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# Comparison of Specific Exemption Regulations for Consumer Products Containing Radioactive Isotopes

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ABSTRACT

**Background:** Practices involving radionuclides at levels below the International Atomic Energy Agency (IAEA) generic exemptions are exempt from regulation without further consideration. Practices involving radionuclides at levels above those generic exemptions may also be exempt from regulation if they meet certain conditions. These are known as specific exemptions, and each country has established its own specific exemption criteria based on the conditions set out in the IAEA General Safety Requirements (GSR) Part 3. Those conditions relate to the physical or chemical form of the radioactive material as well as to its use or the means of its disposal.

**Materials and Methods:** The specific exemption criteria of eight countries (i.e., the United States of America [US], Japan, France, China, Australia, Canada, the United Kingdom of Great Britain and Northern Ireland [UK], and Germany) were analyzed. Their similarities and differences as compared with the specific exemption criteria of the Republic of Korea (ROK) were analyzed, and suggestions for revision of the Korean regulations were formulated.

**Results and Discussion:** Each country's specific exemption criteria are defined based mostly on the IAEA criteria but tailored to its domestic circumstances. The nine countries with their specific exemption criteria can be broadly categorized into three groups: nuclide-specific exemptions for specific products (the ROK and the US), common criteria for all nuclides without specification of particular products (Japan, France, and China), and both specific and common criteria (Australia, Canada, the UK, and Germany).

**Conclusion:** The specific exemption criteria of the different countries examined in this study could be helpful in reviewing the ROK's specific exemption criteria. Development of common criteria alongside specific criteria for products requiring special attention may be a good way to determine whether new consumer products containing radioisotopes should be regulated.

**Keywords:** Radiation Regulation, Specific Exemption Criteria, Products Containing Radioactive Isotopes

Original Research

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## Introduction

The International Atomic Energy Agency (IAEA) has established the following exemption criteria for radioisotopes in Part 3 of the General Safety Requirements (GSR): (1) 'The equipment containing radioactive material is of a type approved by the regulatory body'; (2) 'The radioactive material is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or is in the

form of an unsealed source in a small amount such as sources used for radioimmunoassay'; (3) '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/hr at a distance of 0.1 m from any accessible surface of the equipment'; and (4) 'Necessary conditions for disposal of the equipment have been specified by the regulatory body' [1]. On this basis, the IAEA proposes that consumer products containing radioisotopes in quantities above the general exemption criteria may yet be exempted from regulation if certain conditions are met [2–5]. The conditions are that (1) there must be a benefit to be gained from using a product containing radioactive material; (2) the dose assessment results for all foreseeable scenarios must meet the criteria set forth by the IAEA; and (3) the design and performance of the product must be tested. The IAEA dose assessment criteria are that the effective dose to the general population is 10 μSv/yr or less per year for all foreseeable scenarios, and that an additional criterion of a maximum of 1 mSv/yr may be applied to account for low probability scenarios [6]. Many countries have developed specific exemption criteria based on these IAEA conditions to suit their own circumstances. In the Republic of Korea (ROK), the 'Regulation on substances excluded from radioisotopes' (i.e., the exemption regulation for radioisotopes) and the 'Regulation on kinds and quantities of nuclear fuel materials not subject to acquisition of a permit for use' (i.e., the exemption regulation for nuclear fuel materials) define exemptions based on use [7, 8]. Under these notices, consumer products containing radioisotopes have been marketed without regulation. However, as the specifications and usage of consumer products containing radioisotopes change over time, it is necessary to periodically review the validity of exempting them from safety regulations. In this regard, studies have been conducted to develop foreseeable exposure scenarios and evaluate the risks of consumer products containing radioisotopes, taking into account their distribution and use [9–12]. In this study, in order to determine the validity of the exemption criteria set out in the domestic Korean exemption notices, we compared the national (ROK) criteria with the specific exemption criteria of various countries.

## Materials and Methods

### 1. Republic of Korea

The ROK provides exemption criteria for products containing radioisotopes or nuclear fuel material. It identifies the specific products that can be exempted from regulation, and sets different exemption criteria for each use and nuclide. The official name of the exemption regulation for radioisotopes is 'Regulation on substances excluded from radioisotopes,' and the products covered are (1) smoke detectors; (2) safety indicator lights ($^{3}$H); (3) luminescent materials for aircraft ($^{147}$Pm); (4) luminescent materials embedded in gauges or indicators (including watches); (5) electrical and gas appliances; (6) military equipment ($^{241}$Am, $^{3}$H, $^{147}$Pm, $^{63}$Ni); (7) sealed sources for calibration; and (8) $^{14}$C certified as a radiopharmaceutical for diagnosis. In addition, there is the exemption regulation for nuclear fuel materials, formally known as the 'Regulation on kinds and quantities of nuclear fuel materials not subject to acquisition of a permit for use.' This regulation sets standards for products containing uranium, thorium, and plutonium, including (1) uranium for aircraft counterweights; (2) shielding uranium contained in irradiators; (3) shielding uranium in design-approved transport containers; (4) natural thorium for chemical analysis; (5) thorium-containing vacuum tubes, indoor lamps, germicidal or outdoor lamps, welding rods, gas-lamp wicks, optical lenses, alloys (nickel, tungsten, or magnesium); and (6) natural water. The products and exemption criteria for both regulations (i.e., the exemption regulation for radioisotopes and nuclear fuel materials) are summarized in Table 1.

### 2. United States of America

In the United States of America (US), 'Certain items containing byproduct material' (i.e., 10 Code of Federal Regulations [CFR] Part 30.15) provides criteria for products that can be exempted from regulation for those who receive, possess, use, transfer or acquire them [13]. In addition, 'Self-luminous products containing $^{3}$H, krypton-85, or promethium-147,' 'Gas and aerosol detectors containing byproduct material,' 'Radioactive drug: capsules containing carbon-14 urea for *in vivo* diagnostic use for humans,' and 'Certain industrial devices' (i.e., 10 CFR Parts 30.19-22) specify products that are exempt from regulation for activities other than manufacturing, processing, production, and sale, without criteria [14–17]. Anyone who intends to apply or incorporate byproduct material into an exempt product, or who intends to initially transfer it for sale or distribution, must apply for a special license under 10 CFR 32, and anyone who intends to use a radiopharmaceutical for research involving human subjects must apply for a special license under 10 CFR 35. There is no


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**Table 1.** Products and Exemption Criteria Listed in Republic of Korea Regulations

