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IAEA SAFETY STANDARDS SERIES

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Radioactivity in Material not requiring Regulation for Purposes of Radiation Protection

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INTERNATIONAL ATOMIC ENERGY AGENCY VIENNA

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

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OTHER SAFETY RELATED PUBLICATIONS

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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**.

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 for 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 fulfill 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 fulfill all of their international obligations effectively.

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.]

CONTENTS

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 the basic international requirements for protection of health against exposure to ionizing radiation (hereinafter termed radiation), and for the safety of radiation sources (including their security). The BSS are based on the estimates of the detrimental effects attributed to radiation exposure provided by the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) [2], as well as on recommendations of the International Commission on Radiological Protection (ICRP) [3] and are intended to provide the basis for the regulation of both '*practices*'[1] and '*interventions*'[2]. The BSS presume the existence of a national infrastructure for radiation safety and a complementary document [4] establishes the basic requirements for the legal and governmental infrastructure that is necessary in order to implement the BSS effectively. An essential component of this infrastructure is the existence of a competent national regulatory body that has the authority to establish regulations. Such regulations shall, inter alia, define the scope of situations to be regulated for purposes of radiation protection. There should also be provision for notification and authorization of practices and sources within practices, and for exemption from the requirements for practices, subject to the criteria defined in the BSS.

1.2. Humans incur radiation doses from exposure to radionuclides, which can cause either direct irradiation from outside the body or be taken into the body and irradiate from within. Some radionuclides are primordial or are created by the continuous interaction of cosmic rays with the atmosphere, and they are usually referred to as 'naturally occurring[3]'. Others have been produced by artificial means.

1.3. Naturally occurring radionuclides are ubiquitous in the environment, although their activity concentrations vary considerably. Uranium or thorium may be extracted from ores containing relatively high concentrations and, where this is done, the BSS clearly regard the

[1] A practice is defined as 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.
[2] An intervention is defined as 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.
[3] The term naturally occurring radionuclides is defined as those radionuclides that occur in significant quantities on Earth and usually refer to ^{40}K, ^{235}U, ^{238}U, ^{232}Th and their radioactive decay products.

situations as falling under the requirements for practices. The position regarding ores and other materials with above average concentrations of the naturally occurring radionuclides in the Earth's crust is however undefined.

1.4. Radionuclides of artificial origin are produced and used within practices. As such, the provisions for exemption and clearance given in the BSS apply. In addition, many of these radionuclides are widely spread in the environment as a result of, for instance, fallout from the testing of nuclear weapons in the atmosphere and from routine or accidental releases from past and current practices.

1.5. As a result of the widespread presence of radionuclides in the environment, a certain amount of radioactivity, of natural or artificial origin, is always present in material[4], (including goods, merchandises, consumer products, buildings, soil and, in general, in any *'commodity'*[5]). Not everything that contains radioactivity should therefore need to be regulated. The specification of the radionuclide content in material requiring regulation for purposes of radiation protection is essential for defining the scope of the relevant regulations, the implication being that material containing an amount of radioactivity higher than a prescribed level will require regulation. There are however, different approaches that can be used to determine the scope of application of regulations, very often determined by already established national practices.

OBJECTIVE

1.6. The objective of this Safety Guide is to provide guidance to national authorities, including regulatory bodies, and operating organizations on specific levels of activity concentrations for both naturally occurring radionuclides and those of artificial origin below which regulation of the material for the purposes of radiation protection in accordance with the BSS should not be required, irrespective of the amounts involved. These activity concentrations of radionuclides in material may be derived using different methodological approaches, in the case of naturally occurring radionuclides, from the concept of exclusion, and in the case of radionuclides of artificial origin, from the concepts of exemption and clearance. For this reason, the use of a generic label for these activity concentrations will be

[4] The term material is defined as the matter from which a thing is made, the elements or constitute parts of a substance.

[5] Commodities are any article or raw material. that can be bought or sold.

avoided. Guidance is also provided on how these levels should be applied in a regulatory context.

SCOPE

1.7. The activity concentrations developed in this document apply to all material including those materials with elevated levels as a consequence of technological processing (also see paragraph 3.2. of this Guide).

