

**IAEA  
SAFETY  
STANDARDS  
SERIES**

**Application of the Concepts of Exclusion,  
Exemption and Clearance**

**DRAFT SAFETY GUIDE**

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*(Front inside cover)*

## IAEA SAFETY RELATED PUBLICATIONS

### IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish standards of safety for protection against ionizing radiation and to provide for the application of these standards to peaceful nuclear activities.

The regulatory related publications by means of which the IAEA establishes safety standards and measures are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (that is, of relevance in two or more of the four areas), and the categories within it are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

**Safety Fundamentals** (blue lettering) present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.

**Safety Requirements** (red lettering) establish the requirements that must be met to ensure safety. These requirements, which are expressed, as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.

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The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA.

Information on the IAEA's safety standards programme (including editions in languages other than English) is available at the IAEA Internet site

<http://www-ns.iaea.org/standards/>

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### OTHER SAFETY RELATED PUBLICATIONS

Under the terms of Articles III and VIII.C of its Statute, the IAEA makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued in other series, in particular the **IAEA Safety Reports Series**, as informational publications. Safety Reports may describe good practices and give practical examples and detailed methods that can be used to meet safety requirements. They do not establish requirements or make recommendations.

Other IAEA Series that include safety related sales publications are the **Technical Reports Series**, the **Radiological Assessment Reports Series** and the **INSAG Series**. The IAEA also issues reports on radiological accidents and other special sales publications. Unpriced safety related publications are issued in the **TECDOC Series**, the **Provisional Safety Standards Series**, the **Training Course Series**, the **IAEA Services Series** and the **Computer Manual Series**, and as **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**.

**DRAFT**

**FOREWORD**  
**by Mohamed ElBaradei**  
**Director General**

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following bodies oversee the development of safety standards: the Commission on Safety Standards (CSS); the Nuclear Safety Standards Committee (NUSSC); the Radiation Safety Standards Committee (RASSC); the Transport Safety Standards Committee (TRANSSC); and the Waste Safety Standards Committee (WASSC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed on a case-by-case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA. Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet

their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

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## EDITORIAL NOTE

*An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.*

*The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.*

*The English version of the text is the authoritative version.*

[For editions in other languages, add on the copyright page a disclaimer for the translation if necessary.]

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## PREFACE

In September 2000, the General Conference of the IAEA requested the Secretariat to develop radiological criteria for long lived radionuclides in commodities, particularly foodstuffs and wood (Resolution GC(44)/RES/15). The Secretariat was requested to accomplish the task by using the Agency's radiation protection advisory mechanisms and in collaboration with the competent organs of the United Nations and the specialized agencies concerned.

The present Safety Guide has been prepared in partial fulfilment of that request and the guidance provided in it can be applied to all commodities other than foodstuffs and drinking water. In order to comply with the request relating to foodstuffs, the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO) has been requested to review its radiological criteria for foodstuffs.

The request contained in the resolution has been addressed by reviewing and expanding on the concepts of exclusion, exemption and clearance as discussed in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS; Safety Series No. 115). The guidance provided in this Safety Guide is fully consistent with the concepts of the BSS and, when the BSS are revised as part of the review and revision process for safety standards, this guidance is expected to be considered for inclusion in the revised BSS.



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# 1. INTRODUCTION

## BACKGROUND

1.1 The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [1] specify requirements for the protection of health against exposure to ionizing radiation (hereinafter termed radiation) and for the safety of radiation sources. The BSS, which are based on information on the detrimental effects attributed to radiation exposure provided by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [2] as well as on the recommendations of the International Commission on Radiological Protection (ICRP) [3], are intended to provide the basis for the regulation of both ‘practices’<sup>1</sup> and ‘interventions’<sup>2</sup>. The presence of national infrastructures for radiation protection is presumed in the BSS. A Safety Requirements publication [4] establishes the requirements for the legal and governmental infrastructure that are necessary to implement the BSS effectively. An essential element of this legal and governmental infrastructure is a national regulatory body that has the authority to establish, or adopt regulations (Ref. [4], para. 2.2). Furthermore, “In order to discharge its main responsibilities, the regulatory body shall establish a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption, or for removal from regulatory control” (Ref. [4], para. 3.3). The BSS [1] establish mechanisms for exclusion, exemption and clearance.