| Products | Nuclides | Exemption amounts | Exemption criteria |
|---|---|---|---|
| Radioisotopes | | | |
| Smoke detector | $^{241}$Am | - | (1) Approved and tested design<br>(2) Labeling to provide precautions for handling (including disposal instructions) and to indicate radioactive material in a conspicuous place on the back of the smoke detector<br>(3) A valid written maintenance contract between the building owner and the supplier |
| Safety indicator light (safety exit sign) | $^{3}$H | 925 GBq per unit product | (1) Approved and tested design<br>(2) Fixed or permanently attached to a facility or product<br>(3) Structured to prevent contact with radioisotopes<br>(4) Surface dose rate less than or equal to 1 μSv/hr<br>(5) Personal dose from handling less than 10 μSv/yr |
| Luminescent materials for aircraft | $^{147}$Pm | 3 GBq | (1) Approved and tested design<br>(2) Fixed or permanently attached to a facility or product |
| Gauges or indicators (including watches) | | 50 Times the general exempt quantity per unit product | (1) Luminescent material firmly embedded in the product<br>(2) Does not contain radionuclides with a minimum quantity of less than 100 kBq as specified in the general exemption criteria<br>(3) Structured to prevent contact with radioisotopes<br>(4) Surface dose rate less than or equal to 1 μSv/hr |
| Electrical and gas appliances | | 100 Times the general exempt quantity per unit product | (1) Does not contain radionuclides with a minimum quantity of less than 10 kBq as specified in the general exemption criteria<br>(2) Surface dose rate less than or equal to 1 μSv/hr |
| Military equipment | $^{241}$Am<br>$^{3}$H<br>$^{147}$Pm<br>$^{63}$Ni | 9.25 MBq<br>37 GBq<br>3 GBq<br>1 GBq | - |
| Calibration sources | | (1) 3.7 MBq; or<br>(2) 10 times the general exempt quantity | (1) Sealed radioisotopes that meet the durability criteria specified in ISO 2919-1999(E) or ANSI N542-1977 |
| Radiopharmacy | $^{14}$C | 37 kBq | (1) The use of granulated embedded capsules for human diagnostics |
| Nuclear fuel materials | | | |
| Aircraft counterweight<br>Irradiator shielding<br>Design-approved container shielding | Natural or depleted uranium | - | (1) Covered with durable paint or surrounded by other external materials to prevent contact with uranium<br>(2) Marked on the surface of the device to identify it as uranium |
| For chemical analysis | Natural thorium | 100 g per package | - |
| Vacuum tube or indoor lamp | | 50 mg of each ingredient | - |
| Germicidal or outdoor lights | | 2 g of each ingredient | - |
| Welding rods or wick for gas lamps | | 700 Bq or 1 g of each ingredient | - |
| Nickel, tungsten, or magnesium alloys | | Products made with a thorium weight ratio of 4 w/o or less | - |
| Optical lenses | | Products manufactured with a thorium weight ratio of 30 w/o or less in the plating material | - |
| Natural water | | - | (1) Unconcentrated radioactivity in nature |

ISO, International Organization for Standardization; ANSI, American National Standards Institute; w/o, without.

generic exemption for thorium, uranium, and plutonium, which are source materials and special nuclear materials, and a license is required to handle them. However, there are exceptions: products that meet the conditions listed in 10 CFR 40.13 may be transferred, possessed, used, or given away without a license [18]. The relevant regulatory exemption products and exemption criteria are summarized in Table 2.

### 3. Japan

In Japan, Article 12(2) of Law No. 167 of Showa 32 requires that equipment containing radioisotopes be approved by the Nuclear Safety and Technology Center, a registered certification body, for its prevention of radiation interference during storage and transportation and, thus, clearance for manufac-

Table 2. Products and Exemption Criteria Listed in United States of America Regulations [13–18]

| Products | Nuclides | Exemption amounts | Exemption criteria |
|---|---|---|---|
| 10 CFR Part 30.15 | | | |
| Timepieces | $^{3}$H<br>$^{147}$Pm<br>$^{226}$Ra | 925 MBq<br>(Watch) 3.7 MBq<br>(Other) 7.4 MBq<br>(Manufactured prior to November 30, 2007) 37 kBq | (1) The levels of radiation from hands and dials containing $^{147}$Pm do not exceed, when measured through 50 mg/cm$^2$ of absorber<br>a. (Wrist watch) 0.1 mrad/hr at 10 cm<br>b. (Pocket watch) 0.1 mrad/hr at 1 cm<br>c. (Other timepiece) 0.2 mrad/hr at 10 cm |
| Hands | $^{3}$H<br>$^{147}$Pm | 185 MBq<br>(Watch hand) 740 kBq<br>(Other) 1.48 MBq | |
| Dials | $^{3}$H<br>$^{147}$Pm | 555 MBq<br>(Watch dial) 2.22 MBq<br>(Other) 4.44 MBq | |
| Static elimination devices | $^{210}$Po | 18.5 MBq | - |
| Ion-generating tubes | $^{210}$Po<br>$^{3}$H | 18.5 MBq<br>1.85 GBq | - |
| Balances of precision | $^{3}$H | 37 MBq<br>(Manufactured before December 17, 2007) 18.5 MBq | - |
| Marine instruments | $^{3}$H gas | (Compass) 27.75 GBq<br>(Others manufactured before December 17, 2007) 9.25 GBq | - |
| Smoke detectors | $^{241}$Am | 37 kBq | - |
| Electron tubes | - | - | (1) Does not contain more than one of the following specified quantities<br>a. (Microwave) 5.55 GBq of $^{3}$H<br>b. (Other) 370 MBq of $^{3}$H<br>c. 37 kBq of $^{60}$Co<br>d. 185 kBq of $^{63}$Ni<br>e. 1.11 MBq of $^{85}$Kr<br>f. 185 kBq of $^{137}$Cs<br>g. 1.11 MBq of $^{147}$Pm<br>(2) The levels of radiation from each electron tube containing byproduct material do not exceed 1 mrad/hr at 1 cm when measured through 7 mg/cm$^2$ of absorber |
| Ionizing radiation measurement instruments (containing calibration source) | 10 CFR 30.71 Schedule B<br>$^{241}$Am | 1.85 kBq | (1) Each source contains no more than 10 exempt quantities set in 10 CFR 30.71<br>(2) Each instrument contains no more than 10 exempt quantities |
| 10 CFR Part 30.19 | | | |
| Self-luminous products | $^{3}$H<br>$^{85}$Kr<br>$^{147}$Pm | - | (1) Dose not include anything that is primarily for frivolous purposes or applied to toys or adornments |
| 10 CFR Part 30.20 | | | |
| Gas and aerosol detectors | - | - | (1) Includes detectors manufactured or distributed before November 30, 2007 |
| 10 CFR Part 30.21 | | | |
| Radioactive drug | $^{14}$C | 37 kBq | - |
| 10 CFR Part 30.22 | | | |
| Certain industrial devices | - | - | (1) Industrial devices containing byproduct materials designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for production of an ionized atmosphere |

CFR, Code of Federal Regulations.


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ture or importation [19]. Additionally, Article 12(3) states that a design certification (i.e., common criteria) or specific design certification (i.e., nuclide-specific exemptions for specific products) shall be granted if the equipment to be approved meets the technical criteria specified in the rules of the Nuclear Regulation Authority (NRA). The technical criteria are set out in Article 14(3) of Prime Ministerial Decree No. 56 and include criteria for (1) the design of functions to prevent interference and (2) conditions of use, storage, and transport [20]. The design certification threshold is 1,000 times the general exemption limit for each type of radioisotope. Specific design certification targets are specified in Article 12 of Law No. 259 of showa and the 'Notification of subdivisions on technical standards for design certification,' etc. [21, 22]. These standards cover smoke detectors, switching discharge tubes for radar receivers, and devices designated by the NRA (i.e., contact potentiometers and thermoparticulate sensors) as having a dose equivalent rate of 1 μSv/hr or less at a distance of 10 cm from a surface. When selling or leasing an appliance that has received such certification, a document stating the certification number of the appliance and the conditions for its use, storage, transportation, and disposal must be included. The technical criteria for design certification and regulatory exemption in Japan are summarized in Table 3. In the case of nuclear fuel materials, a license must be obtained in accordance with Article 52 of the Nuclear Reactor Regulation Act. However, a license is not required for the use of nuclear fuel materials within the types and amounts of nuclides specified in Article 39 of the Enforcement Decree of the Nuclear Reactor Regulation Act (even in this case, a license as an internationally controlled material is required pursuant to Article 61(3) of the Nuclear Reactor Regulation Act). In addition, the "Guidelines for ensuring safety of raw materials and products containing uranium or thorium" provides its own safety management guidelines for materials not regulated by the Nuclear Reactor Regulation Act (e.g., gas mantles containing thorium, high-intensity discharge lamps, welding rods, etc.) [23].

