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Application of the Concept of Exemption

Draft Safety Guide
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IAEA
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FOREWORD

By
Director General

[standard text to be added]

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1] establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. GSR Part 3 [1] addresses three types of exposure situation: planned exposure situations involving the deliberate introduction and operation of sources; emergency exposure situations; and existing exposure situations that already exist when a decision on control needs to be taken.

1.2. IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [2] establishes requirements on the regulatory framework for all exposure situations. The scope of regulatory control in planned exposure situations is defined by the application of the concepts of exclusion, exemption and clearance. Exclusion is the deliberate excluding of a particular type 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 [3]. Exemption refers to the determination by a regulatory body that a source or practice[1] need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects, or that this is the optimum option for protection irrespective of the actual level of the doses or risks [1, 3]. Clearance is the removal of regulatory control by the regulatory body or government from radioactive material or radioactive objects within notified or authorized practices [1, 3].

1.3. Requirement 8 of GSR Part 3 [1] makes provision for the exemption of practices and sources within practices and for the clearance of sources within notified or authorized practices, in

[1] A practice is any human activity that introduces additional sources of exposure or additional exposure pathways, 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.

accordance with the use of a graded approach. Schedule I of GSR Part 3 [1] contains generic values for granting exemption and clearance of material containing radionuclides, as follows:

(a) The exemption of moderate amounts of material, based on activity or activity concentration of radionuclides (Table I.1 of GSR Part 3 [1]);
(b) The exemption and clearance of bulk amounts of solid material containing radionuclides of artificial origin, based on activity concentration (Table I.2 of GSR Part 3 [1]);
(c) The clearance of material containing radionuclides of natural origin based on activity concentration (Table I.3 of GSR Part 3 [1]).

Detailed recommendations of the application of the values in Tables I.1 and I.2 of GSR Part 3 [1] for exemption purposes are provided in Sections 4 and 5 of this Safety Guide.

1.4. The exemption values for artificial radionuclides are derived from conservative exposure scenarios as described in Ref. [4]. The exemption values for radionuclides of natural origin are mostly derived using a pragmatic approach that places greater emphasis on optimization of protection, considering the worldwide distribution of these radionuclides in material present in the environment. The scenario based dose calculations underlying the exemption levels were intentionally performed with a high degree of caution to ensure a sufficient level of protection. Hence, additional conservatism, either with respect to the practical aspects of verification of compliance with the exemption levels, or with the formal embedding of these exemption levels in national regulations, needs to be avoided.

1.5. This Safety Guide, together with IAEA Safety Standards Series No. DS500, Application of the Concept of Clearance [5], supersedes the Safety Guide on Application of the Concepts of Exclusion, Exemption and Clearance, issued in 2004[2].

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Standards Series No. RS-G-1.7, IAEA, Vienna (2004).

OBJECTIVE

1.6. The primary objective of this Safety Guide is to provide recommendations and guidance on the application of the concept of exemption within the framework of planned exposure situations. This includes recommendations on the application of the exemption levels in Schedule I of GSR Part 3 [1] (hereinafter termed as 'generic exemption'), the application of the concept of case by case exemption (hereinafter termed as 'specific exemption'), and guidance on the exemption of surface contaminated items.

1.7. This Safety Guide explains the concept of exclusion. It also provides a suggested approach based on the application of screening values for decision making in existing exposure situations, including the trade of commodities.

1.8. This Safety Guide is mainly intended for governments, regulatory bodies and operating organizations, to assist them in the application of Requirement 8 of GSR Part 3 [1] in relation to the exemption of sources and practices from regulatory control. It will be of interest to practices that handle sources, materials containing radionuclides and/or radiation generators. It will also be of interest to technical service providers in radiation protection.

SCOPE

1.9. This Safety Guide addresses the exemption of practices or sources within practices from regulatory control, as established in Requirement 8 of GSR Part 3 [1], and as further described in Schedule I of GSR Part 3 [1]. It is applicable to all facilities and activities for which the concept of exemption is relevant. It also addresses the application of a graded approach to the concept of exemption through the use of generic exemption and specific exemption.

1.10. In this Safety Guide, exemption from regulatory control solely refers to the radiological aspects of the justified practice or source(s) within the justified practice. Regulatory control to address non-radiation-related hazards may still be appropriate.

1.11. This Safety Guide explains the concept of exclusion and its relationship to exemption and clearance.

1.12. This Safety Guide primarily addresses exemption from regulatory control in planned exposure situations. Although, the concept of exemption is only applicable to planned exposure situations, guidance on the application of a screening approach for decision making in managing certain existing exposure situations is also provided. These situations include those involving construction materials or residual radioactive material derived from past activities[3], and following the transition from an emergency exposure situation. Emergency exposure situations are outside the scope of this Safety Guide, although the relationship between different exposure situations is explained.

1.13. This Safety Guide provides guidance on a possible screening approach to international trade of non-food commodities containing radionuclides. Additional detailed technical information on radiation safety in the trade of commodities is provided in Ref. [6].

1.14. This Safety Guide does not address the application of the concept of clearance, which is addressed separately in DS500 [5].

1.15. Recommendations on applying the provisions for exemption in GSR Part 3 [1] to consumer products containing small amounts of radionuclides or radiation generators, and to consumer products containing radionuclides as activation products are provided in IAEA Safety Standards Series No. SSG-36, Radiation Safety for Consumer Products [7].

1.16. The terms used in this Safety Guide are to be understood as defined and explained in GSR Part 3 [1] and the IAEA Safety Glossary [3].

STRUCTURE

1.17. Section 2 gives an overview of the basic definitions and concepts of exclusion, exemption and clearance, focussing on the application of the concept of exemption in planned exposure situations and the application of a screening approach to support decision making in existing exposure situations. Section 3 provides recommendations on the responsibilities of government,

[3] Any material contaminated or contained in by radionuclides from past activities that were never subject to regulatory control or that were subject to regulatory control but not in accordance with GSR Part 3 requirements [1].

regulatory bodies and the applicant and on other organizational and administrative arrangements in relation to exemption.

1.18. Section 4 and Section 5 provide recommendations and guidance on the concepts of generic exemption and specific exemption, respectively. Section 6 provides recommendations and guidance on other exemption issues, such as monitoring and verification of compliance with exemption levels and revoking or revising exemptions, and Section 7 considers the use of screening values in existing exposure situations and provides recommendations on a generic approach to the trade of non-food commodities containing radionuclides.

1.19. Appendix I reproduces Table I.1. and Table I.2. from GSR Part 3 [1], for convenience. Appendix II provides more detailed recommendations on monitoring and verification of compliance with exemption criteria. Annex I provides examples of determining exemption for materials containing more than one radionuclide. Annex II provides information relating to the dosimetric modelling of surface contamination, and Annex III provides examples of the practical use of screening values for decision making as applied in existing exposure situations, the management of residual waste material in Japan after the Fukushima Daiichi accident and a screening approach for construction materials.

2. THE CONCEPTS OF EXCLUSION, EXEMPTION AND CLEARANCE

2.1. GSR Part 3 [1] establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. GSR Part 3 [1] addresses all exposure situations and presents the concepts of exclusion, exemption and clearance. These concepts and their interrelationships, with special emphasis on the exemption of practices or sources within practices, are described in this section.

EXPOSURE SITUATIONS

2.2. GSR Part 3 [1] applies to all situations involving radiation exposure that is amenable to control, for three different types of exposure situation: planned exposure situations, emergency exposure situations and existing exposure situations. Paragraph 1.20 of GSR Part 3 [1] states:

"Together, these three types of exposure situation cover all situations of exposure for which these Standards apply:

(a) *A planned exposure situation* is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, the associated exposures and their likelihood of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations are by good design of facilities, equipment and operating procedures and by training. In planned exposure situations, exposure at some level can be expected to occur.(..omitted text on potential exposure).

(b) An *emergency exposure situation* is a situation of exposure that arises as a result of an accident, a malicious act, or any other unexpected event, and requires prompt action in order to avoid or to reduce adverse consequences. Preventive measures and mitigatory actions have to be considered before an emergency exposure situation arises. However, once an emergency exposure situation actually arises, exposures can be reduced only by implementing protective actions.

(c) An *existing exposure situation* is a situation of exposure that already exists when a decision on the need for control needs to be taken. Existing exposure situations include situations of exposure to natural background radiation that are amenable to control. They also include situations of exposure due to residual radioactive material that derives from past practices that were not subject to regulatory control or that remains after an emergency exposure situation."

2.3. GSR Part 3 [1] applies to radionuclides of natural origin and artificial radionuclides. Artificial radionuclides are deliberately produced and/or used in practices and therefore the requirements for planned exposure situations in Section 3 of GSR Part 3 [1] apply. Such practices (or sources within these practices) then enter into the scope of the regulatory system using a graded approach. Within the legal and regulatory framework for planned exposure situations, the concepts of exemption and clearance are used to further define the scope of regulatory control.