1.2. Humans incur radiation doses from exposure to radionuclides, which can either cause direct irradiation from outside the body or be taken into the body and irradiate it from within. Some radionuclides are primordial and some are created by the continuous interaction of cosmic rays with the atmosphere. Both types are referred to as ‘radionuclides of natural origin’<sup>3</sup> The focus in this Safety Guide for radionuclides of natural origin is on those that are

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<sup>1</sup> A practice is any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

<sup>2</sup> An intervention is any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

<sup>3</sup> The term ‘radionuclides of natural origin’ means radionuclides that occur naturally in significant

primordial. Radionuclides are also produced by artificial means.

1.3. Radionuclides of natural origin are ubiquitous in the environment, although their activity concentrations vary considerably. Uranium and thorium may be extracted from ores containing relatively high concentrations and the BSS clearly consider such extraction as falling under the requirements for practices. However, exposure that is essentially unamenable to control through the requirements of the BSS, such as exposure due to “unmodified concentrations of radionuclides in most raw materials” (Ref. [1], footnote 2) “is deemed to be excluded from the Standards” (Ref. [1], para. 1.4.

1.4. Radionuclides of artificial origin are produced and used within practices. As such, the provisions in Schedule I of the BSS [1] for the exemption of moderate<sup>4</sup> quantities of material and the provisions for clearance given in the BSS may be applied.

1.5. The BSS define the terms and explain the use of the concepts of exclusion, exemption and clearance for establishing the scope of regulatory control. In the case of exclusion, they provide a qualitative description of the concept, leaving much of the interpretation to national regulators. In the case of exemption, the BSS set out the radiological basis for exemption and provide generic exemption levels, which may be used by national regulators for determining which sources or practices may be exempted from regulatory control. However, it is acknowledged in the BSS that the exemption levels apply only to ‘moderate’ amounts of material and that for larger amounts additional consideration is necessary. In the case of clearance, the BSS define the concept and the radiological criteria to be used as a basis for determining clearance levels but leave the establishment of clearance levels to national authorities.

## OBJECTIVE

1.6 The objective of this Safety Guide is to provide guidance to national authorities, including regulatory bodies, and operating organizations on the application of the concepts of

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quantities on Earth. The term is usually used to refer to the primordial radionuclides potassium-40, uranium-235, uranium-238 and thorium-232 (the decay product of primordial uranium-236) and their radioactive decay products, but could also include tritium and carbon-14, low concentrations of which are generated by natural activation processes.

<sup>4</sup> The term moderate quantities means quantities that “are at most of the order of a tonne” of material [5]. Anything greater than this amount is considered bulk quantities.

exclusion, exemption and clearance<sup>5</sup> as established in the BSS [1]. The Safety Guide includes specific values of activity concentration for both radionuclides of natural origin and those of artificial origin that may be used for bulk amounts of material for the purpose of applying exclusion or exemption. It also elaborates on the possible application of these values to clearance.

## SCOPE

1.7. The values of activity concentration provided in this Safety Guide can be used in the practical application of the concepts of exclusion, exemption and clearance as established in the BSS. Exclusion relates to exposures that are essentially unamenable to control and this publication provides regulatory bodies with quantitative guidance on the application of this concept to exposures from naturally occurring radioactive material. Exemption means exemption from the requirements for practices as outlined in the BSS. Clearance is similar to exemption, but relates specifically to the removal of radioactive material within authorized practices from any further control by the regulatory body. Bulk amounts of material may be involved in clearance and for this reason regulatory bodies may wish to adopt more stringent values of activity concentration than those given in Schedule I of the BSS, which apply only for the exemption of moderate quantities of material. This Safety Guide provides values of activity concentration that may be used by regulatory bodies for determining when controls over bulk amounts of material are not required or are no longer necessary.

1.8. The values of activity concentration provided in this Safety Guide do not apply to the following:

- foodstuffs, drinking water, animal feed and any material intended for use in food or animal feed; specific levels for drinking water are provided in Ref. [6] and specific levels for foodstuffs (applicable for up to one year after an accident) are given in Ref. [7];

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<sup>5</sup> 'Exclusion' means the deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control on the grounds that it is not considered amenable to control through the regulatory instrument in question. Such exposure is termed excluded exposure. 'Exemption' means the determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure (including potential exposure) due to the source or practice is too small to warrant the application of those aspects. 'Clearance' means the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body. Removal from control in this context refers to control applied for radiation protection purposes.

- radon in air, as action levels for the concentration of radon in air are provided in the BSS [1];
- potassium-40 in the body, which is excluded from the BSS;
- material in transport in accordance with the IAEA Transport Regulations [8].