**Table 3.** Technical Criteria for Design Certification and Regulatory Exemption in Japan [20]

| Article section | Exemption criteria |
|---|---|
| Technical criteria for design certification | |
| Department of Radiation Protection | (1) The dose from external exposure during use, storage, and transport is below the dose limit set by the Nuclear Regulation Authority (1 mSv/yr)<br>(2) Surface dose rate of 1 μSv/hr or less at 10 cm from the surface<br>(3) No risk of ingestion of radioisotopes embedded in the device during use, storage, or transport<br>(4) Embedded radioisotopes must comply with device-specific specifications<br>(5) Containers and fixed supports containing radioisotopes must not be subjected to temperature, pressure, shock, vibration, or breakage during handling<br>(6) Check that the radiation protection part is the same as the design applied |
| Conditions of use, storage, and transport | (1) Take steps to prevent access within 50 cm of the surface of the unit beyond the annual hours of use<br>(2) Do not disassemble or reassemble the radiation protection part<br>(3) Store in a special container marked 'Radioactive'<br>(4) When transporting the radioisotope unit, ensure that the container in which the radioisotope unit is stored meets the following criteria:<br>a. Qualifies as an L-type item<br>b. Something that can be handled easily and safely<br>c. Not likely to crack or break due to expected changes in temperature and internal pressure, vibration, etc. during transport<br>d. There are no unnecessary protrusions on the surface, and contamination on the surface is easily removed<br>e. There is no possibility of hazardous physical or chemical reactions between the packaged radioisotopes<br>f. Provisions are made to prevent tampering with the valve<br>g. The marking 'Radioactive' and the marking [L-Type Transport] are affixed in a conspicuous place unless otherwise specified by the Nuclear Regulation Authority<br>h. The surface dose equivalent rate does not exceed 5 μSv/hr<br>i. The density of radioisotopes at the surface does not exceed the surface density of the shipments referred to in Article 18(4)(8)<br>j. The conditions of use, storage, and transport of the radioisotope equipment, other than those specified in this subparagraph, are adequate and reasonable to prevent radiation interference |

### 4. France

In France, Chapter III: Ionising Radiation (Articles R.1333-1 to R.1333-93) of the Public Health Code provides for the exemption of consumer and construction products that meet certain conditions, and Directive 2013/59/Euratom provides common criteria for the exemption of products containing radioisotopes above the general exemption limits [24, 25]. In addition, the 'Implementing Regulations of 5 May 2009' specify the content to be included in the application for exemption, and two notices list the types of cement and certain lamps that are exempt from regulation [26–28]. The detailed exemption criteria presented in each regulation are summarized in Table 4.

### 5. China

In China, Circular No. 49 of the 'General Administration of Ecology and Environment' authorizes the preparation of exemption applications for equipment that meets the requirements for general and conditional exemptions [29]. In addition, the 'Basic standards for protection against ionizing radiation and safety of radiation sources' specifies the conditions under which general and conditional exemptions can be granted [30]. The detailed exemption criteria presented in each regulation are summarized in Table 5.

Table 4. Specific Exemption Criteria in France

| Article section | Exemption criteria |
|---|---|
| Public Health Code | |
| R.1333-4 | (1) Regulated products may be exempted from regulation by order of the Minister of Consumer Affairs and the Minister of Construction, after consultation with the various authorities (Minister of Health, Nuclear Safety Authority, Public Health Commission), if justified by the benefits of their use |
| R.1333-106 | (1) Provides exemption for all or part of the ownership, manufacture, use, distribution, import and export of consumer and construction products under R.1333-4 |
| | (2) Products above the general exemption limit may be exempted from regulation by a decision of the nuclear safety authority, as approved by the competent minister, and must comply with 2013/59/Euratom Appendix 7 3-(e) |
| 2013/59/Euratom | |
| Appendix 7 3-(e) | (1) In assessing whether a regulatory exemption is warranted when the general exemption limit is exceeded, the assessment should be made in light of all of the general criteria (1) to (3) |
| | (2) General criteria (1): the radiation risk to individuals from the practice is sufficiently low that it is not a regulatory concern for artificial and naturally occurring radionuclides, the effective dose expected to be received by the public from exempted practices is 10 μSv and 1 mSv, respectively, for 1 year |
| | (3) General criteria (2): the type of practice has been determined to be justified |
| | (4) General criteria (3): the practice is inherently safe |

Table 5. Specific Exemption Criteria in China [29, 30]

| Article section | Exemption criteria |
|---|---|
| General administration of ecology and environment No. 49 | |
| For completing exemption applications | (1) For radioisotopes or radiation generators meeting the exemption criteria, the general importer or user may complete and submit an exemption application for radioisotopes and radiation generators to the local environmental authority |
| | (2) For radionuclides not covered by the basic criteria, IAEA GSR Part 3 may be applied |
| | (3) For devices containing level 5 radionuclides that meet the requirements for conditional exemption from the basic criteria (hereinafter referred to as "devices containing conditionally exempted sources"), the domestic manufacturer or general importer may complete an application |
| Basic standards for protection against ionizing radiation and safety of radiation sources | |
| Conditions for exemption | (1) A conditional exemption may be granted if the conditions set by the verifying authority (e.g., disposal conditions and physical/chemical form) are met |
| | (2) Equipment containing radioactive material that is not exempted under the general exemption criteria may be granted a conditional exemption if the following conditions are met: |
| | a. It is in a format recognized by the regulatory authorities |
| | b. The radioactive material is in the form of a closed circle which can effectively prevent any contact with the radioactive material or prevent leakage |
| | c. Under normal operating conditions, the ambient dose rate at a distance of 10 cm from the surface of the equipment does not exceed 1 μSv/hr |
| | d. The study management has clearly specified the conditions for disposal |

IAEA, International Atomic Energy Agency.


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## 6. Australia

The Australian Radiation Protection and Nuclear Safety Act 1998 provides for exemptions from regulation [31]. The Australian Radiation Protection and Nuclear Safety Regulations 2018 also provide specific exemption criteria for specific products that are exempt from regulation, along with common criteria for exempting products that are not listed [32]. The detailed exemption criteria presented in each regulation are summarized in Table 6.

## 7. Canada

The Nuclear Substances and Radiation Devices Regulations provide exemptions for deuterium-containing compounds, aircraft counterweights, natural uranium, depleted

Table 6. Specifically Exempted Dealings Listed in Australian Regulations [31, 32]

