.19. In view of the magnitude and international scope of this practice, and the potential for higher activities and different radionuclides to be used in other models of lamp, the regulatory body should

[8] 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 required to comply with both.

keep the practice under review and should obtain further safety assessments, as appropriate. This is particularly important for lamps that 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 ionization chamber smoke detectors, gaseous tritium light devices and luminous watches.

Thoriated tungsten welding electrodes

4.21. The use of an inert gas such as argon to blanket the environment of the welding arc so as to prevent the intrusion of oxygen and hydrogen provides a practical way of welding aluminium, magnesium and other reactive metals. Thoriated tungsten electrodes are used in the welding industry. Thorium, in the form of thorium oxide, is added to tungsten electrodes which are used in tungsten inert gas arc welding. The addition of thorium improves the arc and weld characteristics and gives longer electrode use. However, thorium is a naturally occurring radioactive element and as such may pose a radiation hazard.

4.22. Welders may inadvertently be exposed to radiation during welding and grinding operations with thoriated tungsten electrodes. Inhalation of dust particles during grinding is the main concern. The radiation hazard from grinding can be greatly reduced by wearing a dust mask and any other personal protective equipment suitable for such operations, the use of an effective exhaust system and, whenever possible, the use of preground thoriated tungsten electrodes.

4.23. On average, the committed effective dose that a full time welder receives in a year is well below 1 mSv [33]. However, in certain cases, it is possible to exceed this dose. Factors that could lead to higher doses are described in more detail in Annex VII, together with actions to significantly reduce internal exposure and external exposure.

4.24. Detailed information on technology, radiation factors and doses, control measures and best practices for the use of thoriated tungsten electrodes is also provided in Annex VII.

4.25. Provided that the practice is considered justified and provided that the total activity is less than the exemption value of 10 kBq of ^{232}Th, the regulatory body should exempt the provision of thoriated tungsten electrodes to the public from regulatory control without further consideration in order to comply with the exemption criteria [1]. In situations where the total activity in the thoriated tungsten electrodes exceeds 10 kBq, exemption from regulatory control should still be granted provided that the safety assessment demonstrates that the individual dose criteria of 10 μSv/a for normal use and 1 mSv for low probability (accident) scenarios are met.

RESPONSIBILITIES OF PROVIDERS

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

4.27. The manufacturer should be responsible for applying to the regulatory body for authorization for the manufacture and provision 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 decision on justification for the product. This will involve the provision of a wide range of information, including details of the proposed construction of the product, the source radionuclide and its activity, an assessment of doses to workers during its manufacture and doses to members of the public during its use, disposal options, and assessments of doses as a consequence of disposal, as described in Section 3.

4.28. The manufacturer should ensure that the consumer products are constructed in accordance with relevant international design standards or with other standards recognized by the regulatory body. The manufacturer should also be responsible for arranging any type testing that is specified in the relevant standards.

4.29. Depending on the nature of the consumer products and on national legislation, the provider at the point of sale should obtain an authorization for the storage of the consumer products. Consumer products containing amounts of activity of less than the exemption values are considered to be beyond effective regulatory control at the points of distribution and points of sale to the public. However, in the case of certain consumer products, in particular those containing a radioactive source whose activity exceeds the exemption value, the regulatory body should consider the need to restrict the number of items to be shipped as part of a single consignment or to apply conditions on storage, such as a maximum number of items that can be stored at one location.

4.30. The regulatory body may require the provider at point of sale to hold documentation on storage requirements, emergency plans for dealing with fires, etc. The distributor and provider should confirm with the regulatory body what information is required to be held.

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

4.32. Consumer products that contain radioactive sources with activities greater than the exemption values of activity specified in the BSS should always be labelled 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 United Kingdom National Radiological Protection Board and the OECD Nuclear Energy Agency standards [22, 23] for ionization chamber smoke detectors require the ionization chamber smoke detector to be labelled with the trefoil symbol and the wording 'radioactive' such that the label is clearly visible on opening the housing of the ionization chamber smoke detector. The United Kingdom National Radiological Protection Board and OECD Nuclear Energy Agency have issued radiation protection standards for watches and clocks using gaseous tritium light devices [25, 26] that require that the watches and clocks be clearly marked with the symbol ^{3}H or the word 'tritium'.

4.33. The regulatory body should also consider requiring that these consumer products be labelled at the point of sale to state clearly that the consumer 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 which have been authorized for provision to the public, labelling on the outer box or on the display stand can be beneficial in informing customer choice, in a manner similar to labelling on food products.

4.34. There is no safety benefit to be gained in labelling as radioactive those consumer products that contain activities lower than the exemption values. Such labelling would also be problematic in some cases where the product is physically very small, such as lamp starters or small gaseous tritium light sources. However, in the case of gaseous tritium light devices that contain one or more small gaseous tritium light sources, the regulatory body should consider requiring the product to be labelled to indicate that it contains a radioactive source or to be clearly labelled as such at the point of sale. The purpose of such labelling is to inform customer choice.

4.35. Manufacturers should ensure that suitable instructions are provided with each item in languages that are appropriate for the particular market in which the consumer product is to be sold.

Instructions should include information on correct operation, considerations for safety and procedures to be followed when the consumer product is no longer used. In the case of those consumer products that must be recycled rather than disposed of as waste, information should be given on where the disused consumer product should be taken to or sent for recycling. Where appropriate, instructions should also contain warnings not to dismantle the product where this could result in access being gained to a radioactive source; for example, a warning not to dismantle the internal ionization chamber of an ionization chamber smoke detector. While some consumer products are unlikely to need instructions on their use and disposal, it may still be beneficial to provide the user with information on the radioactive content of the product and on the low level hazard from the source.

IMPORTATION OF CONSUMER PRODUCTS

4.36. In circumstances in which consumer products are imported into a State from a manufacturer in another State, some of the responsibilities described here will transfer to the importer while others will remain with the manufacturer. The manufacturer should retain the responsibility for the construction of the consumer product in accordance with applicable international standards or other standards recognized by the regulatory body. The manufacturer should also retain the responsibility for information on the safe use of the consumer product. Both the manufacturer and the importer should assume equal responsibility for any aspects of labelling and provision of information that are a national requirement rather than an international requirement. These aspects include the provision of information on any national requirements for disposal or recycling of the disused consumer product. The importer should also fulfil any requirements of the authorization with regard to the storage, distribution and provision of the consumer products. In the case of consumer products provided via the Internet direct to members of the public, the company selling the consumer product should be responsible for satisfying the regulatory requirements in places in the State where the consumer products are made available and sold.

TRANSPORT

4.37. As stated in para. 107(e) of Ref. [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 provision 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 amounts of individually exempted consumer products, should be carried out in compliance with the IAEA Transport Regulations.

NUCLEAR SECURITY

4.38. Nuclear security measures should be implemented in line with IAEA nuclear security recommendations and guidance when the aggregated D value[9] 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. The IAEA has issued a publication that provides a comprehensive listing of radionuclide specific D values [34].

DISPOSAL

4.39. Consumer products are considered to be beyond effective regulatory control after provision to members of the public. The safety assessment should assume uncontrolled disposal of consumer products with household waste. The possible doses that could arise due to exposure via various exposure pathways following such disposal should be assessed. This assessment should estimate the total numbers of the specific consumer products that are likely to be disposed of. Each landfill site should be visited each year, and the possible dose to workers at the landfill site, to members of the public who live nearby and to any other individuals or groups likely to be exposed should be assessed. This assessed dose should be below the exemption criterion for dose of 10 μSv/a. Such assessments require knowledge of the number of each consumer product sold per year, the available disposal options for household waste, the number of waste disposal sites and the number of consumer products likely to be disposed of per year.

4.40. The accumulation of consumer products at a waste disposal facility or recycling facility may present a potential radiological hazard and should be subject to a safety assessment. Although uncontrolled disposal of consumer products together with household waste is assumed for the purpose of dose assessment, in practice States may need to place restrictions on the available disposal options for certain types of consumer product.

4.41. These restrictions may be put in place to minimize the amount of radionuclides present in the environment and not under proper control, to encourage recycling or in response to other regulatory controls. For example, in the European Union, the Waste Electrical and Electronic Equipment

[9] The categorization system for radioactive sources is based on the concept of 'dangerous sources' which are quantified in terms of D values. The D value is the radionuclide specific activity of a source which, if not under control, could cause severe deterministic effects for a range of scenarios that include both external exposure from an unshielded source and internal exposure following dispersal (e.g. by fire, explosion or human action) of the source material. Since the activity of radioactive material in sources varies over many orders of magnitude, D values are used to normalize the range of activity in order to provide a reference in comparing risks.

Directive (WEEE Directive) [35] requires European Union member states to have legislation in place to control the disposal of electrical and electronic equipment and to encourage its reuse, 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. This includes sources used in ionization chamber smoke detectors, high intensity discharge lamps and fluorescent lamps.

4.42. If, after the end of their useful lifetime, consumer products are to be collected for disposal, they may need to be treated collectively as radioactive waste. In such circumstances, the Safety Requirements on the predisposal management of radioactive waste [36] and the Safety Requirements on the disposal of radioactive waste [37] will apply. If disused consumer products are to be recycled, this should be considered a practice and should be regulated accordingly.