1.9. The values of activity concentration provided in this publication are not intended to be applied to the control of radioactive discharges of liquid and airborne effluents from authorized practices, or to radioactive residues in the environment. Guidance on the authorization of discharges of liquid and airborne effluents and the reuse of contaminated land is provided in Refs [9, 10].

## STRUCTURE

1.10. Section 2 describes the concepts given in the BSS. Section 3 presents the basis for deriving the values of activity concentration, and is supported by a Safety Report [11] describing the methods used in the derivations. Section 4 provides the values of activity concentration. Section 5 provides guidance on the application of the values of activity concentration.

## 2. THE CONCEPTS

### GENERAL

2.1. In this section, the concepts of exclusion, exemption and clearance from the International Basic Safety Standards (BSS) are explained and elaborated to provide a basis for establishing more extensive quantitative guidance than is provided in the BSS.

2.2. The BSS [1] establish the requirements for protection against the risks associated with radiation exposure. The BSS cover both practices and interventions and present the concepts of exclusion, exemption and clearance. These concepts and the relations between them are briefly presented here.

### EXCLUSION

2.3. The BSS state that “Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards is deemed to be excluded from the Standards” (Ref. [1], para. 1.4).

2.4. Examples of excluded exposure given in the BSS are: “exposure from  $^{40}\text{K}$  in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials” (Ref. [1], footnote 2). All of these examples are of exposure to natural sources of radiation although there is no explicit requirement to limit the concept to such exposure.

2.5. From paras 2.3 and 2.4 above, it is apparent that the BSS guidance in relation to the exclusion of exposures is limited to qualitative statements. In the following sections, the basis for elaborating the guidance into a quantitative form for materials is explained.

### EXEMPTION

2.6. The BSS use the concept of exemption only within the context of practices and sources within practices. Exemption determines a priori which practices and sources within practices may be freed from the requirements for practices on the basis of their meeting certain criteria. In essence, exemption may be considered a generic authorization granted by the regulatory body which, once issued, releases the practice or source from the requirements

that would otherwise apply; in particular, the requirements relating to notification and authorization.

2.7. Consideration should be given, in the context of granting exemptions, to the requirement of the BSS for practices and sources to be justified. “No practice or source within a practice should be authorized unless the practice produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause; that is: unless the practice is justified, taking into account social, economic and other relevant factors” (Ref. [1], para. 2.20). Practices deemed not to be justified include those involving the deliberate addition of radioactive substances to food and beverages, for instance, or those involving the frivolous use of radiation or radioactive substances in commodities or products such as toys and jewellery or personal adornments (Ref. [1], para. 2.22).

2.8. Exemption may be granted if the regulatory body is satisfied that the justified practices or sources within practices meet the exemption principles and criteria specified in Schedule I of the BSS, the exemption levels specified in Schedule I of the BSS or other exemption levels as specified by the regulatory body on the basis of the exemption criteria specified in Schedule I of the BSS. The criteria for exemption are that “(a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10  $\mu$ Sv or less in a year, and (b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man Sv or an assessment for the optimization of protection shows that exemption is the optimum option” (Ref. [1], para. I-3).

2.9. The activity concentrations and total quantities of radionuclides specified in Schedule I of the BSS were derived by establishing a set of representative exposure scenarios and determining the activity concentrations and total activities that would give rise to doses to appropriate critical groups that correspond to the dose criteria for the exemption of practices set out in Schedule I of the BSS, modified to take account of low probability exposure events, as described in Ref. [5] and in para. 3.4 of this publication. These derived radionuclide specific values were based on calculations in which only moderate quantities of material were assumed to be present. A footnote to Schedule I of the BSS indicates that “exemption for bulk amounts of materials with activity concentrations lower than the guidance exemption levels of Table I-I may nevertheless require further consideration by the [regulatory body]” (Ref. [1], footnote 36).



2.10. Thus the quantitative guidance given in the BSS for exemption levels is limited to “moderate quantities” of material; that is, amounts of “at most of the order of a tonne” [5]. There are situations for which the exemption of considerably greater amounts than one tonne of material may be appropriate and the quantitative guidance provided in the BSS may not be suitable for these situations. The approach adopted for providing this additional guidance is described in the following sections.

2.11. The concept of exemption may be applied to radionuclides of both natural and artificial origin.

## CLEARANCE

2.12. While exemption is used as part of a process to determine the nature and extent of application of the system of regulatory control, clearance is intended to establish which material under regulatory control can be removed from this control. As with exemption, a clearance may be granted by the regulatory body for the release of material from a practice.