| Article section | Exemption criteria |
|---|---|
| Dealings that are exempt unless declared (subsection 1) | |
| $^{222}$Rn | The dealing:<br>(1) is with $^{222}$Rn with an activity concentration of less than 1,000 Bq/m$^3$ occurring naturally in a workplace; and<br>(2) Either:<br>a. does not involve any other controlled material; or<br>b. involves another controlled material whose use in the dealing is an exempt dealing (apart from this item) |
| Depleted uranium | The dealing:<br>(1) is with depleted uranium that:<br>a. is being used as radiation shielding in a container for controlled materials; and<br>b. is completely contained in an appropriate metallic sheath; and<br>c. is in a container for controlled materials that comply with the requirements in the Transport Code; and<br>(2) is not with any other controlled material |
| Solid massive form depleted uranium | The dealing:<br>(1) is with depleted uranium that is in solid massive form used for ballast; and<br>(2) is not with any other controlled material |
| Smoke detector | The dealing:<br>(1) is with a smoke detector designed and made in accordance with Australian Standard AS 3786:2014: Smoke Alarms using scattered light, transmitted light or ionization, as existing on December 8, 2018; and<br>(2) is not repair or maintenance of the detector |
| Other items | The dealing is with any of the following items and no other controlled apparatus or controlled material:<br>(1) a television receiver;<br>(2) a visual display terminal;<br>(3) a cathode ray tube;<br>(4) an electron microscope;<br>(5) Arc welding equipment;<br>(6) radar equipment used for detection and ranging;<br>(7) radiofrequency equipment used for communications;<br>(8) an artificial optical source emitting ultraviolet A radiation (315–400 nm);<br>(9) a completely enclosed apparatus containing an ultraviolet radiation light source (e.g., a spectrophotometer);<br>(10) a biological safety cabinet (laminar flow or biohazard) with a failsafe interlocking system;<br>(11) a laser product with an accessible emission that does not exceed the accessible emission limits of a Class 3R laser product, as set out in AS/NZS IEC 60825.1:2014;<br>(12) an optical fiber communication system that does not exceed the hazard level 3R, as set out in AS/NZS IEC 60825.2:2011;<br>(13) a klystron;<br>(14) a range finder with power less than 5 mW;<br>(15) an optical light source that:<br>a. emits infra-red or visible light at a level not exceeding the exposure limits mentioned in AS/NZS IEC 62471:2011; and<br>b. is not a laser product |
| Sealed source | The dealing is with a sealed source used for teaching the characteristics and properties of radiation or radiation sources, and the sealed source contains one or more of the following:<br>(1) $^{60}$Co with an activity not greater than 200 kBq;<br>(2) $^{90}$Sr with an activity not greater than 80 kBq;<br>(3) $^{137}$Cs with an activity not greater than 200 kBq;<br>(4) $^{226}$Ra with an activity not greater than 20 kBq;<br>(5) $^{241}$Am with an activity not greater than 40 kBq |

(*Continued to the next page*)

Table 6. Continued

| Article section | Exemption criteria |
|---|---|
| Geological sample | The dealing is with a geological sample that:<br>(1) contains radioactive material that emits radiation at a level not exceeding 5 μGy an hour, measured at a distance of 10 cm from its surface; and<br>(2) is being used as a sample in teaching or for display as a geological specimen |
| Gaseous $^{3}$H light device | The dealing is with a gaseous $^{3}$H light device that:<br>(1) is used solely for safety purposes; and<br>(2) includes not greater than 74 GBq of $^{3}$H |
| Electron-capture detector or similar device | The dealing is with an electron-capture detector or similar device used in gas chromatography containing:<br>(1) a $^{63}$Ni sealed source with activity not greater than 750 MBq; or<br>(2) a $^{3}$H source with activity not greater than 20 GBq; and no other controlled apparatus or controlled material |
| $^{85}$Kr-containing lighting products | The dealing is with lighting products that include $^{85}$Kr and no other controlled apparatus or controlled material |
| Exemption by declaration of dealings not covered by subsection (1) | |
| Other exempt dealing | For the purpose of paragraph 31(1)(b) of the Act, a dealing that is declared under subsection (4) or (5) of this section is an exempt dealing<br>(1) Subsection (4): The CEO may declare, in writing, that a particular dealing that is not described in the table in subsection (1) is a dealing for which:<br>a. under reasonably foreseeable circumstances, the effective dose to an individual is likely to be not greater than 10 μSv in a year; or<br>b. an accident, misuse or exceptional circumstance affecting the dealing is not likely to produce an effective dose to an individual greater than 1 mSv in a year<br>(2) Subsection (5): The CEO may declare, in writing, that:<br>a. a particular dealing that is not described in an item in the table in subsection (1) is a dealing involving:<br>- a radiological emergency or its after-effects; or<br>- the after-effects of a previous dealing; or<br>- naturally occurring materials; or<br>- bulk material with a mass of more than 1,000 kg; and<br>b. an assessment of the magnitude of individual doses, the number of people exposed and the likelihood that potential exposure will actually occur justifies the dealing being exempt |

AS/NZS, Australian Standard/New Zealand Standard; IEC, International Electrotechnical Commission; CEO, Chief Executive Officer.

uranium, and natural thorium [33]. The regulations also provide more detailed exemption criteria for smoke detectors, $^{3}$H safety labels, devices containing radium-luminous compounds, and calibration sources. Even if a nuclide is not presented as a specific consumer product, it is exempt from transfer, import, export, storage, use, and disposal if it is a radiation device rather than an exposure device and is less than 10 times the general exemption quantity. As the term is used herein, an exposure device is a radiographic instrument designed to perform gamma radiography and includes the components of the instrument such as the sealed source assembly, the drive mechanism, the sealed source assembly guide tube, and the exposure head. A radiation device is a device containing more than an exempt amount of nuclear material and capable of using nuclear material for its radiological properties, including a device containing a radium-luminescent compound. The detailed exemption criteria presented in the regulations are summarized in Table 7.

## 8. United Kingdom of Great Britain and Northern Ireland (UK)

The Ionising Radiations Regulations 1999—Schedule 1 provides both general and common criteria for the exemption of products containing radioisotopes above the general exemption limit [34]. In addition, the scope of and exemptions from the radioactive substances legislation in England, Wales and Northern Ireland: guidance document details the exemption criteria for various products and provides a table of radioacivity levels by nuclides and their respective products [35]. The detailed exemption criteria for each regulation are summarized in Table 8.

## 9. Germany

The radiation protection ordinance provides specific design criteria for regulatory exemptions (i.e., Article 45(1) of the Radiation Protection Act) and establishes exemption criteria for products' specific purposes, such as inert gas extraction and use of natural radioactive materials in educational


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Table 7. Specific Exemption Criteria in Canada