1.8. The activity concentrations developed in this Guide are a practical application of the concepts of exclusion, exemption and clearance established in the BSS. Exclusion is, by definition, outside the scope of the Standards and this Guide provides quantitative guidance on the provision for this in the BSS. Exemption is from the requirements for practices of the BSS. Clearance is similar to exemption, but specifically relates to the removal of radioactive material within authorized practices from any further control by the regulatory body. Bulk quantities may be involved in clearance and for this reason regulatory bodies may wish to adopt more stringent activity concentration levels than those given in the BSS for exemption. This Guide provides activity concentrations that may be used by regulatory bodies for determining when controls over bulk quantities of material that are part of authorized practices are not required.

1.9. The activity concentrations in this document do not apply to:

- foodstuffs, drinking water, animal feed and any material intended for use in food or animal feed. Specific levels for drinking water are contained in [5] and specific levels for foodstuffs (applicable up to one year after an accident) are found in [6];
- radon, as action levels are provided in the BSS; and
- potassium-40 in the body, which is already excluded from the BSS.

1.10. It is not within the scope of this Safety Guide to calculate activity concentration levels for radionuclide concentrations for foodstuffs and drinking water. However, the activity concentration levels for radionuclides of artificial origin were based on a set of typical exposure scenarios for all material causing external irradiation as well as inhalation and ingestion of radioactive material, including foodstuff and drinking water exposure pathways. It should be emphasized that the ingestion of foodstuffs and drinking water used in the

derivation of nuclide-specific levels for all material does not have any relation to activity concentration levels already specified for foodstuffs and drinking water.

1.11. The activity concentration levels in this document 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 authorization of liquid and airborne effluents discharges and reuse of contaminated land is provided elsewhere [7][8].

STRUCTURE

1.12. The Safety Guide is structured as follows: Section 2 describes the conceptual approach used to derive the activity concentrations based on the concepts given in the BSS. Section 3 presents the basis for deriving the levels, and is supported by a Safety Report XXX [9] describing the methodology used. Section 4 provides the activity concentration levels. Section 5 provides guidance on the application of the activity concentrations to practices and Section 6 provides guidance application to trade. Section 7 describes how to account for mixtures of radionuclides and Section 8 provides guidance on averaging procedures. Section 9 identifies concerns with the intentional dilution of material.

2. THE CONCEPTUAL APPROACH

GENERAL

2.1. In this section, the conceptual approach for establishing a set of activity concentrations above which regulatory control for purposes of radiation protection might be needed and below which regulatory control would not be needed is discussed.

2.2. The International Commission on Radiological Protection (ICRP) has recognized the importance of limiting the scope of the system of radiological protection. The ICRP [3] has stated that "*everyone in the world is exposed to radiation from natural and artificial sources … any realistic system of radiological protection must therefore have a clearly defined scope if it is not to apply to the whole of mankind activities"*.

2.3. The International Basic Safety Standards (BSS) [1] establish the requirements for protection against the risks associated with radiation exposure. The BSS covers both practice and intervention situations and includes the concepts of *exclusion, exemption* and *clearance*. These concepts and the relation between them are briefly presented below.

EXCLUSION

2.4. The BSS glossary defines "excluded" as "*outside the scope of the standards"*. The BSS expands on this by stating "*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*." [1, para. 1.4.]

2.5. Examples of excluded exposures given in the BSS are: exposure from ^{40}K in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw material. All of these examples involve natural sources of radiation although there is no explicit requirement to limit the concept to such sources of exposure. In particular, regulatory bodies may wish to apply it to exposures from artificial radionuclides that are now widespread in the environment due to past practices and accidents.

EXEMPTION

2.6. The BSS use the concept of exemption only within the context of practices. Exemption determines *a priori* which practices, sources and radioactive material may be freed from the requirements for practices, and hence regulatory control, based on meeting certain criteria. In essence, it can be considered as a generic authorization for practices granted by the regulatory body, which, once issued, releases persons from the requirements that would otherwise apply.