2.13. Clearance is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body. Furthermore, the BSS state that clearance levels “shall take account of the exemption criteria specified in Schedule I and shall not be higher than the exemption levels specified in Schedule I or defined by the Regulatory Authority” (Ref. [1], para. 2.19). A footnote indicates that “Clearance of bulk amounts of materials with activity concentrations lower than the guidance exemption levels specified in Table I-I of Schedule I may require further consideration by the Regulatory Authority” (Ref. [1], footnote 8).

2.14. In summary, the BSS provide radiological criteria to serve as a basis for the derivation of clearance levels but provide no definitive quantitative guidance on clearance levels. The activity concentration values developed in the following section for use in decisions on the exemption of bulk materials may find use by regulatory bodies as a basis for the clearance of such materials.

### 3. BASIS FOR DERIVATION OF ACTIVITY CONCENTRATION VALUES

3.1. Two different approaches were used to establish the values of activity concentration for use in defining exclusion, exemption or clearance provided in this publication. The first approach makes use of the concept of exclusion to derive values of activity concentration suitable for radionuclides of natural origin. The second makes use of the concept of exemption in order to derive values of activity concentration for radionuclides of artificial origin<sup>6</sup>. This strategy is a simplification of, but is consistent with, the approach described in the BSS, and it facilitates the development of a single set of values of activity concentration covering all radionuclides. A full discussion of the methods used is given in the supporting Safety Report [11].

#### EXCLUSION

3.2. Exclusion, as described in the BSS, relates to the amenability of exposure to regulatory control rather than to the actual magnitudes of exposures. Amenability to control is a relative concept; it is a matter of practicability and implies recognition of the cost of exercising regulatory control and the net benefit to be gained by so doing. The examples of excluded types of exposure given in the BSS include exposure from “unmodified concentrations of radionuclides in most raw materials” (Ref. [1], footnote 2). The reference to unmodified concentrations points to the fact that the processing of some raw materials, which may have typical concentrations of radionuclides of natural origin, may give rise to products or to wastes that have higher concentrations of radionuclides or give rise to exposures that should not be excluded from regulatory control. The reference to exposure from most raw materials suggests that exposure from some raw materials should not be subject to exclusion. Thus, whichever the cause of the exposure — whether it results from the modification of the chemical or physical form of the material, thus enhancing its radionuclide content in processing, or is simply because the material inherently has a relatively high radionuclide

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<sup>6</sup> It should be noted that the relationships used in this section between exclusion and radionuclides of natural origin, and between exemption and radionuclides of artificial origin, are made for the purpose of deriving radionuclide concentration levels. For instance, exposures from some radionuclides of artificial origin, such as fallout from the testing of nuclear weapons, may be excluded by the regulatory body. Similarly, some material contaminated by radionuclides of natural origin, if used within a practice, may be a candidate for exemption or clearance, as appropriate.

content — the regulatory body should recognize that there are some exposure situations that warrant consideration and control (e.g., exposure situations in industries in which material containing radionuclides of natural origin is handled or used for which exposure is attributable to its processing). Guidance on occupational exposure that might result from the handling or use of such material is provided in a Safety Guide [12].

3.3. The values of activity concentration for radionuclides of natural origin set out in Table I have been selected on the basis of consideration of the upper end of the worldwide distribution of activity concentrations in soil provided by UNSCEAR [2]. Doses to individuals as a consequence of these activity concentrations would be unlikely to exceed about 1 mSv in a year, excluding the contribution from the emanation of radon, which is dealt with separately in the BSS. .

#### EXEMPTION AND CLEARANCE

3.4. The primary radiological basis for establishing values of activity concentration for the exemption of bulk amounts of material and for clearance is that the effective doses to individuals should be of the order of 10 $\mu$ Sv or less in a year. To take account of the occurrence of low probability events leading to higher radiation exposures, an additional criterion was used; namely, that the effective doses due to such low probability events should not exceed 1 mSv in a year. In this case, consideration was also given to doses to the skin; an equivalent dose criterion of 50 mSv in a year to the skin was used for this purpose. This approach is consistent with that used in establishing the values for exemption provided in Schedule I of the BSS (see Ref. [1]).