| Article section (products) | Exemption criteria |
|---|---|
| Deuterium or a compound containing deuterium | Possess, transfer, store, use, abandon, produce, refine, convert, enrich, process, reprocess, manage or dispose of deuterium or a compound containing deuterium, if the quantity of deuterium is less than 10 kg in any calendar year |
| Depleted uranium | Possess, transfer, store, use or manage depleted uranium, in any quantity, that is used as counterweights in aircraft if<br>(1) Each counterweight manufactured after the coming into force of this subparagraph is durably and legibly impressed with the words "depleted uranium appauvri" and the words are visible through any plating or other covering;<br>(2) Each counterweight manufactured after the coming into force of this subparagraph is durably and legibly labeled or impressed with the name of the manufacturer and its unique identification number and the statement "Unauthorized alterations prohibited/modifications interdites sans autorisation";<br>(3) No alteration is made to the counterweights except in accordance with the requirements set out in subsection 571.02(1) of the Canadian Aviation Regulations; and<br>(4) No chemical, physical or metallurgical treatment or processing of the counterweights is done other than for the repair or restoration of any plating or other covering |
| Depleted uranium, natural uranium or natural thorium | Possess, transfer, use or abandon material that contains not more than 10 kg of depleted uranium, natural uranium or natural thorium in any calendar year and that is not used for its radiation properties |
| Smoke detectors | A person may, without a license to carry on that activity, possess, transfer, use or abandon a smoke detector that contains a nuclear substance, if<br>(1) The smoke detector does not contain more than 185 kBq of $^{241}$Am or, where it is in a commercial or industrial facility, more than 740 kBq of $^{241}$Am;<br>(2) The radiation dose rate does not exceed 1 μSv/hr at 10 cm from any of the accessible surfaces of the smoke detector;<br>(3) The design and construction of the smoke detector prevent persons from making direct contact with the nuclear substance that it contains under normal conditions of use;<br>(4) All markings and labels on the smoke detector are legible;<br>(5) The radioactive nuclear substance contained in the smoke detector is a sealed source that, when it is mounted in its holder, conforms to International Standard 2919, Radiation Protection—Sealed radioactive sources—General requirements and classification (1999), of the International Organization for Standardization; and<br>(6) The smoke detector meets the tests specified in the annex entitled Prototype Tests of the Recommendations for ionization chamber smoke detectors in implementation of radiation protection standards (1977) of the Nuclear Energy Agency of the Organization for Economic Co-operation and Development |
| $^{3}$H safety signs | A person may, without a license to carry on that activity, possess, transfer, use or abandon a $^{3}$H-activated self-luminous safety sign if<br>(1) The only nuclear substance contained in the safety sign is $^{3}$H;<br>(2) The safety sign contains no more than 925 GBq of $^{3}$H in gaseous form;<br>(3) The light-emitting component containing the $^{3}$H consists of glass tubes that are enclosed in a sturdy metal or plastic frame mounted in a manner that prevents the dismantlement and removal of the glass tubes;<br>(4) The amount of $^{3}$H present in the form of oxide does not exceed 1 per cent per volume for each glass tube;<br>(5) The safety sign conforms to ANSI/HPS N43.4-2000;<br>(6) Classification of Radioactive Self-Luminous Light Sources, of the American National Standards Institute/Health Physics Society, or to Standard MILSTD-810F, 2000, Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests, of the United States Department of Defense; and<br>(7) The safety sign, if it is manufactured after the coming into force of this paragraph, is marked with the name and quantity in Bq of the nuclear substance, the manufacturer's recommended expiry date for the sign and the date of manufacture of the sign |
| Devices containing radium-luminous compounds | A person may, without a license to carry on that activity, possess, transfer or use a device that contains a nuclear substance, if<br>(1) The only nuclear substance contained in the device is a radium-luminous compound;<br>(2) The person does not possess more than 10 such devices; and<br>(3) The device is not disassembled or tampered with |
| Check sources | A person may, without a license to carry on that activity, possess, transfer, store, use or abandon a check source that contains a radioactive nuclear substance and that is designed to verify the response of an instrument when exposed to the radiation output of the check source, if<br>(1) The check source contains<br>a. It is a certified model; or<br>b. It is used in accordance with a license that authorizes its use for development purposes;<br>(2) The radiation dose rate does not exceed 1 μSv per hour at 10 cm from any of the accessible surfaces of the check source; |

(*Continued to the next page*)

Table 7. Continued

| Article section (products) | Exemption criteria |
|---|---|
| | (3) The design and construction of the check source, under normal conditions of use, prevent persons from making direct contact with the nuclear substance that it contains;<br>(4) All markings and labels on the check source or exterior packaging are legible;<br>(5) The radioactive nuclear substance in the check source, when it is mounted in its holder, conforms to International Standard 2919, Radiation Protection—Sealed radioactive sources—General requirements and classification (1999), of the International Organization for Standardization; and<br>(6) The check source, if it is a sealed source, meets the tests specified in ANSI/HPS N43.6-1997, Sealed Radioactive Sources—Classification, of the American National Standards Institute/Health Physics Society |
| Not listed nuclides | Possess, transfer, import, export, store, use or abandon a radiation device, other than an exposure device, if the quantity of the nuclear substance or substances contained in the device is less than 10 times the exemption quantity |

ANSI, American National Standards Institute; HPS, Health Physics Society.

Table 8. Specific Exemption Criteria in United Kingdom

| Exemption criteria |
|---|
| Work not required to be notified under regulation 6<br>Work with ionizing radiation shall not be required to be notified in accordance with regulation 6 when the only such work being carried out is in one or more of the following categories—<br>(1) Where apparatus contains radioactive substances in a quantity exceeding the general exemption values—<br>a. The apparatus is of a type approved by the executive;<br>b. The apparatus is constructed in the form of a sealed source;<br>c. The apparatus does not under normal operating conditions cause a dose rate of more than 1 μSv/hr$^{-1}$ at a distance of 10 cm from any accessible surface; and<br>d. Conditions for the disposal of the apparatus have been specified by the appropriate agency;<br>(2) The operation of any electrical apparatus to which these regulations apply other than the apparatus referred to in subparagraph (e) below provided that—<br>a. The apparatus is of a type approved by the executive; and<br>b. The apparatus does not under normal operating conditions cause a dose rate of more than 1 μSv/hr$^{-1}$ at a distance of 10 cm from any accessible surface;<br>(3) The operation of—<br>a. Any cathode ray tube intended for the display of visual images; or<br>b. Any other electrical apparatus operating at a potential difference not exceeding 30 kV,<br>Provided that the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1 μSv/hr$^{-1}$ at a distance of 10 cm from any accessible surface;<br>(4) Where the work involves material contaminated with radioactive substances resulting from authorized releases which the appropriate agency has declared not to be subject to further control |

| Radioactive material and accumulated radioactive waste: values of maximum quantities | | |
|---|---|---|
| Radioactive material or accumulated radioactive waste type | Maximum quantities of radionuclides for each item (Bq) | Maximum quantity of radionuclides (Bq):<br>- on any premises in items of the material or waste which satisfy the limit in column 2; or<br>- in mobile radioactive apparatus held by a person |
| Sealed source of a type not described in any other row of this table | $4\times10^{6}$ | $2\times10^{8}$ |
| Class A gaseous $^{3}$H light device | $2\times10^{10}$ | $5\times10^{12}$ |
| Class B gaseous $^{3}$H light device | $1\times10^{12}$ | $3\times10^{13}$ |
| Class C gaseous $^{3}$H light device | $1\times10^{12}$ | No limit |
| Any sealed source containing only $^{3}$H as a radioactive component | $2\times10^{10}$ | $5\times10^{12}$ |
| $^{3}$H foil source | $2\times10^{10}$ | $5\times10^{12}$ |
| Smoke detector affixed to premises | $4\times10^{6}$ | No limit |
| Electrodeposited source | $^{63}$Ni $6\times10^{8}$ or $^{55}$Fe $2\times10^{8}$ | $6\times10^{11}$ |
| Luminesced article (unsealed source) | $^{147}$Pm $8\times10^{7}$ or $^{3}$H $4\times10^{9}$ | $^{147}$Pm $4\times10^{10}$ or $^{3}$H $2\times10^{11}$ |
| $^{137m}$Ba eluting source | $^{137}$Cs+ $4\times10^{4}$ | $^{137}$Cs+ $4\times10^{5}$ |
| Substance or article which is or contains magnesium alloy or thoriated tungsten in which the thorium concentration does not exceed 4% by mass | No limit | No limit |

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**Table 8.** Continued

| Radioactive material and accumulated radioactive waste: values of maximum quantities | | |
|---|---|---|
| Radioactive material or accumulated radioactive waste type | Maximum quantities of radionuclides for each item (Bq) | Maximum quantity of radionuclides (Bq):<br>- on any premises in items of the material or waste which satisfy the limit in column 2; or<br>- in mobile radioactive apparatus held by a person |
| A uranium or thorium compound | | Up to a total of 5 kg of uranium and thorium |
| A substance or article (other than a sealed source) which is intended for use for medical or veterinary diagnosis or treatment or clinical or veterinary trials | | $^{99m}$Tc $1 \times 10^9$ and<br>$2 \times 10^8$ of all other radionuclides,<br>(no more than $1 \times 10^8$ of which is contained in radioactive material) |