2.7. Exemption should be granted if the regulatory body is satisfied that the practices or sources within practices meet the exemption criteria or the exemption levels specified in Schedule I of the BSS, or other exemption levels specified by the regulatory body on the basis of the exemption criteria. Exemption should not be granted to permit practices that would otherwise not be justified. The grounds for exemption are that the source gives rise to small (trivial) individual effective doses (of the order of 10 μSv or less in a year) and the protection is optimized, i.e. regulatory provisions will produce little or no improvement in dose reduction (this is indicated by a collective effective dose committed by one year of performance of the practice of no more than about 1 man·Sv, or an assessment for the optimization of protection that shows that exemption is the optimum option).

2.8. The levels in Schedule I of the BSS were derived by establishing a set of exposure scenarios and using them to derive activity concentrations and total quantities of radionuclides that correspond to the dose criteria for exemption of practices. These derived radionuclide-specific levels are based on moderate quantities of material. Their use allows exemption from the requirements of the BSS if the criteria are met, except that the practice should be justified, i.e. exemption should not be invoked to allow frivolous or unwarranted usage of radionuclides. 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 given in that Schedule may require further consideration by the regulatory body.

CLEARANCE

2.9. The BSS also use the concept of *clearance* only within the context of practices. While exemption is used as a part of a process to determine the nature and extent of application of the system of radiation protection and regulatory control, *clearance* is intended to establish which sources under regulatory control can be removed from this control. Like

exemption, it can be considered as a generic authorization, granted by the Regulatory Body, for that component of a practice that applies to the release of radioactive material.

2.10. Clearance is defined in the BSS glossary as the "*removal of radioactive materials or radioactive objects within authorized practices from any further control by the Regulatory Authority"*. Furthermore, the BSS state that clearance is subject to clearance levels that are defined as "*values, established by the Regulatory Authority and expressed in terms of activity concentrations and/or total activity, at or below which sources of radiation may be released from regulatory control"*. A footnote indicates that clearance of bulk amounts of material with activity concentrations lower than the guidance exemption levels specified in Schedule I of the BSS may require further consideration by the regulatory body.

3. BASIS FOR DERIVING ACTIVITY CONCENTRATION LEVELS

3.1. Two approaches are used to establish activity concentrations. The first applies broadly to radionuclides of natural origin; the second applies broadly to radionuclides of artificial origin. These approaches are intended to be consistent with the underlying approach given in the BSS whereby exclusion relates primarily to the former, while exemption and clearance relate primarily to the latter, although in neither case are these relationships exclusive. For instance, exposures from some radionuclides of artificial origin should be implicitly or explicitly excluded from regulatory control, such as fallout from the atmospheric testing of nuclear weapons. Similarly, some material contaminated by radionuclides of natural origin, if within a practice, should be a candidate for exemption or clearance, as appropriate. A full discussion of the methodological approaches used is given in the supporting Safety Report [9].

RADIONUCLIDES OF NATURAL ORIGIN

3.2. Exclusion, as described in the BSS, relates to the amenability of exposures to regulatory control rather than to the actual magnitude of those exposures. Amenability to control is a relative concept; it is a matter of reasonableness and implies recognition of the cost of exercising regulatory control and the benefit to be gained by so doing. The examples of excluded exposures given in the BSS include those from "*unmodified concentrations of radionuclides in most raw materials*" [1, footnote 2]. The reference to unmodified concentrations points to the fact that processing some raw material, which may have typical concentrations of radionuclides of natural origin, may lead to products or waste that have higher values or give rise to exposures that should not be excluded from regulatory control. The reference to exposure from most raw material suggests that exposure from some raw material themselves should not be subject to exclusion. Thus, whatever the cause of the exposure - through enhancement of the radionuclide content during processing or simply because the material has an intrinsically relatively high radionuclide content - the regulatory body should recognize that there are some industries handling or using naturally occurring radioactive material where attributable exposures warrant consideration and control. This Guide therefore provides quantitative guidance on the phrase "*unmodified concentrations of radionuclides in most raw materials*". It is noted that some consideration of the occupational exposures that might result from such material has already been given in another Safety Guide [10].