3.5. The second radiological criterion for exemption set out in Schedule I of the BSS concerns the collective effective doses associated with a practice (see para. 2.8 of this Safety Guide). The collective effective doses likely to be associated with the exemption and clearance of materials have been evaluated in a number of studies [5, 13]. It has generally been concluded that the individual dose criterion will almost always be limiting and that the collective effective dose commitments from one year of the practice will usually be well below 1man Sv.

3.6. Many studies undertaken at the national or international levels have derived radionuclide specific levels for the exemption and clearance of solid material [13–19]. The values of activity concentration presented in this Safety Guide draw on the extensive

experience gained in undertaking these studies and on independent calculations performed under the auspices of the Agency [11]. The calculations are based on the evaluation of a selected set of typical exposure scenarios for all material, encompassing external irradiation, dust inhalation and ingestion (direct and indirect). The values selected were the lowest values obtained from the scenarios. Foodstuff and drinking water pathways of intake were taken into account to consider the radiological consequences as appropriate, but values for exempting these items have not been developed in this Safety Guide.

3.7. For a number of short lived radionuclides, the calculations [11] lead to levels that are higher than the exemption levels given in the BSS. This is due to the fact that the scenarios used to develop the values relate to the transport, trade, use or deposition of materials outside the facilities in which they arise (e.g. reactors, accelerators and laboratories), and account was taken of the lapse of time there would be before the beginning of the exposure. In the models on which the exemption levels are based, the direct handling of the material within these facilities is considered, and consequently they do not allow for any radioactive decay of the radionuclides before the exposure begins. For these radionuclides, the values chosen were the exemption levels of Schedule I of the BSS [1].

## 4. VALUES OF ACTIVITY CONCENTRATION

4.1. This section provides the values of activity concentration that may be used, with account taken of a graded approach (see paras 5.11–5.13), for exclusion, exemption and clearance pertaining to exposures from radionuclides of natural origin and bulk amounts of material containing radionuclides of artificial origin. The details of the calculations that yielded these values are provided in a Safety Report [11].

### RADIONUCLIDES OF NATURAL ORIGIN

4.2. The values of activity concentration for radionuclides of natural origin derived using the exclusion concept (paras 3.2–3.3) are given in Table I.

TABLE I. VALUES OF ACTIVITY CONCENTRATIONS FOR RADIONUCLIDES OF NATURAL ORIGIN (see para. 4.2)

Radionuclide	Activity concentration (Bq/g)
$^{40}\text{K}$	10
All other radionuclides of natural origin	1

4.3. The values have been determined on the basis of consideration of the worldwide distribution of radioactivity concentrations for these radionuclides. Consequently, they are valid for the natural decay chains in secular equilibrium; that is, those decay chains headed by  $^{238}\text{U}$ ,  $^{235}\text{U}$  or  $^{232}\text{Th}$ , with the value given to be applied to the parent of the decay chain. The values can also be used individually for each decay product in the chains or for the head of subsets of the chains, such as the subset with  $^{226}\text{Ra}$  as its parent.

### RADIONUCLIDES OF ARTIFICIAL ORIGIN

4.4. The values of activity concentration for bulk amounts of material containing radionuclides of artificial origin, derived using the exemption concept (paras 3.43.7), are given in Table II.

4.5. For noble gases, the exemption levels provided in Schedule I of the BSS [1] should be used. Further discussion is provided in Ref. [11].

TABLE II. VALUES OF ACTIVITY CONCENTRATION FOR RADIONUCLIDES OF ARTIFICIAL ORIGIN IN BULK AMOUNTS (see para. 4.4.)