2.4. For most materials containing radionuclides of natural origin, the requirements for existing exposure situations apply. The exception is exposure to materials containing radionuclides of

natural origin exceeding 1 Bq/g for any radionuclide in the uranium or thorium decay chain and 10 Bq/g for ^{40}K, for which the requirements for planned exposure situations apply: see para. 3.4(a) of GSR Part 3 [1].

2.5. In the case of exposure due to radionuclides in commodities (including food, feed, drinking water, agricultural fertilizer and soil amendments, construction materials) or residual radioactive material in the environment, the requirements for existing exposure situations apply regardless of whether the radionuclides are of artificial or natural origin: see paras 5.1(b) and 5.1(c)(ii) of GSR Part 3 [1].

2.6. Materials containing radionuclides of natural origin with individual radionuclide activity concentrations below 1 Bq/g for nuclides from the uranium and thorium series and 10 Bq/g for ^{40}K, often do not warrant regulatory control, unless in specific cases, the regulatory body considers that it is appropriate. These activity concentration values were derived on the basis of the concept of exclusion (i.e. that any associated exposures were not amenable to control: see paras 2.7 and 2.8) and were selected by considering the upper end of the worldwide distribution of unmodified activity concentrations in soil.

THE CONCEPT OF EXCLUSION

2.7. Paragraph 1.42 of GSR Part 3 [1] states that the requirements of GSR Part 3 "apply to all situations involving radiation exposure that is amenable to control. Exposures deemed not to be amenable to control are excluded from the scope of [GSR Part 3]." For example, it is not feasible to control ^{40}K in the human body or cosmic radiation at the surface of the Earth (see footnote 8 of GSR Part 3[1]). Other examples of excluded exposures are: (a) unmodified concentrations of radionuclides of natural origin in soil, including those in high natural background radiation areas; (b) other primordial radionuclides (e.g. ^{87}Rb, ^{138}La, ^{147}Sm, ^{176}Lu) present in unmodified activity concentrations; and (c) fallout resulting from past atmospheric nuclear weapon tests.

2.8. Excluded exposures are such that control measures are not required, regardless of the magnitude of such exposures. Therefore, sources leading to such exposures are excluded from regulatory control and are out of the scope of the requirements of GSR Part 3 [1].

THE CONCEPT OF EXEMPTION

2.9. GSR Part 3 [1] specifies the concept of exemption only in the context of practices (and sources within practices) in planned exposure situations. Requirement 8 of GSR Part 3 [1] states:

> "**The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.**"

2.10. Exemption determines a priori which justified practices and sources within justified practices may be freed from the obligation to comply with some or all the regulatory requirements for practices — in particular, the requirements related to notification, registration and licensing — on the basis of meeting certain exemption criteria.

2.11. Paragraph I.1 in Schedule I of GSR Part 3 [1] states:

> "The general criteria for exemption of a practice or a source within a practice from some or all the requirements of [GSR Part 3] are that:
>
> (a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or
>
> (b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks."

Criterion (a) refers to both normal exposures (i.e. exposures under normal operating conditions) and potential exposures (exposures potentially resulting from an anticipated operational occurrence or accident). In criterion (b), regulatory control might not be justified since it would not lead to any further optimization of protection, irrespective of the actual level of exposure.

2.12. With regard to the application of the concept of exemption for material containing radionuclides of natural origin, footnote 60 in GSR Part 3 [1] states:

"Material containing radionuclides of natural origin at an activity concentration of less than 1 Bq/g for any radionuclide in the uranium decay chain or the thorium decay chain and of less than 10 Bq/g for ^{40}K is not subject to the requirements in Section 3 [of GSR Part 3] for planned exposure situations (para. 3.4(a)); hence, the concept of exemption from the requirements of these Standards does not apply for such material."

2.13. Paragraph I.8 of GSR Part 3 [1] states that "Radioactive material arising from authorized discharges is exempt from any requirements for notification, registration or licensing unless otherwise specified by the regulatory body."

THE CONCEPT OF CLEARANCE

2.14. While exemption is used as part of a process to determine the nature and extent of regulatory control, clearance is intended to establish which material under regulatory control can be removed from this control. Therefore, a decision on granting clearance usually takes place during or after the planned activities with a source within a practice, while exemption refers instead to an a-priori decision. Clearance is therefore different to exemption, even though the general criteria on which the concepts are based are very similar: see paras I.1 and I.10 of GSR Part 3 [1].

2.15. Clearance may be granted by the regulatory body for the removal of regulatory control from radioactive material or radioactive objects within notified or authorized practices [3]. This can include surface contaminated objects: see para. I.13 of GSR Part 3 [1]. Any material or object within a notified or authorized practice that is radioactive (or becomes radioactive or surface contaminated during the conduct of activities within that practice) is implicitly expected to be considered as part of the notification and authorization processes. The removal of regulatory control from these materials or objects (either during the conduct of the practice or after its cessation) is an issue of clearance, not exemption. Examples include materials (including building materials) and objects that have become radioactive through activation in accelerator facilities or in nuclear power plants, or the surface contamination of objects by unsealed sources. Recommendations on the clearance of materials and objects from a practice are provided separately in DS500 [5] and are not considered further in this Safety Guide.

Application of the justification principle

2.16. Consideration should be given, in the context of granting exemptions, to the requirement of GSR Part 3 [1] for practices and sources to be justified. Paragraph. 1.13 of GSR Part 3[1] states:

> "The operation of facilities or the conduct of activities that introduce a new source of radiation, that change exposures or that change the likelihood of exposures has to be justified in the sense that the detriments that may be caused are outweighed by the individual and societal benefits that are expected. The comparison of detriments and benefits often goes beyond the consideration of protection and safety, and involves the consideration of economic, societal and environmental factors also".

2.17. Paragraph 3.11 of GSR Part 3 [1] explicitly states that "exemption shall not be granted for practices deemed to be not justified." Consequently, exemption never overrides the justification principle.

2.18. Practices deemed not to be justified include those involving the deliberate addition of radioactive substances to food or beverages, or those involving the unnecessary addition of radioactive substances to toys and personal jewellery or adornments: see para. 3.17 of GSR Part 3 [1]. Specific recommendations on the justification of consumer products (i.e. devices or manufactured items into which radionuclides have deliberately been incorporated) are provided in IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-Medical Human Imaging [8].

Graded approach

2.19. Paragraph 2.12 of GSR Part 3 [1] provides the basis for a graded approach and states that "The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation."

2.20. Requirement 6 of GSR Part 3 [1] states:

“The application of the requirements of [GSR Part 3] in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.”

2.21. Paragraph 4.5 of GSR Part 1 (Rev. 1) [2] states:

“The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach…for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control”.

2.22. Paragraph 3.6 of GSR Part 3 [1] states that “The application of the requirements of [GSR Part 3] shall be in accordance with the graded approach and shall also conform to any requirements specified by the regulatory body.” Exemption delineates the boundaries of the scope of regulatory control of planned exposure situations; therefore, it may be considered as the first step by which a graded approach is applied. If not exempted, the practice or source within the practice is within the scope of regulatory control, which is then also required to be applied in accordance with a graded approach commensurate with the radiation risks involved: see paras 2.18 and 2.31 of GSR Part 3 [1].

2.23. The application of a graded approach is also required for existing exposure situations, for which the protection strategy is guided by reference levels. In such situations, a graded approach could include a decision to not apply any controls based on screening using either a dose criterion or a derived operational quantity to demonstrate that this is the optimum approach. In such an approach, where the screening values are exceeded, additional measures for protection and safety should be considered; below the screening levels, no further actions are necessary. In this way, the screening method is a decision-aiding tool in existing exposure situations, similar to the use of exemption levels in planned exposure situations. A graded approach enables an effective use of the resources of the regulatory body in that greater attention and resources can be focused on those practices and sources that give rise to more significant radiation risks.

Generic exemption and specific exemption

2.24. For practices involving sources, exemption can be applied either without further consideration (generic exemption: see Section 4) or by the imposition of specific conditions by the regulatory body (specific exemption: see Section 5). These conditions can refer to a specific type of practice, to specific requirements under which activities involving sources can take place without regulatory control, or to a combination of both. Paragraph I.6 of GSR Part 3 [1] states:

> "Exemptions may be granted subject to conditions established by the regulatory body, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal."

This is referred to as 'specific exemption' in this Safety Guide.

2.25. Specific exemption is described in para. I.6 of GSR Part 3 [1], for instance, for type approved equipment containing radioactive material that is not otherwise automatically exempted without further consideration. There are other cases of specific exemption, which are described in detail in Section 5, such as the following;

(a) Consumer products (see para. 2.32 of SSG-36 [7]);
(b) Bulk amounts of solid material with radionuclides of natural origin (see para. I.4 of GSR Part 3 [1]);
(c) Surface contaminated items.

Other equipment containing radioactive materials may also be considered for specific exemption; otherwise is required to be notified to the regulatory body and, where appropriate, authorized by the regulatory body.