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

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5. CONSIDERATIONS FOR IRRADIATED GEMSTONES

JUSTIFICATION OF IRRADIATION OF GEMSTONES

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

5.2. Paragraph 3.17 of the BSS [1] 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 consumer products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation". A footnote to this requirement states that "This requirement is not intended to prohibit those practices that may involve the short term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as made available".

5.3. It follows that, provided there is no increase in activity in irradiated gemstones that are released for sale to members of the public, there should be no prohibition, in principle, of 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, including ^{54}Mn (half-life 312 days) and ^{134}Cs (half-life 752 days). As is the case for all consumer products, irradiated gemstones are required not to be provided to the public unless they comply with the exemption criteria in the BSS [1]. This ensures that possible doses to end users of the gemstones are very low. At the time of sale, the gemstones do have an increase in activity compared with their state prior to irradiation. However, provided that the exemption criteria are met, this increase in activity is small and the associated individual doses are low.

5.4. In view of these considerations, the practice of irradiation of gemstones for subsequent sale to members of the public can be considered to fall within the context of para. 3.17 of the BSS [1] and, as such, is deemed not to be justified. However, the requirements of the BSS allow for 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 decisions on justification should be subject to review from time to time. This should include a review of those practices that are deemed to be not justified as well as those practices deemed to be justified. In reviewing existing practices involving the irradiation of gemstones, the regulatory body should take all relevant factors into account, including national and

international markets in irradiated gemstones, the employment benefits, possible doses to workers and to members of the public who wear the gemstones, and the long-term effectiveness of the irradiation procedure. Annex IX provides the description of the regulatory approach to irradiation of gemstones and the sale of irradiated gemstones in one State.

THE PRACTICE OF IRRADIATION OF GEMSTONES

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

5.7. The practice of irradiation of gemstones for sale to the public involves a number of persons and organizations. The various steps in the process, as illustrated in Fig. 1, are as follows:

(a) Rough gemstones are mined (in or outside the State of their irradiation);
(b) Mined gemstones are sent to the wholesaler or distributor or through a buyer and gemstone 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 the gemstones are prepared for irradiation at the irradiation facility or are prepared at a processing facility and subsequently transferred to the irradiation facility;
(d) Gemstones are irradiated to achieve the desired colour enhancement and then kept 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 surface contamination and subsequently analysed to identify the radioisotopes present and to determine their activity concentrations. This may be done at the irradiation facility or at a processing facility. In either case, the activity in the gemstones is almost always high enough to warrant regulatory control;
(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 regulatory requirements associated with transport, and with export and import, if applicable, should be applied to gemstones transported between facilities;

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

(h) Irradiated gemstones are then transported from the irradiation facility or the processing facility to the wholesaler or distributor. The regulatory body has required that at this point the activity associated with the irradiated gemstones is below the level specified for 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;

(i) The gemstones are sold to retailers, who make the finished jewellery available to the consumer.

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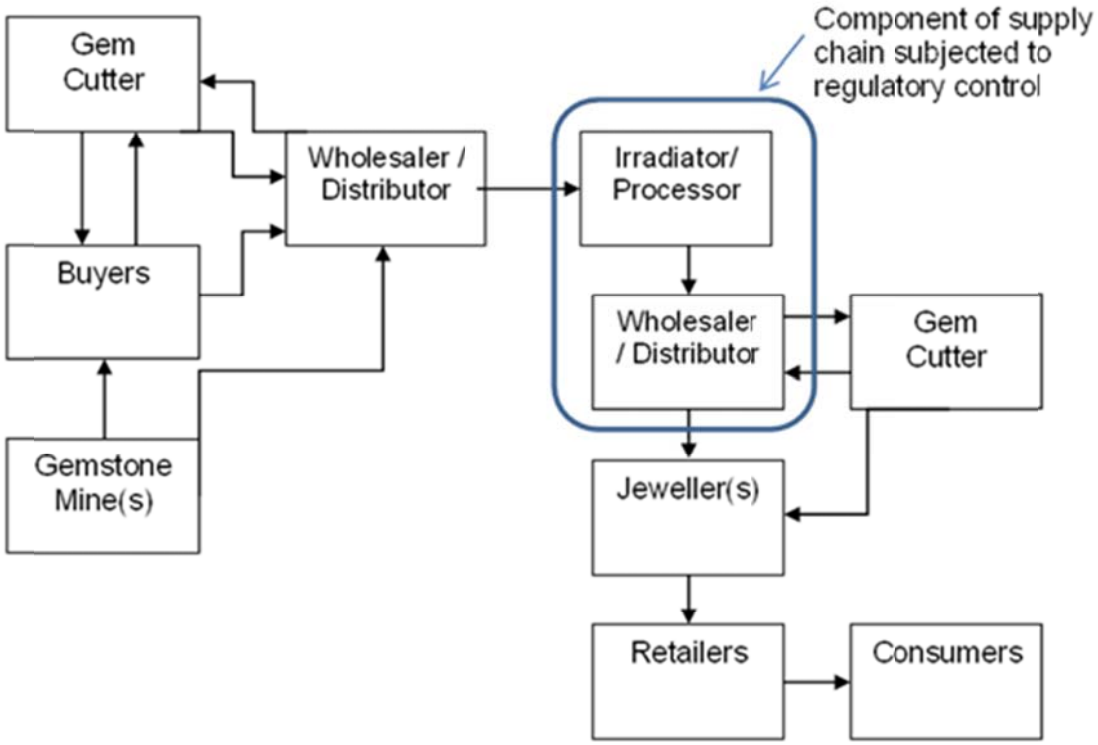


FIG. 1. Persons and organization involved in the practice of irradiation of gemstones and the sale of irradiated gemstones to the public.

5.8. The radionuclides within irradiated gemstones are an undesired by-product of the irradiation process, resulting from the activation of impurities in the irradiated gemstones. Unlike most other consumer products, for which the added radionuclides fulfil an important function, the activation products induced in irradiated gemstones serve no useful purpose. However, storage of the gemstones for an appropriate period of time after irradiation can ensure that most of the activation products decay to insignificant levels before sale of the gemstones.

5.9. Activities carried out during the irradiation process and post-irradiation, prior to the sale of irradiated gemstones to the public, may involve occupational exposure at high dose rates and are required to be subject to appropriate regulatory control. Occupational exposure may also occur if gemstones are released for further processing, such as sorting or cutting, before the activation products has decayed to trivial concentrations. Occupational exposure is outside the scope of this Safety Guide; however, such exposure should also be subject to regulatory control.

5.10. Special attention should be paid 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 [38].

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 gemstones 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 provision 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 ASSURANCE AND VERIFICATION PROCEDURES

5.12. An effective quality assurance 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 provided to the public after irradiation and that specific batches of gemstones are traceable. This programme should include:

(a) Effective batch labelling 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 material 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 assurance 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 considerations for storage and disposal should be discussed and agreed between the irradiation facility operators and the gemstone owners to determine responsibilities for the management of radioactive waste generated from the gemstone irradiation process.

5.16. Direct provision 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 VIII, 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 provided 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 material and the processing of the gemstones. The irradiation facility should also confirm and agree on the release criteria with the customer.

5.18. The IAEA has produced recommendations and guidance on nuclear security that may apply to licensed gemstone irradiation facilities such as nuclear research reactors and cobalt irradiators [39]. 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 considerations for nuclear security occur when the aggregated D value for any particular radionuclide in a single location is exceeded [34].

TRANSPORT OF IRRADIATED GEMSTONES

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 regulatory 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] and any additional national regulations. Any handling or inspection of transport labelled 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 material.

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 sale. Importers have general responsibilities to ensure that consumer 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 gemstones. The importer should know whether the activity concentrations are below the exemption values and hence whether or not the gemstones can be sold 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 sold 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 labelling 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. The Confédération Internationale de la Bijouterie, Joaillerie, Orfèvrerie, des Diamants, Perles et Pierres has

recommended that, in order to inform customers, packages containing irradiated gemstones should be labelled as ‘irradiated’.

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 decided that the practice of irradiation of gemstones is not justified, the export of irradiated gemstones to that State may need to be prevented. Decisions on such matters, including the means of their implementation, should be taken 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 being sold to the public only when the activity concentrations are below the appropriate exemption values.

OTHER IRRADIATED ITEMS

5.24. Currently several different types of gemstone have their colour enhanced by irradiation. It is possible that new types of consumer product that have been irradiated may be introduced onto the market in the future. For example, gamma irradiation of golf balls has been shown to increase the toughness of the balls’ cover and to strengthen the materials used in their core, allowing the golf ball to last longer and to travel further [40]. The regulatory body’s decisions on the justification and authorization of future consumer products will be subject to the requirements of the BSS and the recommendations of supporting Safety Guides.