3.3. The activity concentrations for naturally occurring radionuclides have been selected from a consideration of the worldwide distribution of the activity concentrations given by UNSCEAR [2]. Doses to individuals as a consequence of the use of these activity concentrations are 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. Situations involving the contamination of the water pathway may require a case-by-case evaluation of possible doses. In this context, it is noted that WHO has issued guidelines for drinking water, which include levels for naturally occurring radionuclides [5].

RADIONUCLIDES OF ARTIFICIAL ORIGIN

3.4. The primary radiological basis for establishing levels for exemption and clearance of bulk amounts of material is that effective doses to individuals should be of the order of 10μSv in a year or less. In order to avoid treating this dose as a limit, which would necessitate the use of extremely cautious models, an additional criterion was used which is that there should be a low probability of the effective dose to any individual approaching 1mSv in any particular year. Consideration was also given to doses to the skin; an equivalent dose criterion of 50 mSv in a year was used for this purpose.

3.5. Many studies undertaken at national or international levels have derived radionuclide specific levels for the clearance of solid material [11 - 13]. The results presented in this document draw upon the extensive experience gained in undertaking these studies and independent calculations performed under the auspices of the Agency [9]. 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). As stated in paragraph 1.10, foodstuffs and drinking water pathways were taken into account to address the radiological consequences as appropriate. The selected levels were the lowest values obtained from the scenarios.

3.6. For a number of short-lived radionuclides, the calculations lead to levels that are higher than the exemption levels given in the BSS. This is due to the fact that the scenarios focus on the transport, trade, use, or deposition of materials outside the facilities in which they arise (i.e., reactors, accelerators, laboratories), and account was taken of the lapse of time

involved before the start of the exposure. The models on which the exemption levels are based, consider the direct handling of the material within these facilities and consequently do not allow for any radioactive decay of the radionuclides before the exposure starts. For these radionuclides, the levels chosen were the exemption levels of the BSS.

4. ACTIVITY CONCENTRATION LEVELS FOR MATERIAL

4.1 The activity concentrations for radionuclides of natural origin derived using the first approach discussed in paragraphs 3.2 and 3.3 are given in Table I.

TABLE I. ACTIVITY CONCENTRATION LEVELS FOR RADIONUCLIDES OF NATURAL ORIGIN

Radionuclide	Concentration Level (Bq/g)
Radionuclides in the ^{235}U decay series	0.05
^{40}K	5
All other naturally occuring radionuclides	0.5

These levels have been determined on the basis of the worldwide distribution of radioactivity concentrations for these radionuclides. Consequently, they are valid for the natural decay chains in secular equilibrium, i.e., ^{238}U, ^{235}U and ^{232}Th, with the value given being applied to the parent of the decay chain. The values can also be used individually for each decay product in the chains or the head of subsets of the chains, such as ^{226}Ra.

4.2. Those for radionuclides of artificial origin derived using the second approach discussed paragraphs 3.4 to 3.6 are given in Table II.

4.3 The details of the calculations that led to these values are contained in Safety Report XXX [9].

TABLE II. ACTIVITY CONCENTRATION LEVELS FOR RADIONUCLIDES OF ARTIFICIAL ORIGIN

Radionuclide	Concentration Level (Bq/g)	
H-3	100	
Be-7	10	
C-14	1	
F-18	10	*
Na-22	0.1	
Na-24	1	*
Si-31	1000	*
P-32	1000	
P-33	1000	
S-35	100	
Cl-36	1	
Cl-38	10	*
K-42	100	
K-43	10	*
Ca-45	100	
Ca-47	10	
Sc-46	0.1	
Sc-47	100	
Sc-48	1	
V-48	1	
Cr-51	100	
Mn-51	10	*
Mn-52	1	
Mn-52m	10	*
Mn-53	100	
Mn-54	0.1	
Mn-56	10	*
Fe-52	10	*
Fe-55	1000	
Fe-59	1	
Co-55	10	*
Co-56	0.1	
Co-57	1	
Co-58	1	
Co-58m	10000	*
Co-60	0.1	
Co-60m	1000	*
Co-61	100	*
Co-62m	10	*
Ni-59	100	
Ni-63	100	
Ni-65	10	*
Cu-64	100	*
Zn-65	0.1	
Zn-69	1000	*
Zn-69m	10	*
Ga-72	10	*
Ge-71	10000	