Regulatory approach for non-exempted practices

2.26. If a practice or source within a practice does not meet the criteria for exemption (i.e. either generic exemption or specific exemption), it is required to be subject to regulatory control as described in Section 3 of GSR Part 3 [1]. As part of a graded approach, the person or organization responsible for the practice or source is required to submit a formal notification to the regulatory body: see Requirement 7 of GSR Part 3 [1]. Notification is sufficient for sources or practices for

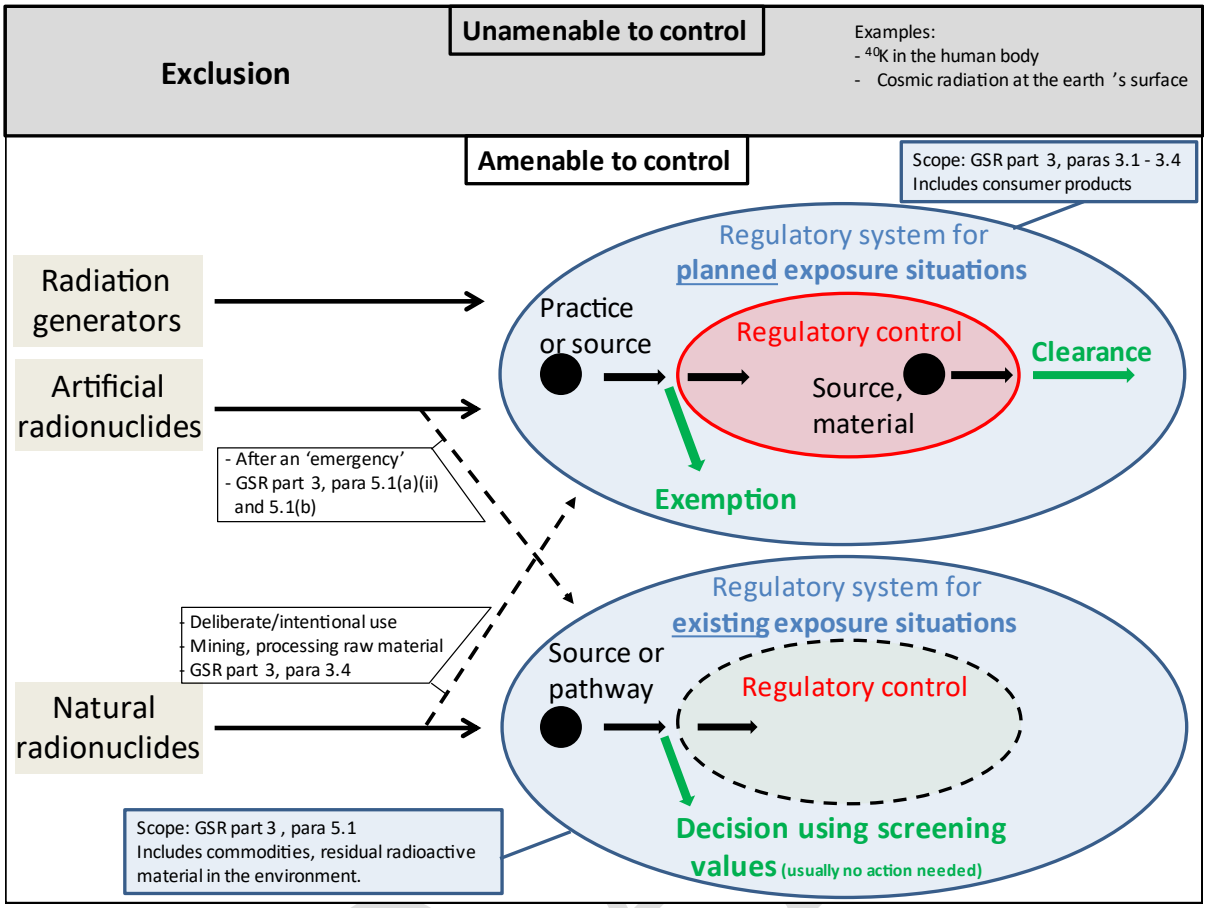
which exposures are unlikely to exceed a small fraction of the dose limits, and where the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible: see para. 3.7 of GSR Part 3 [1]. Recommendations on the process of notification are provided in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [9].

2.27. In cases where notification alone is not deemed sufficient, the person or organization responsible for the intended practice (i.e. the operating organization), is required to apply to the regulatory body for authorization: see para. 3.8 of GSR Part 3 [1]. In accordance with the graded approach, the authorization may take the form of either a registration or a licence.

2.28. Registration is a form of authorization for facilities and activities of low or moderate risks whereby the person or organization responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate [3].

2.29. Practices for which registration is not considered sufficient, should be authorized by means of licensing [3]. This requires a detailed safety assessment (see paras 5.4–5.9 of this Safety Guide) to be performed by the applicant and submitted to the regulatory body [2].

2.30. Figure 1 illustrates the concepts of exclusion, exemption in planned exposure situations and the application of a screening method for decision making in existing exposure situations.



Note: Prior **justification** should be applied for sources or practices amenable to control.

FIG. 1. The concepts of exclusion, exemption and clearance.

3. ROLES AND RESPONSIBILITIES IN RELATION TO THE EXEMPTION OF PRACTICES AND SOURCES

GOVERNMENT AND REGULATORY BODY

3.1. The responsibilities of the government[4] with regard to protection and safety are set out in Requirement 2 of GSR Part 3 [1]. These include establishing an effective legal and regulatory

[4] Since countries have different legal structures, the use of the term 'government' here is to be understood in a broad sense and is accordingly interchangeable with the term 'State'.

framework for protection and safety and establishing an independent regulatory body with the necessary legal authority, competence and resources.

3.2. The responsibilities of the regulatory body with regard to protection and safety are set out in Requirement 3 of GSR Part 3 [1].

3.3. With regard to the application of the concept of exemption, para. 3.10 of GSR Part 3 [1] states:

> "The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of [GSR Part 3], including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I [of GSR Part 3] or any exemption levels specified by the regulatory body on the basis of these criteria."

3.4. The regulatory body should establish a framework for exemption using the criteria defined in Schedule I of GSR Part 3 [1] as a basis. Within this framework, the regulatory body should provide the criteria for generic exemption and additional information relevant to specific exemptions. For specific exemption, interaction between the person responsible for the source or practice and regulatory body may be necessary for the decision-making process. There may be cases where specific exemptions are granted to product types (see paras 5.3 and 5.13 of this Safety Guide), for which the regulatory body might also liaise with the manufacturer. Such interactions could range from simple information to a complete safety assessment depending on the characteristics of the practice and the requirements of the regulatory body.

3.5. In some cases, the regulatory body may identify certain activities that need to be reviewed in order to make the decision regarding their exemption.

3.6. The regulatory body should ensure that the exemption framework is consistent with the overall regulatory framework for safety and, where appropriate, other regulatory frameworks. With regard to the IAEA Transport Regulations [10], para. I.5 of GSR Part 3 [1] states (references omitted):

> "The IAEA Regulations for the Safe Transport of Radioactive Material do not apply to exempt material or exempt consignments…for which the activity concentration…does not exceed the relevant 'basic radionuclide value' given in the IAEA Transport

Regulations...Usually, such basic radionuclide values are numerically equal to the corresponding exempt activity concentrations or exempt activities given in Table I.1 [of GSR Part 3]."

APPLICANT

3.7. Requirement 4 of GSR Part 3 [1] states that "The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety."

3.8. The person or organization responsible for facilities or activities that involve sources should verify if the practice or source(s) within the practice meet the exemption criteria specified in accordance with Requirement 8 of GSR Part 3 [1]. This might either be verified directly by the applicant, alternatively the regulatory body could be requested to confirm whether the intended practice or source is exempted. For example, following notification, the regulatory body could check where the practice or source is subject to generic exemption and also consider whether specific exemption (based on a safety assessment) is possible.

3.9. The applicant has the following responsibilities in relation to exemption:

(a) To comply with any conditions attached to the exemption, and to periodically verify this compliance;
(b) To conduct an adequate safety assessment commensurate with the potential radiation risk from an intended practice, where such an assessment is requested by the regulatory body before issuing a specific exemption;
(c) To ensure that no modifications or changes are made to the practice or source(s) that would invalidate the exemption or any of the conditions of the exemption;
(d) To inform the regulatory body if any changes to the practice invalidate the exemption and notify, register or license the practice, as appropriate.

4. GENERIC EXEMPTION OF PRACTICES OR SOURCES

4.1. The general criteria for exemption of a practice or a source within a practice from some or all of the requirements of GSR Part 3 are set out in paras. I.1(a) and I.1(b) of GSR Part 3 [1]. These general criteria are subjective in nature and involve value judgements by the government or the regulatory body in establishing a regulatory framework for both generic exemption and specific exemption. The establishment and use of dose criteria for reaching a decision on exemption of a practice (see para. 4.2) assist in achieving a consistent and harmonized approach to the protection of workers and the public from radiation risks.

4.2. For artificial radionuclides, para. I.2 of GSR Part 3 [1] states:

> "A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Standards under the terms of para. I.1(a) provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year."