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6. INTERNATIONAL HARMONIZATION OF THE SALE OF CONSUMER PRODUCTS TO THE PUBLIC

GENERAL

6.1. The sale of consumer products to the public is a common practice with a significant international dimension. For example, ionization chamber smoke detectors are constructed in several States and exported for distribution and sale around the world. Modern small gaseous tritium light sources are manufactured and sold to watch manufacturers and other producers for incorporation into watches, key fobs and weapon sights. These consumer products are then exported for sale to members of the public in many States. In the case of small, easily transportable consumer products such as key fobs including gaseous tritium light devices, a primary route of sale is direct to the consumer via Internet. Irradiated gemstones are also traded internationally and have a high intrinsic value. A consistent approach by regulatory bodies to the justification and authorization of such consumer products is beneficial in maintaining an adequate level of control and preventing the sale of consumer products produced in practices that are not justified, while not unnecessarily obstructing the sale of consumer products produced in justified practices.

6.2. The provisions in the BSS represent a consensus among States and Sponsoring Organizations in relation to consumer products regarding:

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

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

(c) The total activities and activity concentrations of many radionuclides to be used in exempting moderate amounts and bulk amounts 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 which have not already done so should consider the formal adoption of these provisions. However, even if these criteria are not fully met, the BSS still provide considerable flexibility by allowing the regulatory body to decide whether or not to exempt certain sources or practices from some or all 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 any 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 it should take fully into consideration the range of doses that may be received in different scenarios, and also the likelihood of each of these scenarios actually 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, "Regulatory control of the practice or the source would yield no benefit, in that 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 that the regulatory body should not impose regulation for its own sake and that any regulation that is deemed necessary should be effective in enhancing protection and safety. Any such regulation should be applied on the basis of 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 in the BSS ultimately demands some decision making by the regulatory body. This Safety Guide provides recommendations on how such decisions should be reached.

ACHIEVING INTERNATIONAL CONSENSUS ON HARMONIZATION OF SALE TO THE PUBLIC

6.7. In general, IAEA safety standards reflect the consensus of Member States and are intended to lead to the harmonization of approaches to safety. Such a harmonization of approaches has not yet happened with regard to consumer products, however. Whatever the reasons 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. At the least, consideration should be given to whether a safety assessment that has been used as the basis for type approval in one State should be used for the purpose of granting type approval in another. This would necessitate an international consensus on the approaches to be taken in determining the benefits associated with the use of consumer products and in undertaking the safety assessment. While the approach to determining the benefits may be the same, it is recognized that the benefits will differ between States.

6.9. One argument in support of greater harmonization relates to the increasing use of the internet for the marketing of consumer products. If a particular consumer product is authorized for sale to the

public in one State, it will be extremely difficult, if not impossible, to prevent its being sold online and purchased by consumers in another State. While it might be possible to intercept and impound such consumer products during transport to a State in which sale to the public is not authorized, this would be likely to involve significant resources in terms of both personnel and training. It is in the interest of all States and all regulatory bodies to adopt a harmonized approach to ensure that consumer products authorized for sale to the public in one State are similarly authorized in other States.

6.10. To this end, regulatory bodies should establish contacts with their counterparts in other States to agree on the procedures and criteria for undertaking safety assessments and for exempting from regulatory control the supply of radiation generators and consumer products to the public. Formal agreements should be entered into either on 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 providers.

6.11. In June 2011, the Heads of the European Radiological Protection Competent Authorities (HERCA) issued an interim statement on lamps, as used in various public and professional settings, to which small amounts of radioactive substances have been added for functional reasons [41]. 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 forums may be used for the discussion of national approaches and the sharing of information on the benefits and detriments associated with particular consumer products. Regulatory bodies should initiate discussions at the national level and internationally at the regional level on issues relating to consumer product with the intention of achieving regional international agreement on the following:

(1) A common approach to the justification process and the sharing of the supporting information that provided the basis for a decision on justification;
(2) The development of a common agreement on the justification of specific consumer 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 on behalf of other States;
(5) Common agreement on the exemption from regulatory control of the sale of specific consumer products;

(6) A common view on the justification of the most widespread consumer products: ionization chamber smoke detectors, watches and key fobs containing gaseous tritium light devices, lamps containing radionuclides and irradiated gemstones.

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

6.13. While regulatory bodies have a common interest in adopting a harmonized approach to regulating radiation safety, this harmonization is also in the interest of the public. Differences in approaches can lead to a situation in which consumer products that are considered inherently safe and are freely available for purchase in one State are not freely available in another. This can create confusion over the significance of any radiological hazards in the minds of the public. Differences in 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 international approach should be used to facilitate the development on a regional basis of international technical standards for new types of consumer product that have been justified and authorized for sale to the public in a State or States. Such international technical standards would reflect the fact that the consumer products in question have been considered justified in a number of States and therefore would provide some assurance regarding the justification generally for consumer products complying with the standard.

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ANNEX I.
CASE STUDY ON JUSTIFICATION:
DOMESTIC SMOKE DETECTORS WITH IONIZATION CHAMBERS

INTRODUCTION

I-1. The justification for the use of ionization chamber smoke detectors by members of the public was considered by an expert group of the OECD Nuclear Energy Agency in the 1970s [I-1]. This is an old example and although some of the data are now out of date, the approach is still valid. The foreword to the group's recommendations states that "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 OECD Nuclear Energy Agency review covered ionization chamber smoke detectors 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 ionization chamber smoke detector (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 ionization chamber smoke detectors has been discontinued as it is no longer considered justified.

BENEFITS

I-3. The main benefit of domestic smoke detectors with ionization chambers 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 OECD Nuclear Energy Agency publication quotes the results of a number of studies which indicate that between a third and a half of the fatalities might not have occurred if fire detection systems had been universally installed. An average figure for 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 ionization chamber smoke detectors containing 40 kBq ^{241}Am under a range of normal use scenarios and accident scenarios. The annual effective dose to an individual householder as a result of normal use was estimated to be about 1 μSv. 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 ionization chamber smoke detector 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.

EVALUATION

I-6. The overall conclusion of the OECD Nuclear Energy Agency Expert Group, which covered both detector systems used in industrial and 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."

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

INTRODUCTION

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

II-2. A small number of safety assessments for high intensity discharge lamps have been carried out and published [II-1–II-3]. No published decisions at the national level addressing specifically the justification of the use of high intensity discharge 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 high intensity discharge lamps is typically 90–100 lumen per watt. This is substantially higher than that for halogen lamps (20–30 lumen per watt). As this energy saving technology is ubiquitously available, the utilization of this lamp technology makes an important contribution to the reduction of CO_2 emissions and helps towards achieving the objectives of the Kyoto Protocol [II-4].

II-4. Energy saving is an important characteristic of high intensity discharge 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 necessary to produce the same amount of light. The use of high intensity discharge lamps is also

economical as the average lifetime of up to 20 000 hours is considerably longer than the average life expectancy of halogen lamps (2000 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 as high intensity discharge lamps. Fluorescent lamps are therefore not a direct replacement for high intensity discharge lamps in certain specialist applications. Also the compactness of high intensity discharge 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 1 μSv per accident scenario in which the lamp mighty lose its integrity. At the end of their lifetime, lamps may be recycled or disposed of to landfill. It is estimated that the dose to members of the public would increase by 2×10^{-6} μSv per year when the ^{85}Kr activity of 1 million consumer products for lighting is released to the atmosphere in 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 in accident scenarios is estimated not to exceed 1 μSv per year. When lamps are sent to a municipal waste landfill site at the end of their lifetime, the resulting annual doses are estimated to be below 0.1 μSv [II-6]. In the unlikely case that an individual 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 2×10^{-4} μSv by incineration involving 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 BSS are not directly relevant to the evaluation of the radiological consequences for members of the public when they are exposed to radiation due to high intensity discharge lamps, under conditions of normal use as well as in accident scenarios. When more realistic scenarios are used, the radiological consequences for members of the public were shown to be insignificant throughout the entire lifetime of the lamps, including following their disposal in landfill

sites.

II-9. The benefits of the use of high intensity discharge lamps is from the savings in terms of energy and cost (due to their energy efficiency), and in helping States to meet the targets on reductions in CO_2 emissions under the Kyoto Protocol. High intensity discharge lamps have certain characteristics that cannot be provided by other types of lamp and therefore they are the only option for certain specialist applications.

II-10. Direct comparison of benefits and detriments is not straightforward as the benefit is in terms of energy saving and cost saving, functionality and protection of the environment, while the detriment is expressed in terms of individual doses. Regulatory bodies therefore need to make subjective decisions on the basis of perceived benefits to society and the inherent safety of the consumer products. However, provided that the regulatory body considers that the practice is justified, the available safety assessments indicate that high intensity discharge lamps can be exempted from regulatory control.

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ANNEX III.
CASE STUDY ON JUSTIFICATION:
DECISION TO NO LONGER JUSTIFY THE SALE OF
IONIZATION CHAMBER SMOKE DETECTORS TO THE PUBLIC

INTRODUCTION

III-1. Ionization chamber smoke detectors generally contain a low level (less than 40 kBq) sealed source of americium as ^{241}Am. Older models contain other radionuclides also, 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 (of 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 non-ionization technologies then available. The use of radiation was thus fully justified in order to comply with fire related standards in force and to protect people against the risk of fire.