Radionuclide	Activity concentration (Bq/g)		Radionuclide	Activity concentration (Bq/g)		Radionuclide	Activity concentration (Bq/g)	
H-3	100		As-74	10	*	Cd-115m	100	
Be-7	10		As-76	10	*	In-111	10	
C-14	1		As-77	1000		In-113m	100	*
F-18	10	*	Se-75	1		In-114m	10	
Na-22	0.1		Br-82	1		In-115m	100	*
Na-24	1	*	Rb-86	100		Sn-113	1	
Si-31	1000	*	Sr-85	1		Sn-125	10	
P-32	1000		Sr-85m	100	*	Sb-122	10	
P-33	1000		Sr-87m	100	*	Sb-124	1	
S-35	100		Sr-89	1000		Sb-125	0.1	
Cl-36	1		Sr-90	1		Te-123m	1	
Cl-38	10	*	Sr-91	10	*	Te-125m	1000	
K-42	100		Sr-92	10	*	Te-127	1000	
K-43	10	*	Y-90	1000		Te-127m	10	
Ca-45	100		Y-91	100		Te-129	100	*
Ca-47	10		Y-91m	100	*	Te-129m	10	
Sc-46	0.1		Y-92	100	*	Te-131	100	*
Sc-47	100		Y-93	100	*	Te-131m	10	
Sc-48	1		Zr-93	10	*	Te-132	1	
V-48	1		Zr-95	1		Te-133	10	*
Cr-51	100		Zr-97	10	*	Te-133m	10	*
Mn-51	10	*	Nb-93m	10		Te-134	10	*
Mn-52	1		Nb-94	0.1		I-123	100	
Mn-52m	10	*	Nb-95	1		I-125	100	
Mn-53	100		Nb-97	10	*	I-126	10	
Mn-54	0.1		Nb-98	10	*	I-129	0.01	
Mn-56	10	*	Mo-90	10	*	I-130	10	*
Fe-52	10	*	Mo-93	10		I-131	10	
Fe-55	1000		Mo-99	10		I-132	10	*
Fe-59	1		Mo-101	10	*	I-133	10	*
Co-55	10	*	Tc-96	1		I-134	10	*
Co-56	0.1		Tc-96m	1000	*	I-135	10	*
Co-57	1		Tc-97	10		Cs-129	10	
Co-58	1		Tc-97m	100		Cs-131	1000	
Co-58m	10000	*	Tc-99	1		Cs-132	10	
Co-60	0.1		Tc-99m	100	*	Cs-134	0.1	
Co-60m	1000	*	Ru-97	10		Cs-134m	1000	*
Co-61	100	*	Ru-103	1		Cs-135	100	
Co-62m	10	*	Ru-105	10	*	Cs-136	1	
Ni-59	100		Ru-106	0.1		Cs-137	0.1	
Ni-63	100		Rh-103m	10000	*	Cs-138	10	*
Ni-65	10	*	Rh-105	100		Ba-131	10	
Cu-64	100	*	Pd-103	1000		Ba-140	1	
Zn-65	0.1		Pd-109	100		La-140	1	
Zn-69	1000	*	Ag-105	1		Ce-139	1	
Zn-69m	10	*	Ag-110m	0.1		Ce-141	100	
Ga-72	10	*	Ag-111	100		Ce-143	10	
Ge-71	10000		Cd-109	1		Ce-144	10	
As-73	1000		Cd-115	10		Pr-142	100	*

Radionuclide	Activity concentration (Bq/g)	
Pr-143	1000	
Nd-147	100	
Nd-149	100	*
Pm-147	1000	
Pm-149	1000	
Sm-151	1000	
Sm-153	100	
Eu-152	0.1	
Eu-152m	100	*
Eu-154	0.1	
Eu-155	1	
Gd-153	10	
Gd-159	100	*
Tb-160	1	
Dy-165	1000	*
Dy-166	100	
Ho-166	100	
Er-169	1000	
Er-171	100	*
Tm-170	100	
Tm-171	1000	
Yb-175	100	
Lu-177	100	
Hf-181	1	
Ta-182	0.1	
W-181	10	
W-185	1000	
W-187	10	
Re-186	1000	
Re-188	100	*
Os-185	1	
Os-191	100	
Os-191m	1000	*
Os-193	100	
Ir-190	1	
Ir-192	1	
Ir-194	100	*
Pt-191	10	

Radionuclide	Activity concentration (Bq/g)	
Pt-193m	1000	
Pt-197	1000	*
Pt-197m	100	*
Au-198	10	
Au-199	100	
Hg-197	100	
Hg-197m	100	
Hg-203	10	
Tl-200	10	
Tl-201	100	
Tl-202	10	
Tl-204	1	
Pb-203	10	
Bi-206	1	
Bi-207	0.1	
Po-203	10	*
Po-205	10	*
Po-207	10	*
At-211	1000	
Ra-225	10	
Ra-227	100	
Th-226	1000	
Th-229	0.1	
Pa-230	10	
Pa-233	10	
U-230	10	
U-231	100	
U-232	0.1	
U-233	1	
U-236	10	
U-237	100	
U-239	100	*
U-240	100	*
Np-237	1	
Np-239	100	
Np-240	10	*
Pu-234	100	*
Pu-235	100	*