Radionuclide	Concentration Level (Bq/g)	
As-73	1000	
As-74	10	*
As-76	10	*
As-77	1000	
Se-75	1	
Br-82	1	
Rb-86	100	
Sr-85	1	
Sr-85m	100	*
Sr-87m	100	*
Sr-89	1000	
Sr-90	1	
Sr-91	10	*
Sr-92	10	*
Y-90	1000	
Y-91	100	
Y-91m	100	*
Y-92	100	*
Y-93	100	*
Zr-93	10	*
Zr-95	1	
Zr-97	10	*
Nb-93m	10	
Nb-94	0.1	
Nb-95	10	
Nb-97	10	*
Nb-98	10	*
Mo-90	10	*
Mo-93	10	
Mo-99	10	
Mo-101	10	*
Tc-96	1	
Tc-96m	1000	*
Tc-97	10	
Tc-97m	100	
Tc-99	1	
Tc-99m	100	*
Ru-97	10	
Ru-103	10	
Ru-105	10	*
Ru-106	0.1	
Rh-103m	10000	*
Rh-105	100	
Pd-103	1000	
Pd-109	100	
Ag-105	10	
Ag-110m	0.1	
Ag-111	100	

Radionuclide	Concentration Level (Bq/g)	
Cd-109	1	
Cd-115	10	
Cd-115m	100	
In-111	10	
In-113m	100	*
In-114m	10	
In-115m	100	*
Sn-113	1	
Sn-125	10	
Sb-122	10	
Sb-124	1	
Sb-125	0.1	
Te-123m	1	
Te-125m	1000	
Te-127	1000	
Te-127m	10	
Te-129	100	*
Te-129m	100	
Te-131	100	*
Te-131m	10	
Te-132	1	
Te-133	10	*
Te-133m	10	*
Te-134	10	*
I-123	10	
I-125	1000	
I-126	10	
I-129	0.1	
I-130	10	*
I-131	10	
I-132	10	*
I-133	10	*
I-134	10	*
I-135	10	*
Cs-129	10	
Cs-131	1000	
Cs-132	10	
Cs-134	0.1	
Cs-134m	10	*
Cs-135	100	
Cs-136	1	
Cs-137	0.1	
Cs-138	10	*
Ba-131	10	
Ba-140	1	
La-140	1	
Ce-139	1	
Ce-141	100	

Radionuclide	Concentration Level (Bq/g)	
Ce-143	10	
Ce-144	10	
Pr-142	100	*
Pr-143	1000	
Nd-147	100	
Nd-149	100	*
Pm-147	1000	
Pm-149	1000	
Sm-151	10000	
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	10	
Ta-182	0.1	
W-181	10	
W-185	1000	
W-187	101000	
Re-186	1000	
Re-188	100	*
Os-185	1	
Os-191	100	
Os-191m	1000	*
Os-193	100	
Ir-190	1	
Ir-192	1	

Radionuclide	Concentration Level (Bq/g)	
Ir-194	100	*
Pt-191	10	
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	10	
U-236	10	
U-237	100	
U-239	100	*
U-240	100	*
Np-237	1	
Np-239	100	
Np-240	10	*
Pu-234	100	*

Radionuclide	Concentration Level (Bq/g)	
Pu-235	100	*
Pu-236	1	
Pu-237	100	
Pu-238	1	
Pu-239	1	
Pu-240	1	
Pu-241	100	
Pu-242	1	
Pu-243	1000	*
Pu-244	0.1	
Am-241	1	
Am-242	1000	*
Am-242m	1	
Am-243	1	
Cm-242	10	
Cm-243	1	
Cm-244	10	
Cm-245	1	
Cm-246	1	
Cm-247	0.1	
Cm-248	1	
Bk-249	100	
Cf-246	1000	
Cf-248	10	
Cf-249	0.1	
Cf-250	1	
Cf-251	1	
Cf-252	10	
Cf-253	100	
Cf-254	1	
Es-253	100	
Es-254	0.1	
Es-254m	10	
Fm-254	10000	*
Fm-255	100	*