DETRIMENTS

III-3. Ionization chamber smoke detectors, owing to their design, do not constitute a radiological risk for people frequenting premises in which detectors of this type of are fitted. However, their removal (when incorrectly done) and their disposal by means of conventional waste management chains are liable to present a risk.

EVALUATION

III-4. Since the large scale installation of detectors of this type, their efficiency in comparison with that of other non-ionizing technologies has been progressively reassessed. This has followed the successive technological developments of non-ionizing detectors (particularly optical detectors and thermal detectors) that enable the detection of smoke as early as do ionization chamber smoke detectors. International standards (in particular the Construction Products Regulation 305/2011 in the

European Union [III-5] relating to consumer products) now recognize the performance of these new technologies.

III-5. The use of 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 requirements for the optimization of protection and safety.

DECISION

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

III-7. The installation of ionization chamber smoke detectors in new fire detection systems has been prohibited, however, and, after consultation with the relevant interested parties, requirements for the gradual withdrawal of these 7 million ionization chamber smoke detectors over a 10 year period were introduced into the French regulations at the request of ASN.

III-8. Specific regulations [III-1–III-3] now permit the authorities:

- to ban all manufacture and import of new ionization chamber smoke detectors;
- to prohibit the installation of ionization chamber smoke detectors in new fire detection systems;
- to guarantee the availability of disposal chains (disassembly, collection, storage, etc.), thus limiting the duration of the removal operations;
- to introduce a staggered replacement programme for the ionization chamber smoke 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;
- to avoid illegal dumping of ionization chamber smoke detectors in management chains for conventional waste.

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

resulting from the transposition of European directive 96/29 into the French Public Health Code [III-4]. Since 2002, French regulations have prohibited the intentional addition of radionuclides to consumer goods (which include ionization chamber smoke detectors), foodstuffs and construction materials.

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[III-3] L'AUTORITÉ DE SÛRETÉ NUCLÉAIRE, 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, recovery and disposal of ionising smoke detectors (confirmed by the order of 6 March 2012), Paris (2012).

[III-4] OECD NUCLEAR ENERGY AGENCY, National Legislative and Regulatory Activities, Ordinance No. 2001-270, 28 March 2001, OECD Publications, Paris (2001). http://www.oecd-nea.org/law/nlb/nlb-68/053_072.pdf

[III-5] EUROPEAN PARLIAMENT, Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0005:0043:EN:PDF

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ANNEX IV.
SUMMARY OF THE UNITED KINGDOM STANDARD FOR DESIGN, CONSTRUCTION AND PERFORMANCE FOR IONIZATION CHAMBER SMOKE DETECTORS

SCOPE

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

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

IV-3. The standard only relates to ionization chamber smoke detectors containing ^{241}Am.

DEFINITIONS

IV-4. An ionization chamber smoke detector 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 ionization chamber affects the ionization current and this triggers an alarm.

IV-5. A single-station ionization chamber smoke detector is a self-contained device (operated on mains current and/or battery) in which the alarm is incorporated in the ionization chamber smoke detector and the ionization chamber smoke detector 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 radioactive substances under the conditions of use and wear for which the sealed source was designed. This includes cut foil sources where the radioactive source is sandwiched between inactive layers.

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

PRINCIPAL SPECIFICATIONS

IV-8. The radioactive source(s) used in an ionization chamber smoke detector shall[10] be ^{241}Am sealed source(s) conforming to the relevant requirements of ISO standard 9978 [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 functioning of the ionization chamber smoke detector 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[13] be tamper proof.

IV-11. Ionization chamber smoke detectors (or parts of ionization chamber smoke detectors 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 ionization chamber smoke detector submitted for approval. A separate ionization chamber smoke detector may be submitted for each test. The source shall not become detached or suffer loss of integrity as a result of each test.

[10] 'Shall' and 'should' statements in this Annex are reproduced verbatim from the original United Kingdom Standard for Design, Construction and Performance for Ionization Chamber Smoke Detectors. They are not requirements and recommendations of the IAEA safety standards.

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Temperature

IV-13. The ionization chamber smoke detector shall be cooled to –25 ºC, kept at this temperature for one hour and then allowed to return to ambient temperature. It shall then be heated to 100 ºC, 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 [IV-3]. A steel hammer of mass 0.5 kg shall be dropped from a height of 0.5 m on to the ionization chamber smoke detector, which should be positioned on a steel anvil.

Drop

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

Vibration

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

Evaluation

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

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Tests for the effects of fire

IV-18. A fire test shall be carried out on the complete ionization chamber smoke detector or on the source mounted in its source holder in the presence of parts of the ionization chamber smoke detector that 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 the air shall be condensed and filtered before release to atmosphere. The ionization chamber smoke detector (or its parts) shall be heated from room temperature to 600 ºC and shall be kept 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 testing or by immersion testing) is less than 200 Bq, then the ionization chamber smoke detector 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 ionization chamber smoke detector or on the source mounted in its source holder in the presence of parts of the ionization chamber smoke detector 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 ionization chamber smoke detector (or its parts) shall be heated to 1200 ºC 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 ionization chamber smoke detector, then the ionization chamber smoke detector shall be considered to have passed the test.

MARKING AND LABELLING OF IONIZATION CHAMBER SMOKE DETECTORS

IV-20. The ionization chamber of each ionization chamber smoke detector 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 ionization chamber smoke detector. The outer housing of the ionization chamber smoke detector should be marked in the same way.

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

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QUALITY CONTROL

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

REFERENCES TO 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, pp. 9–20, HMSO (1992).

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

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

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ANNEX V.
RADIATION DOSES FROM IONIZATION CHAMBER SMOKE DETECTORS

INTRODUCTION

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

V-2. The estimated doses arising from normal use, incidents, misuse and disposal of ionization chamber smoke detectors 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. In normal use of ionization chamber smoke detectors the doses to members of the public are limited to those due to external exposure to radiation. The dose equivalent rate in air, D, at a distance d (m) from the surface of an ionization chamber smoke detector, 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 [V-2][11]. The value of t for ^{241}Am is 2.4×10^{-6}.

V-4. The standard for ionization chamber smoke detectors (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 ionization chamber smoke detector that satisfies this requirement will be 2.4×10^{-5} µSv h^{-1}.

Normal use

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

V-5. Most ionization chamber smoke detectors 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 ionization chamber smoke detector 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. Ionization chamber smoke detectors 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 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 4×10^{-4} μSv h^{-1}. In estimating the potential doses the following assumptions have been made:

(i) The ionization chamber smoke detector 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 0.001 μSv each year.

Disposal

V-6. Ionization chamber smoke detectors 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 United Kingdom;

(ii) Each household in the United Kingdom has one ionization chamber smoke detector;

(iii) Of these ionization chamber smoke detectors, 20% are disposed of each year;

(iv) Of those disposed of each year, 80% are distributed between 500 landfill sites, i.e. a maximum of 6 400 ionization chamber smoke detectors per site each year;

(v) Of those disposed of each year, 20% are distributed between 200 incinerators, i.e. a maximum of 4 000 ionization chamber smoke detectors per incinerator each year.

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Disposal to a landfill site

V-7. The two main pathways for exposure associated with disposal to a landfill site are ingestion of drinking water contaminated with leachate from the site and inhalation of airborne contamination caused by a waste fire. The standard for ionization chamber smoke detectors (see Annex IV) states that an ionization chamber smoke detector 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) Of the ionization chamber smoke detectors disposed of at a single landfill site, 1% are involved in waste fires during the year;

(ii) 200 Bq are released from each ionization chamber smoke detector 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 landfill site;

(v) The ground level time integrated concentration for unit release (1 Bq) in normal weather conditions (Pasquill category D) at 200 m from the landfill site 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 0.1 μSv.

V-8. The committed effective dose equivalent to an adult drinking contaminated water during one year was estimated in NRPB-R205 as 0.001 μSv from a shallow inland burial of 1 TBq [V-6]. If 6 400 detectors of the maximum activity allowed by the 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 3×10^{-7} μSv from one year's intake.

Disposal via incineration

V-9. The standard for ionization chamber smoke detectors (see Annex IV) states that an ionization chamber smoke detector 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) Of the radioactive substances in the ionization chamber smoke detectors, 1% 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 0.16 μSv. 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 ionization chamber smoke detectors can be categorized as follows:

(i) fire;

(ii) misuse and mutilation.

Fire

V-12. In a survey of known incidents involving smoke detectors in the United Kingdom, fire was found to be the most common occurrence [V-7]. The standard for ionization chamber smoke detectors (see Annex IV) states that an ionization chamber smoke detector 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 ionization chamber smoke detector contains 40 kBq ^{241}Am;

(ii) 200 Bq becomes airborne;

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

(iv) the firefighter attends 20 fires involving ionization chamber smoke detectors each year.

After fire

(i) the ionization chamber smoke detector contains 40 kBq ^{241}Am;

(ii) the ionization chamber smoke detector was protecting an area of 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} $m^3 \cdot s^{-1}$.

The maximum annual committed effective doses to an adult are therefore 4 μSv during fires and 0.024 μSv after fires.