The phrase "of the order of 10 μSv or less in a year" is intended to be considered as trivial dose. In this context, ICRP Publication 104 [12], uses the phrase "some tens of microSieverts per year"[5]. A lower boundary value of 10 μSv in a year was used for the derivation of generic exemption levels, since an individual could be exposed to more than one exempted source.

4.3. Paragraph 1.2 of GSR Part 3 [1] states that the effective annual dose expected to be incurred by any individual are to be "normally evaluated on the basis of a safety assessment". Although a detailed safety assessment would demonstrate compliance with the dose criteria, it is not always necessary to undertake such an assessment for sources for which exposures are expected to be very

[5] This is intended to cover the range 10–100 μSv in a year (see para.67 of ICRP Publication 104 [12].

low. A list of such sources that are automatically exempted without further consideration (i.e. generic exemption) is provided in para. I.3 of GSR Part 3 [1].

4.4. For automatic exemption without further consideration (i.e. generic exemption), values of total activity (Bq) and activity concentration (Bq/g) for a wide range of radionuclides have been derived (see para. I.2(a) and (b), and Tables I.1 and I.2 of GSR Part 3 [1]). These generic exemption levels have been derived using models based on a set of limiting (bounding) exposure scenarios and conservative calculations (see footnote 59 of GSR Part 3 [1] and Refs [4,11]), taking into account the most relevant exposure pathways (external irradiation, dust inhalation, ingestion and skin contamination).

4.5. In the generic exemption levels, a distinction is made between moderate amounts of material and bulk amounts of material. The term ‘moderate amounts’ refers to “practices involving small scale usage of activity where the quantities involved are at the most of the order of a tonne”: see footnote 58 in GSR Part 3 [1]. The term ‘bulk amounts’ can be taken as quantities of material that are greater than moderate amounts. The phrase “of the order of” should be interpreted in a pragmatic way to allow flexibility for classification of the amount of material as either moderate or bulk when considering the generic exemption levels. Recommendations on the practical application of the generic exemption levels for moderate amounts and bulk amounts of material are provided in paras 4.12–4.22.

4.6. The use of generic exemption levels for making decisions on granting exemption has practical benefits in that they are easy to apply. The use of generic exemption levels also leads to more consistency in decision making and also promotes a harmonized approach to exemption between States.

4.7. In case of surface contaminated items, there are no generic exemption levels specified in Schedule I of GSR Part 3 [1]. Such items should be addressed as cases of specific exemption as described in paras. 5.18 – 5.21.

4.8. There are no generic exemption levels specified in Schedule I of GSR Part 3 [1] for bulk amounts of material containing radionuclides of natural origin: see para. 5.14.

4.9. Bulk amounts of materials should not be interpreted as several moderate amounts for exemption purposes.

4.10. Table 1 summarizes the applicability of the generic exemption levels for moderate or bulk amounts of material with artificial radionuclides or radionuclides of natural origin. For all other cases (e.g. liquids and gases in bulk amounts, surface contaminated items), specific exemption should be considered (see Section 5).

TABLE 1. APPLICABILITY OF THE GENERIC EXEMPTION LEVELS IN GSR PART 3 [1] TO MODERATE AMOUNTS AND TO BULK AMOUNTS OF MATERIAL

Type of radionuclide	Moderate amounts (solids, liquids, gases)	Bulk amounts (solids*)
Artificial radionuclides	Table I.1	Table I.2
Radionuclides of natural origin	Table I.1	Not applicable**

* There are no generic exemption levels specified in GSR part 3 [1] for bulk amounts of liquids or gases. Consequently, exemption should be considered on a case by case basis (specific exemption).

** Exemption is required to be considered on a case by case basis (specific exemption) using a dose criterion of the order of 1 mSv in a year: see para. I.4 of GSR Part 3 [1].

4.11. If a practice involves materials containing radionuclides for which exemption levels are not listed in Tables I.1 or I.2 of GSR Part 3 [1], the applicant and/or the regulatory body may refer to publications (such as Ref. [11]) that provide values for additional radionuclides following the methodologies provided in Refs [4, 13].

GENERIC EXEMPTION LEVELS FOR MODERATE AMOUNTS OF MATERIAL

4.12. The generic exemption levels for moderate amounts of material, in terms of total activity and activity concentration, are presented in Table I.1 of GSR Part 3 [1] and are reproduced in Appendix I. The values were derived using conservative models based on the dose criteria in para. I.2 of GSR Part 3 [1] and rounded to powers of 10 (see footnote 9 of Ref. [4]). The values apply to solids, liquids, and gases [13].

4.13. As stated in para. I.3(a) of GSR Part 3 [1] (footnote omitted), generic exemption may be applied to:

> "Material in a moderate amount for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration as used in the practice does not exceed the applicable exemption level given in Table I.1".

With regard to the total activity on the premises, if there are several locations in a single authorized facility, the total activity within the whole facility should be considered (i.e. each location should not be considered separately). Where a single owner has multiple facilities operating at separate sites, each of these should be considered individually, i.e. as separate premises.

4.14. For material containing a mixture of radionuclides, the exemption levels in Table I.1 are to be used following the summation method described in para. I.7. of GSR Part 3 [1] (see also paras 4.23–4.28 of this Safety Guide).

4.15. In cases where the exemption levels in Tables I.1 and I.2 of GSR Part 3 [1] cannot be met or cannot be applied, the practice or source could still be eligible for specific exemption, as described in Section 5 of this Safety Guide.

GENERIC EXEMPTION LEVELS FOR BULK AMOUNTS OF SOLID MATERIAL

4.16. As stated in para. I.3(b) of GSR Part 3 [1] (footnote omitted), generic exemption may be applied to "Material in bulk amount for which the activity concentration of a given radionuclide of artificial origin used in the practice does not exceed the relevant value given in Table I.2".

4.17. The generic exemption criteria for bulk amounts of solid material and the exemption levels specified in Table I.2 of GSR Part 3 [1] are only applicable to artificial radionuclides. In accordance with para. I.4 of GSR Part 3 [1], exemption of bulk quantities of material containing radionuclides of natural origin is to be considered on a case by case basis (i.e. specific exemption), as described in paras 5.14–5.17 of this Safety Guide.

4.18. For bulk amounts of materials containing artificial radionuclides, the dose criteria stated in para. I.2. of GSR part 3 [1] apply, i.e. the same as for moderate amounts.

4.19. For an intended practice involving bulk amounts of material containing artificial radionuclides, exemption without further consideration (generic exemption) may be granted if the activity concentration is less than or equal to values specified in Table I.2 of GSR Part 3 [1]. Since

the intended practice involves bulk amounts of material (i.e. for which no upper limit on the amount is implied) there are no generic exemption levels in terms of total activity.

4.20. For materials containing a mixture of radionuclides, the exemption levels in Table I.2 are to be used in accordance with the summation method described in para. I.7. of GSR Part 3 [1] (see also paras 4.23–4.28 of this Safety Guide).

4.21. The exemption levels for bulk amounts of solid material in Table I.2 of GSR Part 3 [1] also apply to the clearance of materials without further consideration (see paras 2.14 and 2.15 of this Safety Guide). As such, materials that have been unconditionally cleared may also be exempted, i.e. to prevent from re-entering the system of regulatory control (see also para. 2.12 of this Safety Guide).

4.22. For bulk amounts of liquids and gases, specific exemption should be considered (see Section 5).

GENERIC EXEMPTION LEVELS FOR MIXTURES OF RADIONUCLIDES

4.23. Paragraph I.7 of GSR Part 3 [1] states:

> "exemption of radioactive material containing one or more radionuclides, on the basis of the levels given in Tables I.1…and I.2…[of GSR Part 3], the condition for exemption from some or all of the requirements of [GSR Part 3] is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture (X_m), determined as follows:

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

> "where

> *f*(i) is the fraction of activity or activity concentration, as appropriate, of radionuclide i in the mixture;

X(i) is the applicable exemption level for radionuclide i as given in Table I.1 or Table I.2; and n is the number of radionuclides present."

4.24. As an alternative to the equation in Paragraph I.7 of GSR Part 3 [1], the following formula can be used (weighted summation rule).

$$\sum_{i=1}^{n} \frac{C_i}{EL_i} \leq 1 \quad (1)$$

where C_i is the activity concentration (Bq/g) or total activity (Bq) of the i^{th} radionuclide in the material, EL_i is its corresponding exemption level in the material and n is the number of radionuclides present.

4.25. In the case of bulk amounts of solid material containing a mixture of natural and artificial radionuclides, the summation rule cannot be applied, and therefore a specific exemption should be considered. The dose criteria to be independently complied with are those given in para. I.2 of GSR Part 3 [1] for artificial radionuclides, and in para. I.4 of GSR Part 3 [1] for radionuclides of natural origin.

4.26. In applying the equations in paras 4.23 or 4.24, it is important to take note of the footnotes to Tables I.1 and I.2 of GSR Part 3 [1] regarding parent radionuclides and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered) .