* indicates half life less than 1 day

5. APPLICATION OF ACTIVITY CONCENTRATIONS TO PRACTICES

RADIONUCLIDES OF NATURAL ORIGIN

5.1. In this document, the concept of exclusion has been used in the context of exposures from natural sources of radiation. The activity concentrations of such radionuclides in material should be used to define that material that should be outside or inside, as the case may be, the scope of regulatory control. If the activity concentration is below the activity concentration values in Table I for the radionuclides in question, then the handling and use of the material should be regarded as outside the scope of regulatory control. If the activity concentration is above the activity concentration levels in Table II, the regulatory body should decide on the extent to which the regulatory requirements for practices set out in the BSS [1] should be applied.

5.2. In addition, the activity concentrations of radionuclides of natural origin should be used to determine when material within a practice can be released from regulatory control. This applies irrespective of the amount of material involved.

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

RADIONUCLIDES OF ARTIFICIAL ORIGIN

5.4. In this document, 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[3].

5.5. The BSS, in Schedule I, indicate that radioactive substances 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 specified by the

[3] It should be noted that the justification principle applies to practices as a whole and not separately to its component parts such as the disposal of waste. Thus the means whereby material that is contaminated as a consequence of a practice is disposed is 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 practice without further consideration..

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 specifically required to do so by the Regulatory Body. In particular, any subsequent use of the material within a practice should not necessitate application of the principle of justification from a radiation protection point of view.

5.6. The way in which these levels should be incorporated into national regulatory requirements will depend on the particular approach to be adopted. Any of the approaches proposed in paragraph 5.3 for the naturally occurring radionuclides might be used. However, it is noted that many regulatory bodies have adopted the activity concentrations given in Schedule I of the BSS into their national requirements. Where that is the case, one possibility would be to express the levels in a specific regulatory instrument in which the requirements relating to exemption and clearance of bulk amounts of material are given.

6. APPLICATION OF ACTIVITY CONCENTRATIONS TO TRADE

6.1. The terms 'practice' and 'intervention' were intended to assist regulatory and national bodies in determining those situations that should be under some form of control, particularly regulatory control. If the activity concentrations developed in this Guide are used as indicated in the previous section, then there should be no need to give attention to intervention. In particular, national and international trade in commodities containing radionuclides with activity concentrations below the activity concentrations values in Table I and II should not be subject to regulatory controls.

6.2. Compliance with the activity concentrations given in this Guide should be verified at the first point of entry into trade. Thus, authorities in exporting countries should ensure that systems are in place to prevent unrestricted trade in material containing higher levels of radioactivity. Authorities in importing countries should ensure that any monitoring that is undertaken at borders and elsewhere, such as scrap recycling plants, to detect for the presence of 'orphan sources'[4] should take account of the activity concentrations given in this Safety Guide in order to prevent unnecessary restrictions on the movement and use of material. In general, however, it should not be necessary for each country 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 producing country.

6.3. In cases where there are reasonable grounds for believing that the activity concentrations may be exceeded, arrangements should be made to determine the actual levels either by obtaining the information from the supplier or by measurement. In such cases, measurements should be performed using appropriate techniques and equipment capable of measurement of activity concentrations at the specified levels. In general, countries should coordinate their regulatory strategies and implementation with neighboring countries, including monitoring programmes for commodities, in order to avoid unnecessary hindrance to trade at boundary transfer points.

[4] Orphan source means a source which poses sufficient radiological hazard to warrant regulatory control but is not under regulatory control, either because it has never been under regulatory control, or because it has been abandoned, lost, misplaced, stolen or transferred without proper authorization.