Misuse and mutilation

V-13. The most significant possible misuse is dismantling of the ionization chamber smoke detector 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 ionization chamber smoke detector to comply with the standard. An estimate of the possible dose to an infant who manages to break open the chamber and damage the source has been made using the following assumptions.

(i) Of the source activity, 1% is released owing to damage;

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

(iii) The committed effective dose equivalent per unit intake to a three month old 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 possible doses arising from normal use, incidents, misuse and disposal of ionization chamber smoke detectors which comply with the Standard do not exceed the appropriate dose criteria.

REFERENCES TO ANNEX V

[V-1] NATIONAL RADIOLOGICAL PROTECTION BOARD, Criteria of acceptability relating to the approval of consumer goods containing radioactive substances. Documents of the NRPB, Vol. 3, No. 2, pages 3–8, HMSO (1992).

[V-2] NATIONAL RADIOLOGICAL PROTECTION BOARD, Radiological Protection Standards for Ionisation Chamber Smoke Detectors (ICSDs) Documents of the NRPB, Vol. 3, No. 2, pp. 9–20, HMSO (1992).

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[V-3] CLARKE, R.H., A Model for Short and Medium Range Dispersion of Radionuclides Released to the Atmosphere, NATIONAL RADIOLOGICAL PROTECTION BOARD, Report NRPB-R91, Chilton (1979).

[V-4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Report of the Task Group on Reference Man, ICRP Publication 23, Pergamon Press, Oxford and New York (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, Vol. 26 No. 1 (1996).

[V-6] SMITH, G.M., FEARN, H.S., DELOW, C.E., LAWSON, G., DAVIS, J.P., Calculations of the Radiological Impact of Disposal of Unit Activity of Selected Radionuclides, Report NRPB-R205, Chilton (1987).

[V-7] OECD NUCLEAR ENERGY AGENCY, Recommendations for Ionisation Chamber Smoke Detectors in Implementation of Radiation Protection Standards, OECD/NEA, Paris (1977).

[V-8] NATIONAL RADIOLOGICAL PROTECTION BOARD, Committed Doses to Selected Organs and Committed Effective Doses from Intakes of Radionuclides, Chilton, NRPB-GS7, Her Majesty's Stationery Office, London (1987).

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ANNEX VI.
UNITED KINGDOM STANDARD FOR WATCHES AND COMPASSES INCORPORATING GASEOUS TRITIUM LIGHT SOURCES

SCOPE

VI-1. This standard details the radiological protection requirements for time measurement instruments containing gaseous tritium light sources [VI-1]. 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 gaseous tritium light sources.

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

DEFINITIONS

VI-4. A gaseous tritium light source is a sealed glass tube internally coated with a phosphor and filled with tritium gas.

VI-5. A time measurement instrument is a watch or a clock.

VI-6. Total activity is the total activity of tritium present in all the gaseous tritium light sources contained in a single gaseous tritium light device.

VI-7. A gaseous tritium light device is a time measurement instrument or compass containing one or more gaseous tritium light sources.

PRINCIPAL CONSIDERATIONS

VI-8. Watches and compasses shall[12] satisfy the tests described below.

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[12] 'Shall' statements in this Annex are reproduced verbatim from the original United Kingdom Standard for Watches and Compasses Incorporating Gaseous Tritium Light Sources. They are not requirements of the IAEA safety standards.

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

SPECIFICATION FOR GASEOUS TRITIUM LIGHT SOURCES

VI-10. The total activity of the gaseous tritium light device shall be as low as reasonably achievable, consistent with effective illumination, and shall not exceed 7.4 GBq for watches and clocks and 10 GBq for compasses.

VI-11. The percentage of the activity of a single gaseous tritium light source 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 gaseous tritium light source, except for a gaseous tritium light source 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 gaseous tritium light sources in the gaseous tritium light device shall not exceed a total of 2 kBq per day.

INSTRUMENT SPECIFICATION

VI-13. The equivalent dose rate shall not exceed 0.1 μSv/h at the surface of the gaseous tritium light device.

VI-14. The gaseous tritium light sources shall be fixed in a suitable metal or plastic support that will provide a secure and shock absorbing attachment over the lifetime of the gaseous tritium light device.

MARKING AND LABELLING

VI-15. The gaseous tritium light device 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 gaseous tritium light devices 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.

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PROTOTYPE TESTS

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

Temperature

VI-19. The gaseous tritium light device 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 gaseous tritium light device 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 gaseous tritium light device.

Vibration

VI-21. The gaseous tritium light device shall be subjected to three complete test cycles in the range 25–500 Hz at an acceleration of 50 $m \cdot s^{-2}$. 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 gaseous tritium light device shall be tested. The gaseous tritium light device shall then be vibrated for 30 min at any resonant frequencies found.

Pressure

VI-22. The gaseous tritium light device 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 gaseous tritium light device shall be dropped from a height of 1 m on to a hard, unyielding surface. The test shall be performed three times with the gaseous tritium light device in a different orientation each time.

Crushing

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

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Puncture

VI-25. A weight of mass 10 g with a small pin fixed to its lower surface shall be dropped on to the face of the gaseous tritium light device 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 gaseous tritium light device shall be examined visually; there shall be no evidence of loss of integrity of the gaseous tritium light sources or that the gaseous tritium light sources have been dislodged from their support or have become readily accessible.

(ii) The gaseous tritium light device 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 TO 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, pp. 47–59, Her Majesty's Stationery Office (1992).

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

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ANNEX VII.
SAFETY RELATED ASPECTS OF THORIATED TUNGSTEN WELDING ELECTRODES

INTRODUCTION

VII-1. The use of an inert gas (such as argon) to blanket the welding arc environment in order to prevent intrusion of oxygen and hydrogen provides a practical way of welding aluminium, magnesium and other reactive metals [VII-1]. Carbon and tungsten are the two materials used to form thermionic cathodes for welding. Pure tungsten, however, when operated in the cathode spot mode, allows the tip to melt, forming an enlarged sphere, which in turn allows the arc column to wander (loss of arc stability). Thoriated tungsten electrodes are used in the welding industry. Thorium, in the form of thorium oxide, is added to tungsten welding electrodes which are used in tungsten inert gas arc welding. The addition of thorium improves arc starting and stability, reduces weld contamination and gives longer electrode life. However, thorium is a naturally occurring radioactive element and as such may pose a radiation hazard [VII-2]. When an electrode becomes molten, material is sputtered off in relatively large quantities on arc starting and in lesser quantities during welding. The electrode is slowly consumed. Welders may inadvertently be exposed to radiation during welding and grinding operations with thoriated tungsten electrodes. Inhalation of dust particles during grinding is the main concern. The radiation hazard from grinding can be greatly reduced by wearing a dust mask and any other personal protective equipment suitable for such operations, the use of an effective exhaust system and, whenever possible, the use of preground thoriated tungsten electrodes. Thoriated tungsten electrodes used in tungsten inert gas arc welding normally contain thorium at 0.5, 1, 2, and 4%. Their annual production is estimated at 4 to 5 million electrodes per year in the United States of America only [VII-3].

RADIATION FACTORS ASSOCIATED WITH THORIATED TUNGSTEN ELECTRODE WELDING

VII-2. The ^{232}Th isotope represented the predominant mass of thorium in the electrodes tested [VII-3]. No ^{228}Th was found. Thorium-230 was present in quantities less than 1 part per million of the total thorium. On the basis of these quantities, consideration of the ^{230}Th would not significantly add to the exposure. The variability of the isotopic composition within and between manufacturers is unknown. However, these assays reflect what one would expect if the source of the thorium was from monazite sands containing little uranium as a source for ^{230}Th. The variability of the total amount of thorium contained in an electrode labelled as containing 2% was not determined in this study. However, one producer reported that the amount is rigidly controlled.

VII-3. The particle size distribution for manual welding fume was bimodal [VII-3]. The respirable[13] fraction of the aerosol (10 μm or less; see definition of respirable fraction of aerosol adopted by ISO in [VII-4]) was 45% of the total measured aerosol. The activity median aerodynamic diameter[14] for the respirable fraction in the welder's breathing zone (30 cm from the point of operation) was 3.5 μm. The smaller mode of the welding aerosol was believed to represent fume before substantial coagulation of the fume occurred. The respirable fraction of the electrode sharpening aerosol (10 μm or less) was 60% of the total measured aerosol. The activity median aerodynamic diameter for the respirable fraction was 5.0 μm in the grinder's breathing zone (30 cm from the point of operation). The conclusions regarding aerosol characteristics of Ref. [VII-3] are supported by seven other studies overviewed in Ref. [VII-5]. The uncertainty of these data can be overridden by the application of a conservative assumption of 1 μm activity median aerodynamic diameter adopted below for the radiation dose assessments.