4.27. Any radionuclide in a mixture of radionuclides whose contribution to the weighted summation is negligible can be ignored [14]. For example, radionuclides that together contribute to the weighted summation by less than 0.1 can be ignored.

4.28. Examples of determining exemption for materials containing mixtures of radionuclides are provided in Annex I.

LIMITATIONS OF APPLICABILITY OF GENERIC EXEMPTION LEVELS

4.29. The values in Tables I.1 and I.2 of GSR Part 3 [1] cannot be applied to all existing exposure situations because the concept of generic exemption is only related to planned exposure situations.

However, the values of Tables I.1 and I.2 can be used as screening values in certain cases as described in Section 7.

4.30. For exemption of material in transport in accordance with SSR-6 (Rev. 1) [10], the generic exemption values in Table I.1 of GSR Part 3 [1] are the same as those used in SSR-6 (Rev. 1) [10] and the values in Table I.2 of GSR Part 3 [1] are all lower or equal.

4.31. The values provided in Tables I.1 and I.2 of GSR Part 3 [1] are not intended to be applied to the control of radioactive discharges or to the control of residual radioactive material in the environment: see para. I.9 of GSR Part 3 [1].

DILUTION

4.32. Deliberate dilution of material, as opposed to the dilution that takes place in normal operations (i.e. when radioactivity is not a consideration), to meet the generic exemption levels given in Tables I.1 and I.2 of GSR Part 3 [1] should not be permitted without the prior approval of the regulatory body.

GENERIC EXEMPTION OF PRACTICES USING RADIATION GENERATORS

4.33. As stated in para. I.3(c) of GSR Part 3 [1], the following equipment within a practice is automatically exempted without further consideration from the requirements of GSR Part 3 [1]:

> "Radiation generators of a type approved by the regulatory body, or in the form of an electronic tube, such as a cathode ray tube for the display of visual images, provided that:
>
> (i) They do not in normal operating conditions cause an ambient dose equivalent rate or a directional dose equivalent rate, as appropriate, exceeding 1 μSv/h at a distance of 0.1 m from any accessible surface of the equipment; or
>
> (ii) The maximum energy of the radiation generated is no greater than 5 keV."

4.34. Examples of such radiation generators include electron microscopes, electron beam welders, cathode ray tubes, high voltage electronic rectifiers and voltage regulators, vacuum switches, vacuum capacitors, magnetrons, transmitting tubes, television and image tubes. Additional information can be found in Ref. [12].

4.35. Radiation generators that do not fulfil the conditions in para. I.3(c) of GSR Part 3 [1] might be granted a specific exemption, as described in Section 5.

5. SPECIFIC EXEMPTION OF PRACTICES OR SOURCES

5.1. In accordance with para. I.6 of GSR Part 3 [1], exemptions may be granted subject to conditions specified by the regulatory body (i.e. specific exemption – see para. 2.24 of this Safety Guide). Consequently, if a practice or source within a practice does not meet the criteria for generic exemption, or these criteria cannot be applied, a specific exemption might be considered.

5.2. To qualify for specific exemption, the applicant should demonstrate that the intended practice is justified and meets the general criteria for exemption described in para. I.1(a) and (b) of GSR Part 3 [1]. The regulatory body may decide to grant specific exemption with special consideration of para. I.1(b) of GSR Part 3 [1] and other relevant criteria to show that there would be no benefit in applying regulatory controls. The granting of a specific exemption should be based on a safety assessment that demonstrates compliance with these general criteria for exemption.

5.3. As described in para 3.4, for specific exemption, interaction between the applicant and regulatory body may be necessary. However, there may be certain practices or sources for which no interaction is necessary between the applicant and the regulatory body, for example where consumer products meeting the exemption criteria have been available for many years and the exemption of such products can be included into the regulatory framework without the need for interaction.

SAFETY ASSESSMENT

5.4. A safety assessment is an assessment of all aspects of a practice that are relevant to protection and safety [3]. For the purposes of exemption, it should be an evaluation of the safety of an intended practice or source within a practice, which considers the magnitude of radiation risks, and the adequacy of any safety measures. The assessment of radiation risks in terms of the expected likelihood and magnitude of exposure should consider exposures from normal operation and also

potential exposures from anticipated operational occurrences and accident conditions. Requirements for safety assessment are established in paras. 3.29–3.36 of GSR Part 3 [1].

5.5. In accordance with para. 3.29 of GSR part 3 [1], the person or organization responsible for facilities and activities is required to submit a safety assessment when applying for an authorization.

5.6. A specific safety assessment is usually needed in cases where a decision on specific exemption is to be made, i.e. when generic exemption cannot be applied. Such a safety assessment should demonstrate that the general criteria for exemption in para I.1 of GSR Part 3 [1] are met.

5.7. The regulatory body may impose requirements on the method and structure of the safety assessment used to underpin an application for specific exemption. Examples of this include: a complete characterization and description of the source and/or equipment containing the source (e.g. equipment and source description, function, radionuclide, activity, half-life, chemical and physical form, the number of sources or pieces of equipment to which specific exemption is being applied for); a description of the safety measures (e.g. shielding, containment); a demonstration of the integrity of the source or equipment; a description of the operating conditions and maintenance programme; and an evaluation of doses in normal operation, anticipated operational occurrences and accident conditions.

5.8. With regard to consumer products, recommendations on safety assessment are provided in paras 3.30–3.35 of SSG-36 [7]. In such cases, the scope of the safety assessment should cover the lifetime of the consumer product, including production, storage, transport, use and disposal. Even though certain consumer products may be granted exemption, this normally relates to the end user. As such, the manufacturing of the products may still be under regulatory control, or regulatory control may be considered necessary if the number of consumer products exceeds a certain amount (see para. 3.33 of SSG-36 [7]), for instance in terms of storage, transport, or disposal. There may thus be several limitations or conditions applied to the exemption of consumer products. These limitations and conditions will be based on the underlying safety assessment.

5.9. In general, the safety assessment for specific exemption of a practice (or source or equipment within a practice) should consider all the stages associated with the practice, source or equipment. Based on the results of the safety assessment, the regulatory body should then decide whether to:

(i) grant exemption without further conditions; (ii) grant exemption with specific conditions (e.g. the number of consumer products); (iii) exempt only certain practices within the chain of supply; or (iv) refuse to grant exemption and impose some form of regulatory control.

EXAMPLES OF THE APPLICATION OF SPECIFIC EXEMPTION

Consumer products

5.10. A consumer product is defined as a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale [3].

5.11. SSG-36 [7] provides recommendations on how the provisions for exemption specified in Schedule I of GSR Part 3 [1] should be applied to consumer products. In para 1.1 of SSG-36 [7], the following categories of consumer products are identified:

(a) Products to which small amounts of radionuclides have been added, either for functional reasons or because of their physical or chemical properties;
(b) Equipment capable of generating radiation;
(c) Products that, as a result of being intentionally exposed to radiation, contain activation products.

5.12. As described in SSG-36 [7], consumer products include the following:
(a) Ionization chamber smoke detectors;
(b) Gaseous tritium light devices;
(c) Radioluminous products, such as clocks and watches;
(d) Certain lamps and lamp starters;
(e) Irradiated gemstones;
(f) Thoriated tungsten welding electrodes.

5.13. Some consumer products have been available for many years. For such products, the regulatory body may decide to grant specific exemption without the need for interaction in every

case, by confirming that an overarching safety assessment has been performed and is applicable to all consumer products of the same type.

Bulk amounts of solid material with radionuclides of natural origin

5.14. In accordance with para. 3.4 (a) of GSR Part 3 [1], any practice involving material with activity concentration of any radionuclide in the uranium or thorium decay chain above 1 Bq/g or above 10 Bq/g of ^{40}K is required to be treated as a planned exposure situation.

5.15. Paragraph I.4 of GSR Part 3 [1] (footnote removed) states:

> "For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation."

This dose criterion should be interpreted as being the dose increment as a result of the practice, i.e. in addition to the dose from local background radiation. In addition, the dose criterion of the order of 1 mSv in a year takes into account the dose contributions from the progeny radionuclides in the uranium and thorium decay series, as appropriate, but does not include the exposure due to radon. The phrase "of the order of 1 mSv" should be interpreted in a pragmatic way as including doses in the range 1–3 mSv.

5.16. In addition to a dose criterion of the order of 1 mSv in a year, the general criteria for exemption, especially the need for regulatory control of a practice or source to produce a net benefit (see para. I.1(b) of GSR Part 3 [1]) also need to be considered.

5.17. The regulatory body may take into account several factors in deciding on the exemption of bulk amounts of material containing radionuclides of natural origin. These factors may include: the amount of material involved; the magnitude of the exposures; the prevailing circumstances; societal implications; national or regional factors; past experience with the management of similar situations; and international guidance and good practice elsewhere.