7. MIXTURES OF RADIONUCLIDES

7.1. For material containing a mixture of radionuclides, either of natural or artificial origin, comparison with the activity concentration levels should be undertaken as indicated by the formulas below:

for each naturally occurring radionuclide

$$\frac{C_{natural}}{Activity\ concentration} \leq 1$$

where $C_{natural}$ is the concentration (Bq/g) of the naturally occurring radionuclide in the material or, for those radioactive decay chains in secular equilibrium, it is the concentration of the parent radionuclide, and the activity concentration is the level specified for the relevant naturally occurring radionuclide (or for those in secular equilibrium, the parent nuclide);

for radionuclides of artificial origin

$$\sum_{i=1}^{n} \frac{C_{i(artificial)}}{Activity\ concentration_i} \leq 1$$

where $C_{i(artificial)}$ is the concentration (Bq/g) of the i^{th} radionuclide of artificial origin in the material, $Activity\ concentration_i$ is the level for that radionuclide in the material and n is the number of radionuclides present.

7.2. If both (1) and (2) are satisfied and are less than or equal to 1, then the material should not be subject to regulatory control. If the result of either equation is greater than one, the requirements of the BSS [1] should be applied to the material. This type of relationship should be used by the regulatory bodies in their specific guidance on application of the BSS [1] to account for situations where multiple radionuclides are present in mixtures.

8. AVERAGING

8.1. When applying the above activity concentrations, the regulatory body should consider methodologies for sampling, averaging, monitoring, and detection of radionuclides. In doing this, the regulatory body should recognize that these activity concentrations were derived for large quantities and therefore the averaging should be done accordingly.

Consideration should also be given to surface contamination levels that would equate to the specified dose criteria. The Agency is currently preparing guidance on these issues.

9. DILUTION OF MATERIAL

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

10. SUMMARY

10.1. A summary of extracts of relevant parts from the BSS [1], from the Safety Guide "Occupational Radiation Protection" [11] are given in the Annex along with a summary of the overall guidance on exclusion, exemption and clearance for material.

REFERENCES

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[13] EUROPEAN COMMISSION, Practical Use of the Concepts of Clearance and Exemption (Part I and II), RP-122, EC, Belgium (2001).

ANNEX – SCOPE OF REGULATORY CONTROL FOR PRACTICES

Practices are defined in the Glossary of the BSS as follows:

> *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.*

This definition does not unequivocally indicate which sources of exposure should be included and which should be excluded. However, the BSS provides the following statements, which provide further clarification:

201. The practices to which the Standards shall apply include:

- *(a) the production of sources and the use of radiation or radioactive substances for medical, industrial, veterinary or agricultural purposes, or for education, training or research, including any activities related to that use which involve or could involve exposure to radiation or radioactive substances;*
- *(b) the generation of nuclear power, including any activities in the nuclear fuel cycle which involve or could involve exposure to radiation or radioactive substances;*
- *(c) practices involving exposure to natural sources specified by the Regulatory Authority as requiring control; and*
- *(d) any other practice specified by the Regulatory Authority.*

202. The sources within any practice to which the requirements for practices of the Standards shall apply include:

- *(a) radioactive substances and devices that contain radioactive substances or produce radiation, including consumer products, sealed sources, unsealed sources, and radiation generators, including mobile radiography equipment;*
- *(b) installations and facilities which contain radioactive substances or devices which produce radiation, including irradiation installations, mines and mills processing radioactive ores, installations processing radioactive substances, nuclear installations, and radioactive waste management facilities; and*
- *(c) any other source specified by the Regulatory Authority.*

204. The exposures to which the requirements of the Standards apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or source within the practice, including both normal exposures and potential exposures.

205. Exposure to natural sources shall normally be considered as a chronic exposure situation and, if necessary, shall be subject to the requirements for intervention, except that[5]:

- *(a) public exposure delivered by effluent discharges or the disposal of radioactive*

[5] At the time of the endorsement of the Standards, the available quantitative recommendations of the ICRP for protection against exposure to natural sources were confined to radon. It was therefore decided that the General Obligations for practices concerning protection against natural sources will be that exposure to natural sources, which is normally a chronic exposure situation, should be subject to intervention and that the requirements for practices should be generally limited to exposure to radon, the exposure to other natural sources being expected to be dealt with by exclusion or exemption of the source or otherwise at the discretion of the Regulatory Authority.