RADIATION DOSES

VII-4. On average, the committed effective dose a full-time welder receives in a year is well below 1 mSv [VII-6]. However, in certain cases it is possible to exceed this dose. Factors that could lead to such doses include: welding with alternating current, welding with absence of ventilation, welding inside vessels or in orientations where the welder receives high exposure to welding fumes, or welding with an excessive amount of electrode grinding. Surface contamination from settled welding fumes or electrode grinding dust may also create difficulties in identifying the source of, and responding to, contamination events. Implementation of standard accepted work practices for industrial hygiene will be adequate to address any radiological concern. Relatively simple actions, such as the proper use of ventilation and the position of the individual's head while welding or grinding, can also significantly lower potential intakes. Detailed dose estimates are described in Ref. [VII-5] with brief explanations given by Ref. [VII-7] for different scenarios of the exposure.

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[13] The respirable aerosol fraction (or alveolar fraction) is the subfraction of the inhaled particles (diameter <10 μm) that penetrates into the alveolar region of the lung (including the respiratory bronchioles and the alveolar ducts and sacs) and is pertinent to the development of such chronic diseases as pneumoconiosis and emphysema [VII-4].

[14] The activity median aerodynamic diameter is the value of aerodynamic diameter such that 50% of the airborne activity in a specified aerosol is associated with particles smaller than the activity median aerodynamic diameter, and 50% of the activity is associated with particles larger than the activity median aerodynamic diameter. The aerodynamic diameter of an airborne particle is the diameter that a sphere of unit density would need to have in order to have the same terminal velocity when settling in air as the particle of interest. See the IAEA Safety Glossary [VII-8].

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Doses from grinding

VII-5. The grinding of the electrode to form a pointed end can take anywhere from 20 to 60 seconds depending on the skill of the grinder. For welders who grind their own electrodes, this can take a minute or even longer. Individuals who specialize in this activity can complete the task much quicker. At a large facility (e.g. with 50 welders), a grinder might grind as many as 150 electrodes per day (ca. 3 per day per welder). For the purpose of the calculations, it was assumed in Ref. [VII-5] that the particle size activity median aerodynamic diameter was 1 μm. An individual welder sharpening electrodes was estimated to receive 0.2 mSv per year. This would be reduced by a factor of ten or so if a local exhaust system were used. A dedicated grinder sharpening electrodes for 200 hours per year without the benefit of a local exhaust system was estimated to receive approximately 0.8 mSv (if a dust mask as personal protective equipment was not used).

Doses from welding operations

VII-6. As Ref. [VII-5] acknowledges, any estimation of the dose due to welding operations is highly speculative. Assumptions have to be made about the amount of thorium becoming airborne, the amount of time spent welding, the effect of the welder's mask, the ventilation rate, the size distribution of the particulates, and so on. Assuming that 1000 hours per year were spent in actual welding operations, Ref. [VII-5] estimated that the dose would be 0.2 mSv per year for DC operations and 0.5 mSv per year for AC operations. These estimates assume that no local exhaust system is used. If local exhaust is employed, the estimated doses would be a factor of ten or so lower. The external exposure due to beta particles and gamma rays was determined to be an insignificant fraction of the dose due to inhalation.

Dose from carrying welding electrodes in pocket

VII-7. The estimated effective dose to an individual carrying three thoriated welding electrodes (0.9 g thorium) in a shirt pocket for 2000 hours (40 h/week × 50 weeks/year) was 0.08 mSv.

Doses from distribution and transport of thoriated welding electrodes

VII-8. Doses from distribution and transport of thoriated tungsten welding electrodes were estimated [VII-9]. Distribution and transport were assumed to involve handling by parcel delivery workers, truck drivers and retail store workers; exposures to customers in retail stores were also considered. Estimates of average individual doses resulting from an annual distribution of 1 million electrodes obtained are 0.002 μSv (truck drivers), < 0.001 μSv (parcel terminal employees), 0.06 μSv (retail employees), 0.15 μSv (warehouse employees) and <0.001 μSv (customers in retail stores) [VII-9].

ASSESSMENT OF EXPOSURE

VII-9. An assessment of exposure may include the following factors in determining the magnitude of the exposure and whether additional assessment is needed:

- The total amount of time spent welding with thoriated electrodes;
- Type and adequacy of ventilation;
- Amount of time grinding thoriated electrodes;
- DC versus AC welding.

VII-10. If the assessment of exposure suggests that an individual might have had elevated exposures while working with thoriated tungsten welding electrodes, workplace controls, e.g. local exhaust ventilation, may be reviewed to verify that exposures are appropriately controlled [VII-6].

VII-11. Table VII-1 provides information on annual occupational intake of ^{232}Th compared with the annual limit on intake. The annual number of work hours was assumed to be 2000 hours per year [VII-10].

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TABLE VII-1. ANNUAL INTAKE OF ^{232}TH FOR THE OPERATOR (ESTIMATED FROM THE OBSERVED AIRBORNE RADIOACTIVITY CONCENTRATIONS OF ^{232}Th AND HOURS SPENT WELDING [VII-10])

Case number	1	2	3	4	5	6
Dust respirator	Without (PF[a]=1)			With (PF[a]=10)		
Electrode sharpening (hours/day)	0.17	0.17	0.17	0.17	0.17	0.17
Tungsten inert gas/aluminium arc welding (hours/day)	7	0	3.5	7	0	3.5
Tungsten inert gas/stainless steel arc welding (hours/day)	0	7	3.5	0	7	3.5
Other kind of work (hours/day)	0.83	0.83	0.83	0.83	0.83	0.83
Estimated annual intake (Bq)	33.2	10.2	21.7	3.3	1.0	2.2
Ratio to annual limit on intake (90 Bq[b])	0.4	0.12	0.28	0.04	0.012	0.028

[a] PF is a penetration factor of the dust respirator.

[b] Annual limit on intake (ALI) for ^{232}Th is based upon 20 mSv annual dose limit for occupational exposure established in the Basic Safety Standards [VII-11].

VII-12. Table VII-2 [VII-6] provides useful information on radiation safety in relation to welding work with thoriated tungsten electrodes.

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TABLE VII-2. THORIATED TUNGSTEN WELDING ELECTRODES: INFORMATION ON HAZARDS AND CONTROL MEASURES [VII-6]

Radionuclide	Thorium-232 (^{232}Th) and 10 radioactive progeny including ^{228}Ra, ^{228}Th, ^{224}Ra and ^{220}Rn.
Radiation	Alpha, beta and gamma radiation from mix of parent and progeny radionuclides.
External radiation hazard	The contact dose rate from an electrode is ~ 1 μSv h^{-1} falling off rapidly with distance.
Internal radiation hazard	Despite the high temperatures generated, welding and cutting processes produce only very small quantities of loose airborne or surface radioactive substances. Grinding and regrinding of electrode tips, however, does lead to the production of loose airborne and surface contamination. Possible committed effective doses from grinding operations in the absence of control measures (see below) are estimated as follows: • Inhalation of dust: up to 5 μSv per grinding activity. • Ingestion via contamination transferred from hand to mouth: < 1 μSv per grinding activity. • Injection through a wound or skin abrasion: 7 μSv. All of these doses can be substantially reduced by following the control measures (below).
Control measures during use	Use non-thoriated welding electrodes wherever practicable. Keep non-essential personnel clear of welding and grinding activities — have a no eating, drinking smoking rule in areas where welding or grinding takes place. Wherever practicable, a grinding wheel is to be reserved for the grinding of thoriated electrodes; local exhaust ventilation is to be provided at the site of the grinding wheel; welders are to wear suitable gloves to prevent grinding dust from coming into contact with the skin; hands to be washed thoroughly after grinding is complete. Any cuts or wounds are to be covered before carrying out grinding operations. Any cuts becoming contaminated with grinding dust are to be allowed to bleed and are to be thoroughly washed in running water. In areas where more than 50 grinding operations per week are undertaken, and in units where training is carried out, in addition to extractors venting to the external atmosphere, surface dust is to be frequently removed using a vacuum cleaner fitted with an absolute dust filter. The vacuum cleaner is to be kept solely for the removal of thorium dust and is to be marked with a radiation warning label. Removal of the dust collection bag or replacement of the absolute filter is to be carried out in accordance with local orders and procedures (with adequately trained personnel wearing gloves, coveralls and respiratory protection). In areas where fewer than 50 grinding operations a week take place, a routine cleanup programme is to be adopted. The grinding dust is to be damped down and then removed using a damp cloth. The cloth is to be placed in a plastic bag or container displaying no radiation markings and disposed of with normal refuse.
Storage and labelling	The number of welding electrodes held in a welding store is to be kept to a minimum. When not in use welding electrodes other than those fitted into arc welding equipment are to be segregated from non-radioactive items and are to be stored together in bundles in a drawer, a locked steel cabinet or a metal container. The container is to be marked with a radiation warning sign. The number of welding electrodes held outside the store is to be

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	kept to a minimum and is not to exceed one month's supply where practicable.
Contingency plans: fire/loss/incident	In the event of fire in a welding shop, it is extremely unlikely that any radioactive release will occur from the welding electrodes. Loss of a small number of these consumable electrodes need not be reported.
Transport	Items and bulk quantities can be transported within an excepted package provided that the dose rate on the external surface of the package does not exceed 5 μSv h^{-1}.
Disposal	Arisings from grinding operations are to be placed in a plastic bag or container displaying no radiation markings and disposed of with other refuse.