**Table 9.** Specific Exemption Criteria in Germany [36]

| Article section | Exemption criteria |
|---|---|
| Activities that do not require authorization | |
| Appendix 3 | (1) For use in the human body, if the specific radioactivity of the substance does not exceed 500 μBq/g<br>(2) Storage in a device the design of which has been approved in accordance with Article 45(1), if the total radioactivity of the radioactive substance does not exceed 1,000 times the general exemption criteria<br>(3) Production, use and storage of inert gases (Ar, He, Ne, Kr, Xe, Rn) derived from air if the isotopic ratio of the gas is the same as the isotopic ratio of air<br>(4) Where the surface dose rate at a distance of 10 cm from the surface of natural radioactive materials used for educational purposes is 1 μSv/hr or less<br>(5) Processing of U in the form of compounds for chemical analysis with a total mass of U of up to 30 g |
| Technical requirements for design approval of devices containing other radioactive materials | |
| Article 45(1) | |
| Article 1 | The radiation protection manager shall ensure that radiation protection instructions are issued. Radiation protection instructions may be part of other operating instructions required, inter alia, by occupational safety, radiation protection, dangerous goods or dangerous substances regulations |
| Article 16 | The design of a device containing other radioactive substances in accordance with Section 3 (1) of the Radiation Protection Act may be approved only if it has been approved in accordance with Section 45 (1) of the Radiation Protection Act<br>(1) Contains only other radioactive substances as defined in Article 3(1) of the Radiation Protection Act, and<br>a. is enclosed, and<br>b. covered so that it can be safely touched; and<br>(2) The local dose rate at 10 cm from the accessible surface does not exceed 1 μSv/hr under normal operating conditions; and<br>(3) The device is designed to ensure the safe containment of radioactive material during normal operation and is so designed that no additional leakage testing of the radioactive material contained in the device is required other than the manufacturer's quality control test referred to in Article 24(2) and the leakage test referred to in Article 25(4)<br>(4) The radioactivity of the radioactive material contained in the device does not exceed 10 times the general exemption limit<br>(5) The annual effective dose expected from the use of the device is in the range of 10 μSv/yr |

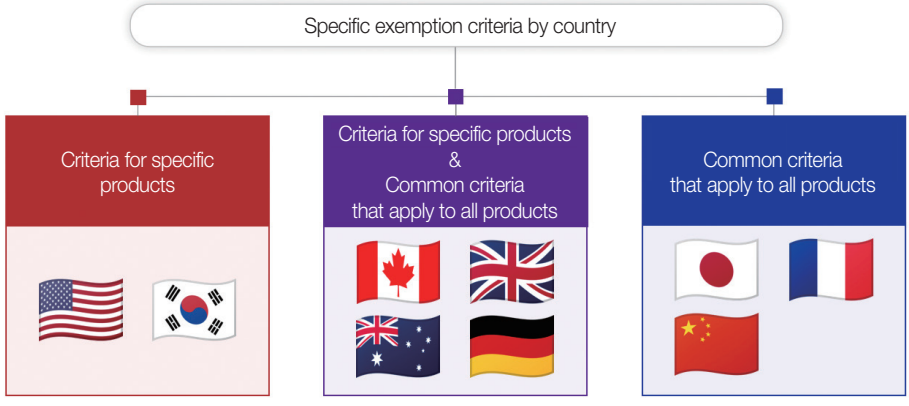


**Fig. 1.** Classification by type of specific exemption criteria among countries.

**Table 10.** Similarities and Differences among the Countries Examined in This Study

| Item | Country | | | | |
|---|---|---|---|---|---|
| | Republic of Korea | USA | Australia | Canada | Germany |
| Smoke detector | No nuclide and quantity criteria<br>(1) Embedded in design approved and tested equipment<br>(2) Radioactive material labelled and warnings attached (including disposal instructions)<br>(3) Building owners and suppliers have valid written maintenance agreements | $^{241}$Am<br>(1) Foil form<br>(2) 1 μCi (37 kBq) or less per unit product | No nuclide and quantity criteria<br>(1) Meets Australian Standard AS 3786:2014<br>(2) Excludes repair and maintenance of detectors | $^{241}$Am<br>(1) General: 185 kBq or less<br>(2) Industrial and commercial: 740 kBq or less<br>(3) Surface dose rate at 0.1 m distance 1 μSv/hr or less<br>(4) Contact resistant construction<br>(5) Radioactive labelling and precautions<br>(6) Conforms to ISO 2919 sealing standards and OECD testing | Human use<br>(1) 500 μBq/g or less<br>Pharmaceuticals<br>(1) Use, storage, and disposal of medicines transported in accordance with Article 2, paragraph 1, subparagraph 2 of the Regulations on Ionizing Radiation-Treated Medicines<br>Design-approved devices (Article 45, paragraph 1 of the Radiation Protection Act)<br>(1) Use of design-approved devices<br>(2) Storage of devices whose design has been approved when the total radioactivity is 1,000 times or less than the generic exemption criteria<br>Noble gas<br>(1) Extraction, use and storage of noble gases obtained from air when the gas isotope ratio is the same as that of air<br>Natural radioactive material<br>(1) Use for educational and training purposes<br>(2) Surface dose rate 1 μSv/hr or less |
| Safety indicator light | $^{3}$H<br>(1) 925 GBq or less per unit product<br>(2) Contact resistant construction<br>(3) Surface dose rate 1 μSv/hr or less<br>(4) Annual personal dose less than 10 μSv/yr | Luminescent materials<br>(1) No quantity criteria<br>(2) Permit application required under §32.21 and §32.22 for production, sale and distribution | $^{3}$H<br>(1) 74 GBq or less<br>(2) For safety | $^{3}$H<br>(1) 925 GBq or less<br>(2) Structure to prevent disassembly and removal of glass tube<br>(3) $^{3}$H as oxide: not more than 1% of the glass tube<br>(4) Conforms to ANSI N43.4 or MIL-STD-810F standards<br>(5) Nuclide information, date of manufacture and expiry date | |
| Luminescent materials for aircraft | $^{147}$Pm 3 GBq or less | - | - | - | |
| Military equipment | $^{241}$Am 9.25 MBq or less<br>$^{3}$H 37 GBq or less<br>$^{147}$Pm 3 GBq or less<br>$^{63}$Ni 1 GBq or less | - | - | - | |
| Radiopharmacy | $^{14}$C<br>(1) 37 kBq or less<br>(2) Human diagnostic granule capsules | $^{14}$C (10CFR30.21)<br>(1) 37 kBq or less<br>(2) Human diagnostic granule capsules | - | - | |
| Gauges or indicators (including watches) | No nuclide criteria<br>(1) Contains no nuclides with a generic exemption threshold of less than 100 kBq<br>(2) Radio-luminescent paint contact protection structure<br>(3) Radioactivity per unit product less than or equal to 50 times the generic exemption criteria<br>(4) Surface dose rate 1 μSv/hr or less | (Watch) $^{3}$H<br>(1) Timepiece: 925 MBq<br>(2) Hand: 185 MBq<br>(3) Dial: 555 MBq<br>$^{147}$Pm<br>(1) Watch: 3.7 MBq, 740 kBq (hand), 2.22 MBq (dial)<br>(2) Other timepiece: 7.4 MBq, 1.48 MBq (hand), 4.44 MBq (dial) | - | - | Uranium compounds<br>(1) Total mass of 30 g or less<br>(2) For chemical analysis or preparation purposes<br>Pharmaceuticals, pesticides<br>(1) Use and storage of drugs, pesticides under Article 2 of the Consumer Goods and Drugs Act<br>(2) Use and storage of pesticides under Article 2 of the Power Plant Protection Act |