Radionuclide	Activity concentration (Bq/g)	
Pu-236	1	
Pu-237	100	
Pu-238	0.1	
Pu-239	0.1	
Pu-240	0.1	
Pu-241	10	
Pu-242	0.1	
Pu-243	1000	*
Pu-244	0.1	
Am-241	0.1	
Am-242	1000	*
Am-242m	0.1	
Am-243	0.1	
Cm-242	10	
Cm-243	1	
Cm-244	1	
Cm-245	0.1	
Cm-246	0.1	
Cm-247	0.1	
Cm-248	0.1	
Bk-249	100	
Cf-246	1000	
Cf-248	1	
Cf-249	0.1	
Cf-250	1	
Cf-251	0.1	
Cf-252	1	
Cf-253	100	
Cf-254	1	
Es-253	100	
Es-254	0.1	
Es-254m	10	
Fm-254	10000	*
Fm-255	100	*

\* Half-life of less than 1 day.

## MIXTURES OF RADIONUCLIDES

4.6. For mixtures of radionuclides of natural origin, the concentration of each radionuclide should be less than the relevant value of the activity concentration given in Table I.

4.7. For material containing a mixture of radionuclides of artificial origin, the following formula should be used:

$$\sum_{i=1}^n \frac{C_i}{(\text{Activity concentration})_i} \leq 1$$

where  $C_i$  is the concentration (Bq/g) of the  $i^{\text{th}}$  radionuclide of artificial origin in the material,  $(\text{Activity concentration})_i$  is the value of activity concentration for the radionuclide  $i$  in the material and  $n$  is the number of radionuclides present.

4.8. For a mixture of radionuclides of both natural and artificial origin, both conditions presented in paras 4.6 and 4.7 should be satisfied.



## 5. APPLICATION OF THE VALUES

### RADIONUCLIDES OF NATURAL ORIGIN

5.1. It is usually unnecessary to regulate radioactive material in activity concentrations below the values given in Table I. However, there are some situations (such as the use of some building materials containing natural radionuclides) for which exposures from materials due to radionuclides with activity concentrations below those given in Table I would necessitate consideration by the regulatory body for some types of regulatory control. Regulatory bodies should retain the authority to investigate such situations and to take whatever action is considered necessary.

5.2. If the activity concentration of the radionuclide exceeds the value of activity concentration given in Table I, the regulatory body should decide on the extent to which the regulatory requirements set out in the BSS [1] should be applied. A graded approach as described in paras 5.11–5.13 may be applied.

5.3. In addition, the values of activity concentration in Table I may be used to determine whether material within a practice can be released from regulatory control.

5.4. The way in which these values should be incorporated into national regulatory requirements will depend on the particular regulatory approach adopted. One approach may be to use these levels in the definition of the scope of the regulations. Another approach may be to use the levels to define radioactive material for the purposes of the regulations.

### RADIONUCLIDES OF ARTIFICIAL ORIGIN

5.5. In this Safety Guide, the concepts of exemption and clearance have been applied to bulk amounts of material containing radionuclides of artificial origin. These concepts relate specifically to practices that are considered by the regulatory body to be justified<sup>7</sup>. If the activity concentrations of radionuclides in materials are below the values of activity

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<sup>7</sup> It should be noted that the justification principle applies to a practice as a whole and not separately to its component parts, such as the disposal of waste. This means that material that is contaminated as a consequence of a practice is disposed of as a matter of optimization of protection, rather than justification. One of the purposes for which the activity concentrations have been established is to permit material in bulk quantities to be 'exempted' or 'cleared' from a justified practice without further consideration.

concentration given in Table II, the handling and use of the material may be considered exempt from the regulatory requirements for practices.

5.6. The BSS, in Schedule I (Ref. [1], para. I-6), indicate that radioactive material from an authorized practice or source whose release to the environment has been authorized are exempted from any new requirements of notification, registration or licensing unless otherwise specified by the regulatory body. Since exemption and clearance are in essence generic authorizations, this provision of the BSS means that 'exempted' or 'cleared' material should be allowed to be used without any further restriction; that is, material that has been exempted or cleared should not re-enter the system of protection for practices, unless the regulatory body specifically requires that it do so.

5.7. The way in which these levels should be incorporated into national regulatory requirements will depend on the particular regulatory approach adopted. Either of the approaches proposed in para. 5.4 for radionuclides of natural origin may be used. The approach does not necessarily have to be the same for radionuclides of natural origin and those of artificial origin. It is noted that many regulatory bodies have adopted the exemption levels of activity concentration given in Schedule I of the BSS [1] into their national requirements. Where that is the case, one possibility would be to express the values in a specific regulatory instrument in which the requirements relating to the exemption and clearance of materials in bulk amounts are given.