Surface contaminated items

5.18. The models used to derive the exemption levels in terms of activity (Bq) and activity concentration (Bq/g) in Schedule I of GSR Part 3 [1] do not specifically consider surface contaminated items. The exposure pathways from the direct handling, machining and processing of surface contaminated items might differ significantly from those for materials in which the activity is distributed throughout the volume. Consequently, meeting the exemption levels (i.e. in Bq or Bq/g) does not necessarily guarantee that the generic exemption criteria in paras I.1 and I.2 of GSR Part 3 [1] are met. It would be more appropriate to grant specific exemption based on surface contamination levels for such items.

5.19. It is expected that there will be less need to grant exemption for surface contaminated items, i.e. that are intended to be used in a practice compared to material containing radionuclides. However, in cases where exemption of surface contaminated items (contaminated with artificial and/or natural radionuclides) is needed, specific exemption should be granted, i.e. on a case by case basis. In applying for such an exemption, compliance with the general exemption criteria in para. I.1 of GSR Part 3 [1] should be demonstrated by an appropriate safety assessment. This safety assessment should include the following:

(a) The use of a dosimetric model that specifically considers exposures resulting from direct handling, processing or machining of surface contaminated items. Annex II describes examples of dosimetric models for surface contaminated items that can be used for the assessment.
(b) An evaluation of exposures from both fixed and non-fixed (removable) contamination.
(c) A consideration of all relevant exposure pathways that might significantly contribute to exposures, such as the following:
    (i) External exposure from radiation emitted from the surface of contaminated items, including exposure of the skin from direct contact with the items;
    (ii) External exposure from contamination transferred to the skin by handling surface contaminated items;
    (iii) Internal exposures from inhalation of airborne activity resulting from resuspension (i.e. due to handling, machining or processing the items);

(iv) Internal exposures from ingestion of activity as a result of handling surface contaminated items.

5.20. For surface contaminated items with a mixture of radionuclides, the recommendations in paras 4.23–4.28 should be followed.

5.21. The surface contamination values specified in para. 508 of SSR-6 (Rev.1) [10] (i.e. 4 Bq/cm^2 for beta and gamma emitters and low-toxicity alpha emitters and 0.4 Bq/cm^2 for all other alpha emitters, for removable surface contamination) were developed based on a simplified dosimetric model that was constructed for purposes specific to transport. Therefore, an appropriate safety assessment is needed to determine the applicability of these surface contamination values for specific exemption. For many radionuclides and exposure scenarios, most of the existing dosimetric models (see Annex II) indicate that these surface contamination values comply with the general criteria for exemption specified in para. I.2 of GSR Part 3 [1].

Type approved equipment containing radioactive material

5.22. Para. I.6 of GSR Part 3 [1] states:

> "Exemptions may be granted subject to conditions specified by the regulatory body, such as conditions relating to the physical or chemical form of the radioactive material, and to its use or the means of its disposal. In particular, such an exemption may be granted for equipment containing radioactive material that is not otherwise automatically exempted without further consideration from some or all of the requirements of these Standards under para. I.3(a) provided that:
>
> (a) The equipment containing radioactive material is of a type approved by the regulatory body.
>
> (b) The radioactive material:
>
> (i) Is in the form of a sealed source that effectively prevents any contact with the radioactive material and prevents its leakage; or
>
> (ii) Is in the form of an unsealed source in a small amount such as sources used for radioimmunoassay.

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

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

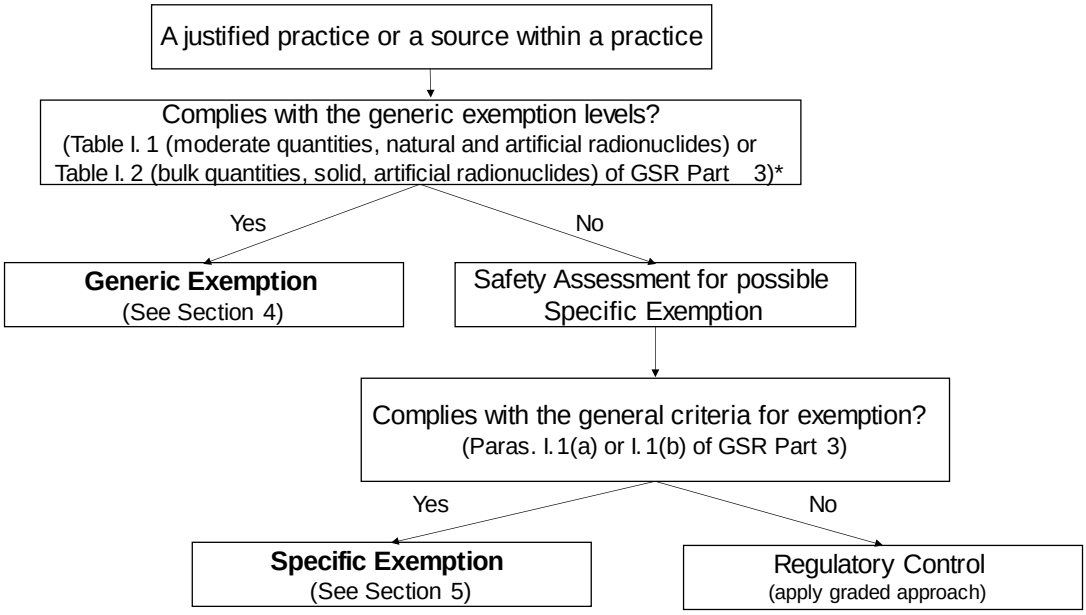
5.23. A safety assessment should be performed to support the initial application for type approval of the equipment, but might not need to repeated for subsequent equipment of a similar type. Typical examples of equipment that "is of a type approved by the regulatory body" includes equipment used in medicine, industry and research such as radioimmunoassay equipment, electron capture detectors and x-ray fluorescence equipment.

Other specific exemptions

5.24. Other practices or sources in practices may be considered on a case by case basis for specific exemption based on a safety assessment. This might include exemptions for bulk amounts of radioactive gases and liquids. The safety assessment should take into account all the relevant exposure pathways, and should demonstrate compliance with the general criteria for exemption specified in para. I.1 of GSR Part 3 [1].

SUMMARY FLOWCHARTS

5.25. Figures 2 and 3 summarize the main steps in granting generic exemption and specific exemption.



*bulk quantities of liquids and gases should be considered as cases of specific exemption

FIG. 2. Flowchart for granting generic exemption and specific exemption (excluding bulk materials containing radionuclides of natural origin).

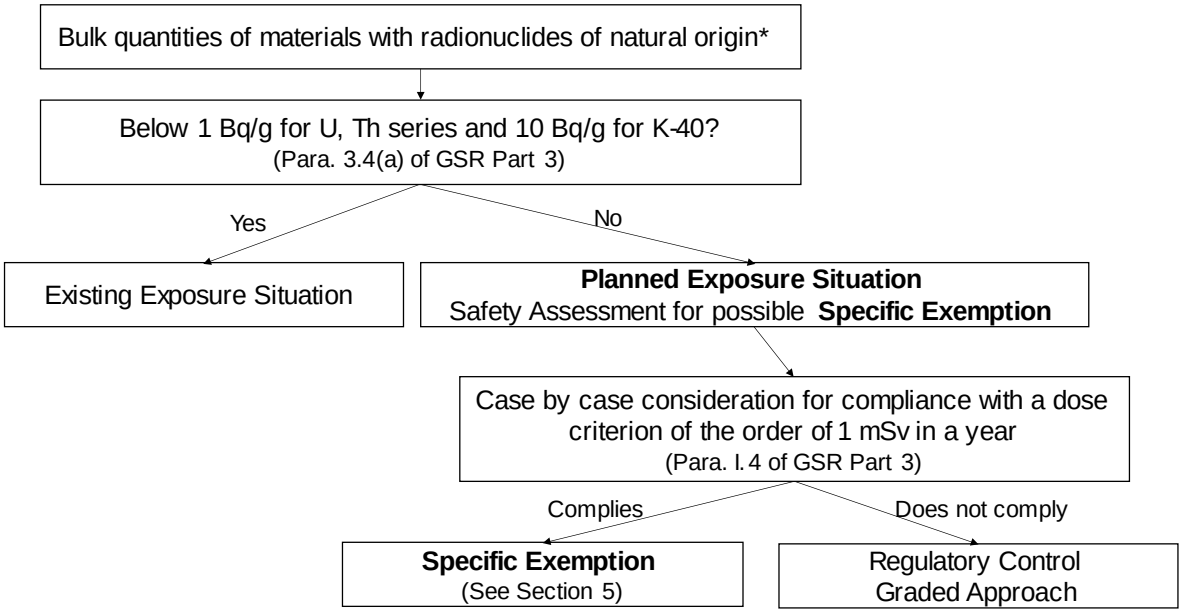


FIG. 3. Flowchart for granting specific exemption for bulk materials with radionuclides of natural origin.