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**Table 10.** Continued

| Item | Country | | | | |
|---|---|---|---|---|---|
| | Republic of Korea | USA | Australia | Canada | Germany |
| Gauges or indicators (including watches) | - | (3) Not exceeding the following when measured at 50 mg per unit area of the absorber<br>a. Wristwatch: 0.1 mrad/hr at 10 cm<br>b. Pocket watch: 0.1 mrad/hr at 1 cm<br>c. Any other timepiece: at 10 cm 0.2 mrad/hr<br>$^{226}$Ra<br>(1) 0.037 MBq<br>(2) Undamaged watches manufactured before November 30, 2007<br>(Marine instruments) $^{3}$H gas<br>(1) Compass: 27.75 GBq or less<br>(2) Other marine navigational instrument: 9,25 GBq or less 17.12.2007 instruments manufactured in the past | - | - | (3) Use and storage of substances under Article 2, paragraphs 1 through 8 of the Fertilizer Act<br>(4) If the exempt quantity is exceeded, the product is taken back free of charge<br>(5) After use, the user returns the product to the collection organization listed in the information<br>(6) Accompanied by a document describing the radioactive substances contained and indicating the purpose of use, the collection organization and the obligation to take back the product |
| Calibration source | No nuclide criteria<br>(1) Sealed sources meeting the ISO 2919 or ANSI N542-1977<br>(2) 3.7 MBq or less or 10 times the generic exemption criteria | Instruments containing an internal calibration source<br>(1) Contains no more than one source from the general exemption criteria<br>(2) Contains no more than 10 exempt quantities for each instrument<br>(3) For a single nuclide, no more than the exempt quantity<br>(4) For mixtures of several nuclides, the sum of the exemption ratios is 1 or less<br>(5) Am-241 1.85 MBq or less | Educational sources<br>(1) $^{60}$Co 200 kBq or less<br>(2) $^{90}$Sr 80 kBq or less<br>(3) $^{137}$Cs 200 kBq or less<br>(4) $^{226}$Ra 20 kBq or less<br>(5) $^{241}$Am 40 kBq or less | Atomic number 81 or greater and alpha emitting nuclides: 3.7 kBq or less<br>Alpha non-emitting nuclides: 370 kBq or less<br>Complies with ISO 2919 or ANSI N43.6 tests<br>Surface dose rate at 0.1 m distance 1 μSv/hr or less<br>Contact resistant construction<br>Radioactive labelling and precautions | Common exemption criteria<br>(1) The radioactivity of the contained nuclides is 10 times or less than the generic exemption criteria<br>(2) Embedded in a device<br>(3) Contact-resistant construction<br>(4) Surface dose rate 1 μSv/hr or less<br>(5) Designed so that no additional testing is required beyond quality control (Article 24(2)) and leakage testing (Article 25(4)) |
| Electrical and gas appliances | No nuclide criteria<br>(1) Contains no nuclides with a generic exemption threshold of less than 10 kBq | Electron tubes<br>(1) Does not contain more than one of the following specified quantities | No nuclide and quantity criteria<br>(1) A television receiver;<br>(2) A visual display terminal;<br>(3) A cathode ray tube; | - | - |

(*Continued to the next page*)

Table 10. Continued

| Item | Country | | | | |
|---|---|---|---|---|---|
| | Republic of Korea | USA | Australia | Canada | Germany |
| Electrical and gas appliances | (2) Radioactivity per unit product less than or equal to 100 times the generic exemption criteria<br>(3) Surface dose rate 1 μSv/hr or less | a. (Microwave) $^{3}$H 5.55 GBq<br>b. (Other) $^{3}$H 370 MBq<br>c. 37 kBq $^{60}$Co<br>d. 185 kBq $^{63}$Ni<br>e. 1.11 MBq $^{85}$Kr<br>f. 185 kBq $^{137}$Cs<br>g. 1.11 MBq $^{147}$Pm<br>(2) The levels of radiation from each electron tube containing byproduct material do not exceed 1 mrad/hr at 1 cm when measured through 7 mg/cm$^{2}$ of absorber<br>Static elimination devices<br>(1) $^{210}$Po 18.5 MBq or less<br>Ion-generating tubes<br>(1) $^{3}$H 1.85 GBq or less<br>(2) $^{210}$Po 18.5 MBq or less<br>Balances of precision<br>(1) December 17, 2007, and prior manufacturing balances: $^{3}$H 37 MBq or less<br>(2) $^{3}$H 1.85 MBq or less<br>Gas and aerosol detectors<br>(1) No nuclide and quantity criteria<br>Industrial devices containing byproduct materials designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for production of an ionized atmosphere | (4) An electron microscope;<br>(5) Arc welding equipment;<br>(6) Radar equipment used for detection and ranging;<br>(7) Radiofrequency equipment used for communications;<br>(8) An artificial optical source emitting ultraviolet A radiation (315–400 nm);<br>(9) A completely enclosed apparatus containing an ultraviolet radiation light source;<br>(10) A biological safety cabinet with a failsafe interlocking system;<br>(11) A laser product with an accessible emission that does not exceed the accessible emission limits of a Class 3R laser product, as set out in AS/NZS IEC 60825.1:2014;<br>(12) An optical fiber communication system that does not exceed the hazard level 3R, as set out in AS/NZS IEC 60825.2:2011;<br>(13) A klystron;<br>(14) A range finder with power less than 5 mW;<br>(15) An optical light source that:<br>a. emits infra-red or visible light at a level not exceeding the exposure limits mentioned in AS/NZS IEC 62471:2011; and<br>b. is not a laser product | | |
| Electrical and gas appliances | | | Electron-capture detector and similar device used in gas chromatography containing $^{63}$Ni (Sealed) 750 MBq or less<br>(1) $^{3}$H 20 GBq or less<br>Lighting products ($^{85}$Kr) | | |

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Table 10. Continued

| Item | Country | | | | |
|---|---|---|---|---|---|
| | Republic of Korea | USA | Australia | Canada | Germany |
| Others | - | - | $^{222}$Rn occurring naturally in a workplace<br>(1) Less than 1,000 Bq/m$^3$<br>Aircraft and ship counterweights<br>(1) Depleted uranium in solid massive form<br>Geological sample<br>(1) Use of samples for education or display of geologic specimens<br>(2) Surface dose rate 5 μGy/hr or less<br>Common exemption criteria<br>(1) Annual personal effective dose of 10 μSv or less<br>(2) Estimated dose for accident and misuse scenarios is below age-specific thresholds | Equipment with embedded radium luminescent compounds<br>(1) Individuals may possess up to 10<br>(2) No disassembly or modification of the device<br>Deuterium or deuterium-containing compounds<br>(1) Less than 10 kg per year<br>Aircraft counterweights<br>(1) Depleted uranium<br>(2) No chemical and physical treatment or modification<br>(3) Labeling, including manufacturer's name and unique identification number<br>Depleted uranium, natural uranium, natural thorium<br>(1) No more than 10 kg per year<br>(2) Do not use radiation attributes | - |
| | - | - | - | Common exemption criteria<br>(1) Contains nuclides less than 10 times the generic exemption limit<br>(2) Radiation device that is not an exposure device<br>(3) Possess, transfer, import, export, store, use, or dispose | - |
| Prohibitions | - | The incorporation of radionuclides into food, beverages, cosmetics, drugs, toys, or other articles designed for ingestion, inhalation, or use | Intentionally adding radioactive materials to toys, jewelry is not justifiable | - | Toys, jewelry, food, cosmetics, feed, tobacco, non-public incandescent gas mantles, lightning protection systems, food contact materials and articles, tattoo products |