## TRADE

5.8. If the values of activity concentration provided in this Safety Guide are used as indicated above, there should be no need for any further action (e.g. to reduce exposures) for materials containing radionuclides at activity concentrations below these values. In particular, national and international trade in commodities containing radionuclides with activity concentrations below the values of activity concentration provided in Tables I and II should not be subject to regulatory control for the purposes of radiation protection.

5.9. Confirmation that the activity concentration values given in Tables I and II should be determined at the first point of entry into trade<sup>8</sup>. This does not imply the need for systematic

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<sup>8</sup> Trade necessarily involves the transport of material. However, activity concentrations for material in transport are established in the IAEA Transport Regulations [8] and not in this Safety Guide.

monitoring of materials, but authorities in exporting States should ensure that systems are in place to prevent unrestricted trade in material with higher activity concentrations. In general, it should not be necessary for each importing State to set up its own routine measurement programme solely for the purpose of monitoring commodities, particularly if there is confidence in the controls exercised by the exporting State.

5.10. In cases where there are reasonable grounds for believing that the values of activity concentration may be exceeded, the regulatory bodies concerned should co-ordinate their activities and share their concerns about matters relating to radiation protection) to facilitate the movement of materials. In general, to avoid unnecessary hindrances to trade at boundary transfer points, States should co-ordinate their regulatory strategies and their implementation, including monitoring programmes for commodities, with neighbouring States. Arrangements should be made to determine the actual activity concentrations in materials either by obtaining the information from their supplier or by measurement organized by the regulatory body. Any measurements should be made by appropriate techniques and with equipment capable of measuring activity concentrations at the values specified.

#### GRADED APPROACH

5.11. A graded approach consistent with the optimization principle can be taken when activity concentrations exceed the values given in Tables I and II of this Safety Guide. Such an approach "...shall be commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures and shall also conform to any requirements specified by the [regulatory body] or, whenever applicable, by the relevant Sponsoring Organizations [of the BSS]" (Ref. [1], para. 2.8).

5.12. For activity concentrations that exceed the relevant values in Table I or Table II by several times (e.g., up to 10 times), the regulatory body may decide (where the national regulatory framework so allows) that the optimum regulatory option is not to apply regulatory requirements to the legal person responsible for the material. The mechanism for giving effect to such a decision will depend on the nature of the national regulatory infrastructure. In many cases, a decision will be made by the regulatory body on a case –by case basis, following notification, and will take the form of exemption. In some cases, the regulatory body may specify that exposure arising from certain human activities involving activity concentrations of this magnitude need not be regulated.

5.13. Where the regulatory body has determined that regulatory controls do apply, the stringency of the regulatory measures should be commensurate with the level of risk associated with the material. When the human activities involving the material are considered to constitute a practice, the regulatory measures that are applied should be consistent with the requirements for practices established in the BSS [1, Section 2]. The minimum requirement is that such practices must be notified to the regulatory body. For some practices involving low or moderate risks, registration as defined in the BSS may be sufficient. Other practices may need to be licensed, with the stringency of the licence conditions reflecting the level of the risk.

#### VERIFICATION OF THE VALUES

5.14. It should be recognized that the values of activity concentration given in Table II were derived for large quantities of homogeneous material and averaging should be done with this taken into account. Averaging procedures should be an integral part of the verification scheme and they need to be selected according to the type of material. Consideration should also be given to areas of concentrated activity on or near the surfaces of materials. The IAEA is preparing guidance on these aspects.

5.15. Verification of the values should be based on a procedure that may include direct measurements on the material, laboratory measurements on representative samples, the use of properly derived radionuclide relationships, adequate traceability of material, including its origin, or other means that are acceptable to the regulatory body by prior approval or on application.

5.16. Depending on the radionuclides present, it may be necessary to supplement direct measurements made on the material with a laboratory analysis of suitably selected samples.

5.17. In deciding on a measurement strategy, the following steps should be considered:

- to group the material under consideration so that it is as homogeneous as possible in relation to both material and origin (and thus radionuclide spectrum and activity level);
- to assess the radionuclide spectrum for the material under consideration by the analysis of samples, account being taken of all pertinent information about the operational history of the material.

5.18. On the basis of this information, the measurement method can be selected and suitable instruments can be chosen and appropriately calibrated.

#### DILUTION

5.19. Deliberate dilution of material, as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration, to meet the values of activity concentration given in Section 4 should not be permitted without the prior approval of the regulatory body.

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