waste arising from a practice involving natural sources shall be subject to the requirements for practices given in the BSS, unless the exposure is excluded or the practice or the source is exempted; and

(b) occupational exposure of workers to natural sources shall be subject to the requirements for practices given in this section if these sources lead to:

(i) exposure to radon required by or directly related to their work, irrespective of whether the exposure is higher or lower than the action level for remedial action relating to chronic exposure situations involving radon in workplaces[6], unless the exposure is excluded or the practice or the source is exempted; or

(ii) exposure to radon incidental to their work, but the exposure is higher than the action level for remedial action relating to chronic exposure situations involving radon in workplaces; unless the exposure is excluded or the practice or the source is exempted: or

(iii) exposure specified by the Regulatory Authority to be subject to such requirements.

The Safety Guide on Occupational Radiation Protection [11] elaborates these requirements as follows:

2.20. The term 'radioactive substance' is not specifically defined in the BSS; it should be noted in particular that the term is not qualified by reference to artificial radionuclides only. Thus, the BSS are intended to apply to naturally occurring radionuclides that have been extracted from ones, irrespective of the use to which those radionuclides are put. Sealed and unsealed sources containing naturally occurring radionuclides such as radium-226 should therefore be treated as being within a practice.

2.20. From para. 2.5(b)(i) of the BSS, it is clear that the mining and milling of radioactive ores should be treated as practices. All exposures in these situations including those from radon, should be subject to the requirements for practices, irrespective of whether the concentrations of radon in air are above the action level specified in the BSS.

2.20. Paragraph 2.5(b)(ii) of the BSS should be taken to mean that exposures to radon in workplaces other than those covered in para. 2.5(b)(i) should be subject to the requirements for occupational exposure if the radon concentration exceeds the action level. This does not, however, apply if the exposure has been excluded or the practice or source has been exempted. Examples of workplaces where exposure to radon is adventious and the levels are likely to exceed the action level include mines (other than those intended to produce radioactive ores), spas and aboveground workplaces in radon prone areas.

2.20. Action levels apply to chronic exposure situations, which are described in Appendix VI of the BSS. The primary purpose of an action level is to define the circumstances under which remedial or protective action should be undertaken. In the case of adventious exposure to radon, the procedure should be for the regulatory authority to identify or determine, by means of a survey or otherwise, those workplaces with radon concentrations above the action level. Consideration should then be given to whether the concentrations can reasonably be reduced below the action level. Where sufficient reduction in concentrations cannot be achieved, the requirements for practices should be applied. Thus, at this stage the numerical value of the action level has a conceptually different significance than that initially given to it. It is no

[6] See BSS Schedule VI, Guidelines for Action Levels in Chronic Exposure Situations, para. VI-3.

longer to be used as the basis for a decision on intervention, but as the basis for a decision to consider the exposures to be arising from a practice.

On the basis of this guidance and the additional guidance given in this Guide (DS-161), the following are regarded as coming under the requirements for practices in the BSS, subject to the provision for exemption:

- All devices containing radioactive sources;
- All mines producing radioactive ores;
- All workplaces with radon concentrations above the action level;
- All workplaces where the activity concentrations of naturally occurring radionuclides in material that is being handled or used are above the levels specified in body of this Guide (DS-161).

The provision for exclusion in the BSS is as follows:

104. 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[7].

Schedule I of the BSS contains the following provision relating to authorized practices or sources.

> *(I.6) Radioactive substances 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 Authority.*

This provision also applies to exemption and clearance, which are effectively generic authorizations.

On the basis of this provision and the additional guidance given in the body of this Guide (DS-161), the following should be excluded from the regulatory requirements for practices:

- exposure from ^{40}K in the body;
- exposure from cosmic radiation at the surface of the earth;
- exposure from radon below the action level;
- exposure from materials containing activity concentrations of the naturally occurring radionuclides below the levels for given in the body of this Guide (DS-161); and
- exposure from materials containing activity concentrations of the radionuclides of artificial origin below the levels for given in the body of this Guide (DS-161).

[7] Examples are exposure from ^{40}K in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials.

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