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**Table 10.** Continued

| Item | Country | | | |
|---|---|---|---|---|
| | Japan | France | China | UK |
| Smoke detector | - | - | - | Premises-mounted smoke detectors (use/storage)<br>(1) No nuclide criteria<br>(2) 4 MBq or less per unit product |
| Safety indicator light | - | - | - | - |
| Luminescent materials for aircraft | - | - | - | - |
| Military equipment | - | - | - | - |
| Radiopharmacy | - | - | - | Substances for medical or veterinary diagnosis, treatment, and testing (use/storage, excluding sealed)<br>(1) $^{99m}$Tc 1 GBq<br>(2) 200 MBq or less for all other nuclides<br>(3) 100 MBq or less if contained in radioactive material |
| Gauges or indicators (including watches) | - | - | - | - |
| Calibration source | - | - | - | - |
| Electrical and gas appliances | - | - | - | - |
| Others | Design certification<br>(1) Application by manufacturers and importers of radioisotope equipment and devices<br>(2) Certification of the design of the radiation protection part and conditions for use, transportation and storage of the equipment<br>(3) If certified by a registered certification body (Nuclear Safety and Technology Center), exemption from regulations on the use, storage, etc. of equipment<br>Subject to design certification<br>(1) Devices with a quantity of 1,000 times or less of the lower limit (based on generic exemption)<br>Specific design certification<br>(1) No nuclide and quantity criteria<br>(2) Exemption from regulation of use, storage and transportation | Application for exemption<br>(1) Products containing radionuclides in amounts higher than the generic exemption standard can be exempted from regulation after consultation with various organizations (Minister of Health, Nuclear Safety Agency, Public Health Commission) through an exemption application if justified by the benefits of use<br>(2) Exemption from possession, manufacture, use, distribution, import, and export regulations<br>(3) Radiation sources of categories A, B, and C, highly radioactive sealed sources, radioactive waste as defined in the Environmental Law, and ionizing radiation sources for human use are not exempt from regulation | Apply for a specific exemption<br>A manufacturer or general importer may complete an exemption application for a device containing a specific exempted source<br>Criteria for granting a specific exemption<br>(1) Have a format recognized by the examination management department<br>(2) Effectively prevent contact with and leakage of radioactive material in the form of sealed source<br>(3) Surface dose rate of 1 μSv/hr or less at a distance of 0.1 m from the surface of the equipment under normal operating conditions<br>(4) Clearly stipulate the conditions to be met for disposal | Gaseous $^{3}$H illuminators (use/storage)<br>(1) Class A: 20 GBq or less per unit product<br>(2) Class B: 1 TBq or less per unit product<br>(3) Class C: 1 TBq or less per unit product<br>(4) Class A: 5 TBq or less (total)<br>(5) Class B: 30 TBq or less (total)<br>(6) Class C: No limit (total)<br>Sealed sources containing only $^{3}$H (use/storage)<br>(1) Radioactivity per unit product: 20 GBq or less<br>(2) Total radioactivity: 5 TBq or less<br>Sealed sources (use/storage)<br>(1) Radioactivity per unit product: 4 MBq or less<br>(2) Total radioactivity: 200 MBq or less<br>$^{3}$H foil sources (use/storage)<br>(1) Radioactivity per unit product: 20 GBq or less<br>(2) Total radioactivity: 5 TBq or less |

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Table 10. Continued

| Item | Country | | | |
|---|---|---|---|---|
| | Japan | France | China | UK |
| Others | Subject to specific design certification<br>(1) Smoke detectors'<br>(2) Radar receiver switching discharge tube<br>(3) Contact potential meter and thermoparticulated sensor with a dose equivalent rate of 1 μSv/hr or less at a distance of 10 cm from the surface | Examples of exempted products<br>(1) Cement using a neutron analyzer in the manufacturing process<br>(2) Smoke detectors according to the Decree of November 18, 2011 | | Electron deposition sources (use/storage)<br>(1) $^{63}$Ni 600 MBq or less per unit product<br>(2) $^{55}$Fe 200 MBq or less per unit product<br>(3) 600 GBq or less (total)<br>Unsealed source emitters (use/storage)<br>(1) $^{147}$Pm 80 MBq or less per unit product<br>(2) $^{3}$H 4 GBq or less per unit product<br>(3) $^{147}$Pm 40 GBq or less (total)<br>(4) $^{3}$H 200 GBq or less (total)<br>Sources of $^{137}$Ba (use/storage)<br>(1) Radioactivty per unit product: 40 kBq or less $^{137}$Cs+<br>(2) Total radioactivity: 400 kBq or less $^{137}$Cs+<br>Magnesium alloy and thoriated tungsten products with a thorium concentration of 4 w% or less (use/storage)<br>Uranium and thorium compounds<br>Mass per unit product and total mass: 5 kg |
| Prohibitions | None | None | None | None |

ISO, International Organization for Standardization; OECD, Organisation for Economic Co-operation and Development; ANSI, American National Standards Institute; AS/NZS, Australian Standard/New Zealand Standard; IEC, International Electrotechnical Commission.

contexts [36]. The detailed exemption criteria presented in the regulations are summarized in Table 9.

## Results and Discussion

A comparison of the nine countries' exemption criteria shows that each country has established its own specific exemption standards based mostly on the IAEA criteria but tailored to domestic circumstances. For example, the ROK and the US specify design conditions for specific products and radioactivity criteria for each nuclide contained therein. Japan, France, and China, on the other hand, do not specify products but allow exemptions to be applied for if certain exemption criteria are met. Canada, the UK, Australia, and Germany each have both types of standard, one standard for all nuclides and another for specific products. Of the countries with common standards, all except France and Australia have an exemption for a surface dose rate of 1 μSv/hr or less at a distance of 10 cm. In addition, France, Australia, and Germany have an exemption for an expected dose to an individual of less than 10 μSv/yr, and Australia, Japan, and France have an additional exemption of 1 mSv/yr. Canada and Germany provide a special exemption threshold of 10 times the general exemption threshold, with Germany providing an additional 1,000 times. Countries with exemptions for specific products typically include smoke detectors containing $^{241}$Am, luminescent materials containing $^{3}$H or $^{147}$Pm, radiopharmaceuticals, and calibration sources. The classification by type of specific exemption criteria for each country is shown in Fig. 1. Table 10 summarizes the similarities and differences in specific exemption criteria among the countries examined in this study.

## Conclusion

Currently, the ROK exempts products with radioactive materials above the general exemption limit for specific purposes under the exemption regulations for radioisotopes and nuclear fuel materials, based on IAEA standards. The regulations need to be periodically reviewed, because products' domestic usage status as well as the types of consumer products containing radioisotopes change over time. Therefore, to review the validity of the ROK's current exemption criteria, the present study examined the corresponding criteria of various countries and compared them with the case of the ROK. The specific exemption criteria of the nine countries,

including the ROK, can be broadly categorized as (1) ROK and the US, which provide nuclide-specific exemption criteria for specific products; (2) Japan, France, and China, which provide common criteria for all nuclides without specifying specific products; and (3) Canada, the UK, Australia and Germany, which provide both specific and common criteria. The number of products containing radioisotopes is increasing but, at the same time, there are products that are no longer in use and have been replaced by other products that do not contain radioisotopes. It is therefore necessary to amend the regulations to remove some products that are no longer manufactured and, where appropriate, to create a regulatory regime for new types of products. The specific exemption criteria of the various countries examined in this study are expected to be helpful in revising the ROK's specific exemption criteria. Additionally, the establishment of common criteria together with specific criteria for products requiring special attention may be a good way to determine whether new consumer products containing radioisotopes should be regulated.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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## Ethical Statement

This article does not contain any studies with human participants or animals performed by any of the authors.

## Author Contribution

Conceptualization: Seo H, Lee S. Methodology: Shin J. Formal analysis: Shin J, Bang Y. Funding acquisition: Seo H. Project administration: Park B, Lee J, Kim M. Visualization: Shin J. Writing - original draft: Shin J. Writing - review & editing: Seo H. Approval of final manuscript: all authors.

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