BEST PRACTICE IN THE DISTRIBUTION, USE AND DISPOSAL OF THORIATED TUNGSTEN ELECTRODES

VII-13. Best practice in the distribution, use and disposal of thoriated tungsten electrodes are briefly summarized in the following [VII-1].

VII-14. While the risks from the distribution, use and disposal of thoriated tungsten electrodes are extremely low, it is still advisable to follow best practice at all times. Those who need to handle or work with thoriated tungsten electrodes adopt the following practices:

(a) Keep the number of thoriated tungsten electrodes in stock to the minimum necessary for those welding applications that require thoriated tungsten electrodes.
(b) Store thoriated tungsten electrodes that are not in use in their boxes in a secure location that is accessible only to authorized persons.
(c) Avoid carrying thoriated tungsten electrodes on the person.
(d) Be familiar with safety procedures governing welding operations including those relating to grinding the tips of thoriated tungsten electrodes.
(e) Keep non-essential personnel clear of welding and grinding operations at all times.
(f) Wear a dust mask while carrying out grinding operations.
(g) Work in a dedicated well ventilated area that is fitted with a dust extraction system or local exhaust ventilation wherever possible.
(h) Use a dedicated grinding wheel, fitted with a protective viewing screen, for grinding thoriated tungsten electrodes.
(i) Grinding of thoriated tungsten electrodes is done by each individual welder whenever this is feasible.
(j) Clean up and remove deposited dust particles from thoriated tungsten electrodes with a vacuum system. If a vacuum system is not practicable, damp down the dust prior to collection.
(k) Collect disused thoriated tungsten electrodes and dust resulting from welding and grinding operation is collected on a daily basis and dispersed in waste intended for landfill.

(l) Do not dispose of disused thoriated tungsten electrodes and dust with scrap metal destined for recycling.

(m) Where possible, replace thoriated tungsten electrodes with non-radioactive electrodes incorporating oxides such as cerium oxide or lanthanum oxide.

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ANNEX VIII.
SAFETY RELATED ASPECTS OF GEMSTONE IRRADIATION TECHNOLOGIES

INTRODUCTION

VIII-1. Terrestrial background radiation in the host rock of a gemstone deposit can alter the colour of the gemstone material if the radiation dose is high enough and the ambient temperature low enough. For example, tourmalines from gemstone 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 [VIII-1].

VIII-2. The natural processes of gemstone 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 irradiation can produce gemstones in colours that are not found or are extremely rare in nature, which can significantly increase their commercial value. For example, the value of irradiated topaz can be increased up to ten times [VIII-2]. There is also evidence of increased hardness of irradiated gemstones, another factor that adds to their commercial value [VIII-3, VIII-4].

VIII-3. A wide variety of gemstones are enhanced in colour by irradiation [VIII-5–VIII-8]. The most common colour changes that can be induced are listed in Table VIII-1.

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TABLE VIII-1. EFFECTS OF IRRADIATION TREATMENT ON VARIOUS GEMSTONE 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	Grey, 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

VIII-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 research reactor), by

electron beams (using a linear accelerator) or by gamma emitting radionuclides [VIII-8]. In some instances, more than one process (e.g. irradiation by neutrons followed by electron beam irradiation) may be applied.

GAMMA IRRADIATION FACILITIES

VIII-5. Many types of gemstone are currently irradiated with gamma rays to produce a colour or to 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. For example, 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 radionuclides are not introduced or produced by activation. The disadvantage of gamma irradiation is that the colour enhancement is not as permanent as with other irradiation technologies.

ELECTRON BEAM ACCELERATORS

VIII-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 of up to and exceeding several megagray per hour. At these dose rates, the gemstone materials must be water cooled to prevent elevated temperatures and thermal shock. High temperatures will anneal or destroy the colour centres in the gemstone materials, while thermal shock will crack or shatter them. For instance, topaz at a typical dose rate of 2.5 to 5 MGy per hour will increase in temperature at the rate of 50 °C to 100 °C per minute if it is not properly cooled.

VIII-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 or no radioactivity in the gemstone. By contrast, beam energies above 12 MeV have higher penetration depths. However, they are not generally used for irradiating gemstone materials because such high energies can induce significant radioactivity in the material, the activity concentration depending on the quantity and nature of impurities present in the gemstone [VIII-9]. According to the ISO standard 11137 [VIII-10], the use of electron beam energies above 12 MeV is not permitted for industrial irradiators (e.g. for sterilization of medical supplies by electron beam irradiation). The induced radioactivity is of relatively short half-life, requiring a cooling off period of from a few days to a few weeks until the radioactivity decays to below the exemption values specified in GSR Part 3 (Interim) [VIII-11]. For example, after electron beam irradiation of topaz, the only radionuclides usually detected are ^{69}Ge (half-life1.63 days) and ^{24}Na (half-life 0.6 days) [VIII-8].

VIII-8. The most significant radiation safety issues arise with neutron exposure of gemstones, which results in activation products in the form of radionuclides in the gemstone. The irradiation is almost exclusively carried out at research reactors, which are often used for other industrial and non-industrial applications.

VIII-9. Topaz is the gemstone most commonly irradiated in research reactors [VIII-12]. 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 Fig. VIII-1). The presence of thermal neutrons is primarily responsible for the generation of activation products impurities in the gemstone, and steps are usually taken to minimize the thermal neutron component.

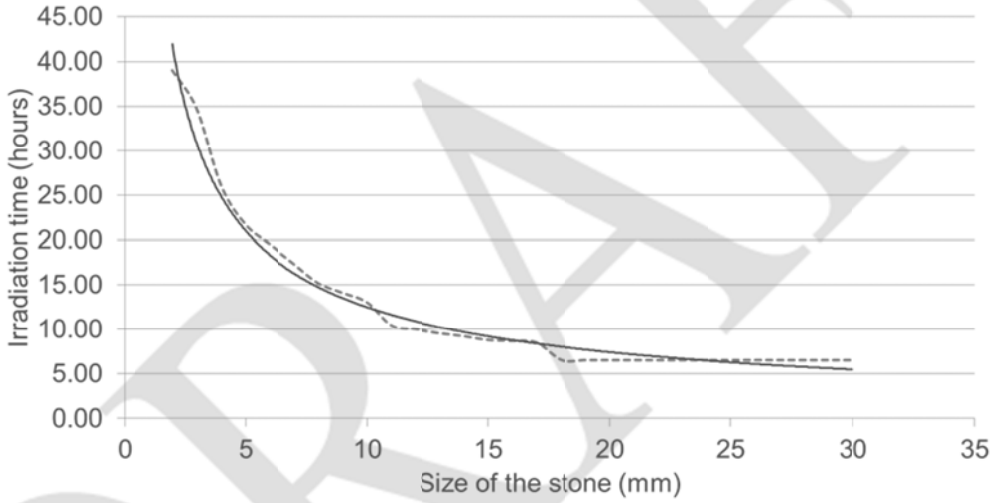


FIG. VIII-1. Irradiation time versus size of topaz gemstone: (experimental (dotted line) and calculated (solid line) dependence of irradiation time to obtain the desired coloration on gemstone size) [VIII-5].

VIII-10. 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 owing to the presence of human sweat and oils as well as by chipping of the tungsten carbide drill bits used for gemstone cutting [VIII-12]. Cleaning minimizes the production of activation products that would otherwise need to be removed following the irradiation and could potentially need to be managed as radioactive waste. In some instances, further cleaning and decontamination take place following irradiation.

VIII-11. Gemstones are typically irradiated in batches using irradiation canisters that are compatible with the research 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 radionuclide concentrations to determine the additional holding period required to achieve the exemption levels. The decay time necessary to reach the exemption criteria for sale to the public may range from a few months to a few years.

OTHER TYPES OF RADIATION TREATMENT

VIII-12. Ion implantation has been shown to be an effective method of enhancing the quality of Thai local natural corundum, including sapphire and ruby [VIII-6, VIII-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.

PRODUCTION OF IRRADIATED GEMSTONES

VIII-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 [VIII-5]. The quantity of gemstones irradiated on an annual basis fluctuates with economic conditions and consumer demand. The technical capacities of research reactors allow for the irradiation of 2000 to 4000 kg (10–20 million carats) of gemstones per reactor per year.

RESIDUAL RADIOACTIVITY AFTER IRRADIATION

Neutron induced activation products

VIII-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 VIII-2). Activity concentrations of these predominant radionuclides may be several hundred becquerels per gram shortly after irradiation. The pure beta emitters ^{32}P and ^{35}S may also be present; these isotopes pose less of a regulatory concern owing to their relatively short half-lives and low energy (in the case of ^{35}S) and their much higher exemption values compared with the exemption values for the gamma emitting activation products.

VIII-15. Several less significant radionuclides may also be present (in the case of topaz: see Table VIII-2); activity concentrations of these radionuclides are typically less than 10 Bq/g. The production of activation products in surface impurities on the gemstones, such as in residual oils from cutting and polishing, 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.