6. VERIFICATION, REVISION AND REVOCATION OF EXEMPTION

VERIFICATION OF COMPLIANCE WITH EXEMPTION LEVELS

6.1. Before applying for exemption or taking any decision on exemption, appropriate measurements should be undertaken. These measurements should enable a reliable comparison with, as appropriate, the generic exemptions levels specified in para. I.3 of GSR Part 3 [1], or criteria for specific exemption established by the regulatory body. To achieve this, the following are needed:

(a) Representative samples or measurements are taken;
(b) The correct measurement and analytical methods are employed;
(c) The desired accuracy and precision of measurements are achieved;
(d) The measurement results are assigned to the correct source, material or type of equipment;

(e) The results are evaluated in accordance with established protocols.

6.2. In the verification process, averaging procedures to ensure representative values of activity or activity concentration should be an integral part of every step and they should be selected in accordance with the type and amount of material, as well as statistical representativeness. Consideration should also be given to the possibility of localized higher activity concentrations within or on the surface of materials.

6.3. Verification should also be conducted on other conditions attached to specific exemption, and in relation to any other circumstances relevant to the application of the exemption.

6.4. Appendix II provides detailed guidance on the verification of compliance with the exemption levels.

REVOKING AND REVISION OF EXEMPTIONS

6.5. It might be necessary for the regulatory body to revoke an exemption, for example when an initially exempted practice or source within a practice is either no longer deemed justified or the original criteria for exemption are withdrawn. Alternatively, the regulatory body might revise an exemption if the original exemption criteria or the conditions attached to a specific exemption are changed. If an exemption was originally granted under specific conditions, one option might be to change these conditions, instead of revoking the exemption.

6.6. If an exemption is revoked, the practice or source within the practice, will no longer be outside the scope of regulatory control; the practice might even be prohibited if it is no longer justified.

6.7. An exemption may be considered to no longer be applicable, for instance if the process of verification of the activity or activity concentration demonstrates that a material does not, in fact, meet the exemption levels. This could be the result of an intended or unintended modification of the practice or source within the practice.

7. THE USE OF SCREENING VALUES IN EXISTING EXPOSURE SITUATIONS

7.1. In accordance with Requirement 8 of GSR Part 3 [1], the concept of exemption is applicable only to planned exposure situations. In existing exposure situations, decisions on optimization of protection and safety are guided by the concept of reference levels, typically expressed as an annual effective dose to the representative person in the range of 1–20 mSv: see para 5.8 of GSR Part 3[1]. Reference levels represent an upper value "above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented" [3]. However, it may also be useful to define a lower boundary below which no further controls are expected to be necessary. Such an 'exemption-like' approach based on screening values is proposed in this Safety Guide for managing certain existing exposure situations. These include supporting long term decision making in an existing exposure situation after the termination of a nuclear or radiological emergency, trade of commodities, and use of construction materials.

7.2. In existing exposure situations, reference levels are required to be used in the optimization of protection and safety: see Requirement 48 of GSR Part 3[1]. They should be used as tools for optimization in defining, selecting, analysing and benchmarking protection strategies. If an exemption-like process in such situations is appropriate, any derived screening levels should be based on dose criteria that are lower than or equal to the selected reference level for the existing exposure situation under consideration In addition, the general criteria for exemption specified in para I.1 of GSR Part 3 [1], should also be taken into consideration. In such cases, an annual effective dose of the order of 1 mSv in a year or less is recommended. This value is consistent with the dose criteria for low probability scenarios for exemption of artificial radionuclides, as well as the dose criteria for specific exemption of bulk amounts of materials containing radionuclides of natural origin. The regulatory body or other competent authority may decide to adopt a different value, depending on the prevailing circumstances.

7.3. For practical application, an approach using screening values expressed in terms of measurable quantities (i.e. derived from the dose criteria described in para. 7.2), is recommended. Such

screening values should be defined by the regulatory body, based on the existing exposure situation to which the values are to be applied.

Existing exposure situations after the termination of a nuclear or radiological emergency

7.4. A large-scale nuclear or radiological emergency involving a significant release of radioactive material to the environment could result in very widespread contamination, including a large quantity of contaminated materials and items. In such cases, it may become appropriate to consider exemptions based on operational screening values established in terms of a measurable quantity, for example activity concentration (Bq/g), or ambient dose equivalent rate (μSv/h). Annex III provides information of the use of screening values for supporting decision making with regard to the management of contaminated materials and items in Japan after the Fukushima Daiichi accident.

Construction materials containing radionuclides of natural origin

7.5. An approach based on screening levels is already used for decision making in relation to construction materials containing radionuclides of natural origin. In particular, an activity concentration index is used as a screening tool for identifying construction materials that might need to be subject to restrictions: see paras 4.17–4.27 of IAEA Safety Series No. SSG-32, Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation [15]. Further information is provided in Annex III.

Trade of commodities

7.6. Commodities used or consumed by the public, such as retail and wholesale goods, foodstuffs and construction materials, might contain radioactive substances. This Safety Guide provides general guidance on the trade of non-food commodities: further supporting technical information is provided in Ref. [6].

7.7. In accordance with para. 5.1 of GSR Part 3 [1], exposure due to commodities that incorporate radionuclides deriving from residual radioactive material (i.e. from past activities not subject to appropriate regulatory control, or following the termination of a nuclear or radiological emergency) should be managed as an existing exposure situation.

7.8. Paragraph 5.22 of GSR Part 3 [1] states:

"The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."

7.9. The regulatory body or other relevant authority is required to consider existing guideline levels for radionuclides in food as a result of a nuclear or radiological emergency, and existing guidelines levels for drinking water: see para. 5.23 of GSR Part 3 [1]. Criteria for radionuclide activity concentrations in food and drinking water (other than in the case of a nuclear or radiological emergency) are provided in Ref. [16].

7.10. Recommendations on adaptation or lifting of restrictions on non-food commodities implemented during the emergency response phase including restrictions on international trade of such commodities are provided in IAEA Safety Standards Series No. GSG-11, Arrangements for the Termination of a Nuclear or Radiological Emergency [17].

7.11. For non-food commodities, radionuclides can either be on the external surface or be distributed throughout the volume of the commodity. The management of trade in such commodities could use a screening-based approach for decision making, as follows:

(a) As a starting point, the values in Table I.1 of GSR Part 3 [1] for moderate amounts of material containing artificial or natural radionuclides, and those in Table I.2 of GSR Part 3 [1] for bulk amounts of solid material containing artificial radionuclides may also serve as corresponding screening values for trade. If measurements demonstrate that activity concentrations are below these levels, trade of non-food commodities can be permitted without further consideration. If activity concentrations in non-food commodities exceed the levels in Table I.1 and Table I.2, this does not necessarily mean that the trade should be restricted. Instead, it indicates that a case by case assessment is needed to determine compliance with specific reference levels, as required by para. 5.22 of GSR Part 3 [1]. This assessment should be based on realistic exposure scenarios.

(b) In the case of bulk amounts of materials with radionuclides of natural origin, a value of 1 Bq/g for each radionuclide in the uranium decay chain or the thorium decay chain and 10

Bq/g for ^{40}K (Table I.3, clearance value) can be used for general screening purposes, although more conservative values may be necessary for building materials. If the measurement results are above these screening values, the requirements established in para. 5.22 of GSR Part 3 [1] are required to be considered.

(c) In the case of non-food commodities with surface contamination, a case by case assessment is needed to determine compliance with specific reference levels, as required by para. 5.22 of GSR Part 3 [1]. This assessment should be based on realistic exposure scenarios and adequate dosimetric models (e.g. see Annex II). As described in para. 5.21, the surface contamination values specified in para. 508 of SSR-6 (Rev. 1) [10] (i.e. 0.4 Bq/cm^2 for alpha emitters, 4 Bq/cm^2 for beta and gamma emitters and low-toxicity alpha emitters) may be considered for use as screening values, where no other options are available, especially where prompt decisions are needed.

7.12. Confirmation that a non-food commodity meets the screening values described in para. 7.11 are met should be obtained at the first point of entry into trade. This does not imply the need for systematic monitoring of all traded commodities in every State, but authorities in exporting States should ensure that a system is established to prevent unauthorised trade of commodities with activity levels exceeding nationally established criteria. In general, it should not be necessary for each importing State to implement 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.

7.13. In cases where there are reasonable grounds for believing that the annual effective dose to the representative person would exceed 1 mSv (see para. 5.22 of GSR Part 3 [1]), the Government might still consider facilitation of trade based on societal, economic or other relevant factors, subject to the requirements in national regulations as well as any flexibility inherent in para. 5.22 of GSR Part 3 [1]. In general, to avoid unnecessary barriers to trade, States should coordinate their regulatory strategies and their implementation, including strategies for monitoring commodities. Arrangements should be made to determine the actual activity concentration levels in commodities either by obtaining the information from the supplier or by monitoring organized by the regulatory body or other relevant authority. Any measurements should be made using appropriate techniques

and with equipment capable of measuring activity concentrations at levels below the values specified (see Appendix II).

7.14. Figure 4 summarizes the main steps in the use of screening values for decision making in trade of non-food commodities.