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TABLE VIII-2. RADIONUCLIDES FOUND IN IRRADIATED TOPAZ [VIII-8]

Predominant radionuclides	Half-life (days)	Less significant radionuclides	Half-life (days)	Less significant 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

VIII-16. As the 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 necessary 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

VIII-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 transforms it into ^{22}Na. The free neutron released in this nuclear reaction can produce another radionuclide, transforming, for example, ^{133}Cs into ^{134}Cs.

VIII-18. These photo-neutron reactions occur only above certain energy levels and they are therefore referred to as threshold reactions. Several different radionuclides can be produced and this

generally occurs with photons of energies from 7 to 18 MeV. As a general rule, the lower the atomic weight, the higher is the photon energy needed to cause the reaction, the fewer is the number of neutrons released, and the shorter is the half-life of the radionuclide produced [VIII-12]. For most gemstone 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. However, positive identification may not always be possible because of their relatively short half-lives ($\leq$ 1 day).

RADIATION DOSES

VIII-19. Radiation exposure of the personnel of the irradiation and processing facility who are working with and handling irradiated gemstones prior to their release for sale to the public are considered to be occupational exposures to which the corresponding dose limits apply. Particular attention may need to be given to those workers who handle irradiated gemstones because, in some circumstances, it may be required to control the dose to the lens of the eye. Retailers and consumers are considered to be members of the public (i.e. not to be subject to occupational exposure) since they only come into contact with irradiated gemstones whose activity concentrations satisfy the exemption values.

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

VIII-21. A study in the United Kingdom [VIII-14] analysed over 5000 samples of gemstones collected from dealers selling 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 batches of topaz irradiated in an electron beam were also analysed to determine the possible consequences of an uncontrolled release of irradiated gemstones. The annual equivalent dose to the skin was calculated for two scenarios: a worst case scenario whereby the gemstone is worn continuously throughout the year (e.g. in a ring) and a second scenario in which the gemstone is worn for three hours a day and 30 days per year (as might be the case with a bracelet or pendant).

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

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

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/a, 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.

VIII-23. In an analysis by the United States Nuclear Regulatory Commission [VIII-12, VIII-15], the external doses likely to be received by an individual from irradiated topaz containing exempt activity concentrations of by-product material as specified in national regulations were assessed [VIII-18]. The exemption activity concentrations are given in Table VIII-3 for the five activation products most commonly found in irradiated gemstones, together 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.

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TABLE VIII-3. COMPARISON OF EXEMPTION ACTIVITY CONCENTRATION VALUES (Bq/g)

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

VIII-24. The dose equivalent to an irradiated skin area of 1 cm^2 while wearing an irradiated 30 carat (6 g) gemstone continuously (24 hours per day for 365 days) was estimated to be approximately 15 mSv.[15] 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 provided to the public are usually lower by a factor of at least two than the exemption values.

VIII-25. A similar calculation has been carried out using the Microshield software [VIII-19] for a combination of the five radionuclides of interest as listed in Table VIII-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 VIII-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 still by at least an order of magnitude.

[15] The report calculates the individual annual dose equivalent as 50 mrem (corresponding to 0.5 mSv), on the assumption that the gemstone is worn for 8 hours per day for 365 days of the year and that the area of skin exposed is 10 cm^2.

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ANNEX IX.
REGULATORY APPROACH TO IRRADIATION OF GEMSTONES AND THE SALE OF IRRADIATED GEMSTONES IN BELGIUM

GENERAL

IX-1. The irradiation of diamonds and semi-precious gemstones may enhance their appearance and can therefore add economic value. For this reason, it is widely practised.

IX-2. From the perspective of radiation protection, this practice may give rise to exposures of a number of people: those professionally involved in the practice of 'irradiation', and also — because of potential contamination and/or activation — all those people handling the gemstones after treatment, and finally members of the public as end users.

IX-3. This annex discusses the considerations leading to the approach with regard to gemstone irradiation — and the possible radiation protection issues resulting from the practice — as applied in Belgium.

BACKGROUND

IX-4. Historically, the irradiation of gemstones by embedding them in radium salts was practiced from the early 1900s until the 1960s in Belgium. Its relative popularity may have been influenced by the easy access to radium because of the presence of one of the then world's largest radium extraction plants (Union Minière, Olen) at close proximity. The city of Antwerp, a diamond trading centre of world importance, is just a few tens of kilometres away and many diamonds were cut and polished in small industries in the farming villages around the radium plant.

IX-5. Neutron irradiation of gemstones has also been practiced in Belgium for many years (1960s to 1990s) in the BR-2 research reactor at the SCK-CEN nuclear research centre in Mol.

IX-6. These activities had never been the object of any authorization specifically referring to irradiation of gemstones, nor had an explicit justification study in the light of radiation protection concerns been done.

IX.7. During the 1990s, a number of individual radioactive diamonds and also batches of diamonds were brought to the attention of the competent authorities for radiological protection. The first event was the discovery of activated black diamonds in Germany in a batch that had been imported from Antwerp. Several similar findings followed, both in Germany and in Belgium, for diamonds and occasionally for semi-precious gemstones. With the exception of some 'historical' green coloured diamonds that had been irradiated in radium salts, none of the gemstones turned out to have been treated in Belgium.

CURRENT POLICY

IX-8. The investigations that followed the discovery of activated and contaminated diamonds made the competent authorities for radiological protection aware of the irradiation activities that had been being — or were still being — practised without their knowledge.

IX-9. Some of the gemstones discovered showed significant surface contamination, and surface dose rates could reach unacceptably high values (up to tens of μSv/h). In combination with new fashions for using gemstones in piercing jewellery applied to various parts of the body, on tooth surfaces, and so on, enabling close contact between the gemstones and the skin or mucosae, radiological risks could be — in a 'worst case' scenario — far from negligible.

IX-10. In agreement with the Ministry of Economic Affairs, which is responsible for the research centre in Mol, commercial gemstone irradiation at the BR-2 research reactor was stopped. This prohibition was largely inspired by a strict application of para. 2.22[16] of the then applicable International Basic Safety Standards.

IX-11. Furthermore, and in agreement with both the Ministry of Economic Affairs and the Antwerp Diamond Board representing the sector, it was agreed that irradiated gemstones, regardless of their origin, could not be marketed unless their contact dose rate was below 0.2 μSv/h. This value corresponds to twice the mean natural background dose rate in Belgium. The Royal Decree on radiation protection was adapted to allow for this so-called 'tolerance limit'[17].

PRACTICAL ARRANGEMENTS

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[16] Para. 2.22. Except for justified practices involving medical exposures, the following practices are deemed to be not justified whenever they would result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products:
(a) practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being; and
(b) practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments. In FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[17] Article 64 of the Royal Decree of July 20, 2001 laying down the general regulation for the protection of the population, workers and the environment against the hazards of ionizing radiation.

IX-12. In addition to occasional field checks, diamonds offered for certification at the Antwerp Diamond Board are systematically screened for radioactivity by specifically designed miniaturized portal detectors. If an alarm is generated, the competent authority for radiation protection has to be notified. The next step is a confirmation measurement. If activity above the tolerated limit is confirmed, diamonds are withdrawn from the commercial circuit and confiscated.

IX-13. The owner is notified of this fact, is informed of his or her rights and possible further steps as well as of his or her (financial) responsibilities.

IX-14. One of the options for the owner is to choose a decontamination procedure[18], which mandatorily will be done at the nuclear research centre. Decontamination can be quite successful if an important fraction of the activation products is located on the gemstone's surface and in superficially located tiny cracks, as often turns out to be the case. If necessary, this procedure can be repeated. If as a result of decontamination the contact dose rate falls to below the limit value of 0.2 μSv/h, then after payment for the decontamination procedure, including the management of radioactive waste, the diamonds are returned to the owner.

IX-16. The owner can also opt for decay storage of the activated gemstones in a safe at the nuclear research centre. In order to estimate the required storage time, this option is almost invariably preceded by a spectroscopic analysis of the radioactive contaminants. Here again, diamonds are returned when the activity, and hence the surface dose rate, has sufficiently decreased and after payment of storage and measurement costs.

IX-17. If radioactivity above the tolerated limit was confirmed, the owner can hand over the activated gemstones for free to the nuclear research centre, where they can then be used for scientific purposes, but they can never be commercialized.

IX-18. The owner could alternatively decide to have the gemstones designated as radioactive waste, in which case they would be destroyed at his or her expense.

IX-19. All of these steps and arrangements, including the transports, are highly structured, secured and extensively documented. The competent authority for radiological protection is systematically informed of every decision or measurement result and solely has the authority to decide on releasing gemstones from regulatory control for further commercial use.

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[18] Referred to, in the gemstone sector, as 'deep boiling'. It is done using a mixture of strong acids or bases in which the gemstones are 'cooked' at a temperature of several hundred degrees Celsius.

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CLOSING REMARK

IX-20. The frequency of discovery of artificially enhanced radioactive gemstones has shown a significant decrease in the last decade and in the rare reported cases the gemstones also now turn out to be less radioactive. It is difficult to say whether these observations reflect a real improvement in radiation safetyy on the gemstone markets, or just demonstrate the flexibility of the trade in avoiding difficulties in a particular State that happens to have a strict approach.

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