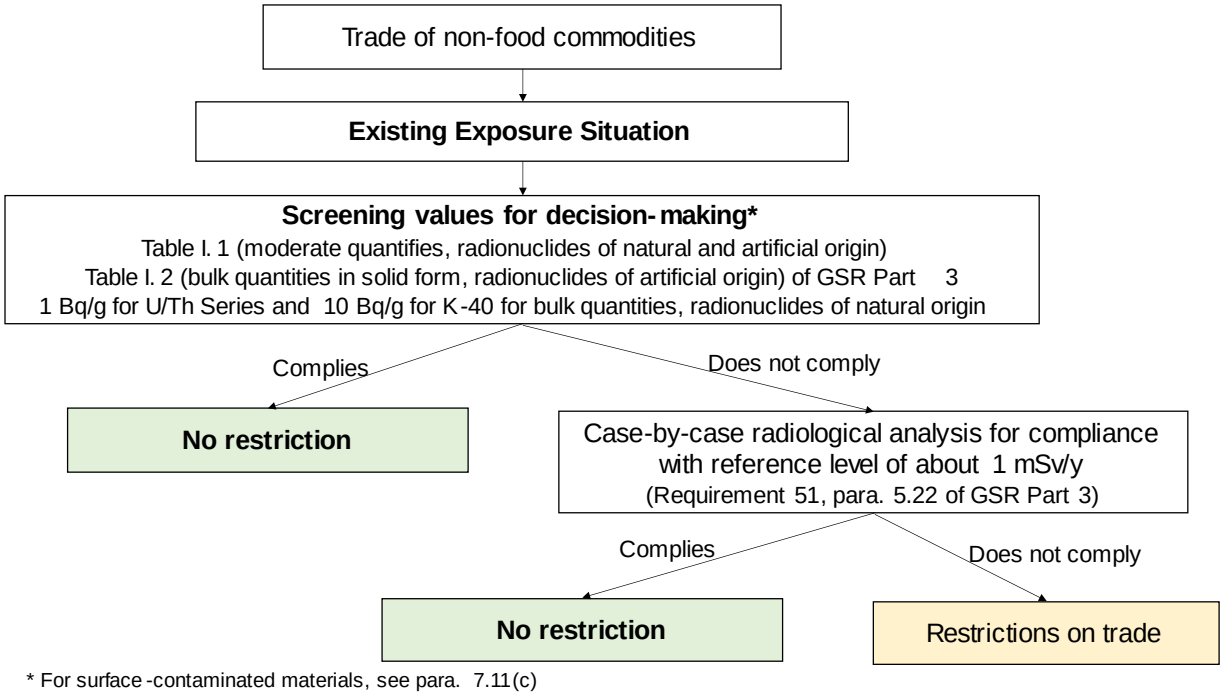


FIG. 4. Flowchart illustrating the use of screening values for decision-making in trade of non-food commodities.

APPENDIX I

EXEMPTION LEVELS FROM SCHEDULE I OF GSR PART 3 [1]

TABLE I.1 LEVELS FOR EXEMPTION OF MODERATE AMOUNTS OF MATERIAL WITHOUT FURTHER CONSIDERATION: EXEMPT ACTIVITY CONCENTRATIONS AND EXEMPT ACTIVITIES OF RADIONUCLIDES

TABLE I.2 LEVELS FOR EXEMPTION OF BULK AMOUNTS OF SOLID MATERIAL WITHOUT FURTHER CONSIDERATION: ACTIVITY CONCENTRATIONS OF RADIONUCLIDES OF ARTIFICIAL ORIGIN

(Note: Tables will be included in the final editing)

APPENDIX II

VERIFICATION OF COMPLIANCE WITH EXEMPTION LEVELS

II.1. For any exempted practice, or source within a practice, monitoring should be considered as a means of demonstrating that the relevant exemption criteria are met.

II.2. The generic exemption levels in Tables I.1 and I.2 of GSR Part 3 [1] are based on the assumption that radionuclides are homogeneously distributed within a material; consequently, in demonstrating compliance with these levels, monitoring should take into account averaging and representativeness. Averaging procedures in determining representative values of activity or activity concentration should be an integral part of every step in a verification process and these procedures should be selected in accordance with the type, nature and amount of material under evaluation as well as statistical representativeness. Consideration should also be given to the possibility of localized areas of concentrated activity (see also paras 4.37–4.40 of DS500 [5]).

II.3. Verification of compliance with the exemption criteria should be based on a procedure that may include direct measurements on the material, source or equipment and/or laboratory based measurements on representative samples of material. Verification should also include, as appropriate, the use of properly derived radionuclide relationships such as secular or transient equilibrium conditions, and adequate traceability of the material and/or samples.

II.4. A graded approach should be applied to the monitoring of sources and materials for verifying compliance with exemption criteria. This approach will, for example, take into account the volume, complexity and homogeneity of the material, and the type of radionuclides and the levels of activity or activity concentration as well as statistical representativeness.

II.5. An organizational structure with clear allocation of responsibilities and adequate resources should be established to plan and conduct monitoring to verify compliance with exemption criteria in a timely and effective manner. The corresponding management arrangements to be considered include the following:

(a) An inventory of the necessary resources, including financial and human resources, and monitoring equipment;
(b) Establishment of a quality management programme;
(c) Establishment of conditions for personnel (including, where appropriate, contractors) with respect to qualifications, expertise and training.

II.6. The following should be specified to assist the process of verification of compliance with exemption criteria:

(a) The number of samples needed to demonstrate compliance;
(b) The number of measurements (and, where appropriate, measurement locations) necessary to demonstrate compliance;
(c) The approach to dealing with mixtures of radionuclides and how to establish correlation factors (see para. II.15);
(d) The approach to dealing with uncertainties and detection limits.

DECIDING ON THE OPTIMUM MEASUREMENT STRATEGY TO VERIFY COMPLIANCE WITH EXEMPTION LEVELS

II.7. An optimum strategy for monitoring for compliance with criteria for exemption should be developed in accordance with the graded approach, taking into factors such as the characteristics of the source or material, monitoring costs and selection of appropriate methods. In deciding on a measurement strategy, the following steps should be considered:

(a) Optimizing the number of samples by grouping materials and aggregating samples. This should be done as uniformly as possible, with samples in a group being representative of the materials for which a decision on exemption is to be made;
(b) Quantitatively assessing mixtures of radionuclides, taking into account information about the history of the material.

II.8. The optimum monitoring strategy also includes the selection of the most suitable measurement methods, the use of appropriately calibrated equipment, and any necessary pretreatment of samples prior to measurement.

II.9. The use of statistically based methods that take into account the degree of homogeneity of radionuclides in a material and the characteristics of the equipment used for measurements can significantly reduce monitoring costs. A material that is very likely to meet exemption levels could be assessed using a simplified monitoring scheme, whereas a material that might approach or exceed these levels may need more extensive monitoring [18]. The decision to apply a simplified monitoring scheme should be based on reliable estimates of the content of radionuclides in the materials.

II.10. For verification of compliance with exemption levels, the following should be ensured:

(a) Samples are collected properly, and they are representative and traceable;
(b) Correct measurement and analytical methods are used;
(c) The measurement results have the necessary accuracy and precision;
(d) The measurement results are assigned to proper material, source or equipment [19].

QUALITY MANAGEMENT TO VERIFY COMPLIANCE WITH EXEMPTION LEVELS

II.11. Quality management is an integral part of the decision-making process for exemption of materials from regulatory control. Assurance of the quality of results ensures and demonstrates that the established criteria have been met, and provides confidence in the monitoring strategy, the techniques and equipment used, sampling and measurement methods, and the analysis and interpretation of results. The implementation of quality management should follow a graded approach that is commensurate with the scope and complexity of the monitoring programme. More details on quality management programmes are provided in Refs [18, 20].

SELECTION OF MONITORING TECHNIQUES TO VERIFY COMPLIANCE WITH EXEMPTION LEVELS

II.12. A monitoring technique consists of monitoring equipment and a corresponding protocol describing its use in either direct or indirect methods. For direct methods, the equipment is used to directly perform measurements on the material, source or equipment; for indirect methods, measurements are performed on secondary media such as wipes or on samples taken from the material.

II.13. Generally, there are three techniques that are used for monitoring purposes: surface scan, bulk measurement or the collection of representative samples that are subsequently analysed in a laboratory. The first two techniques are relatively low-cost and may be sufficient in cases where the composition of radionuclides is known and the key radionuclides are readily measurable. The third technique is usually more expensive but is usually a more precise method of analysing material with a complex mixture of radionuclides.

II.14. Where practicable, a material should be scanned directly to determine which fractions of material are clearly above or below the exemption levels. For radionuclides that cannot be confirmed by the direct measurements, representative sampling should be employed to characterize the material. A monitoring strategy could thus comprise more than one technique [18].

II.15. Typical radioanalytical laboratories will usually be equipped with some or all of the following instruments [19]: gas proportional detectors for alpha and beta counting; scintillation counters (e.g. NaI, LaBr) or HPGe gamma spectrometers for qualitative and quantitative analysis of gamma emitting radionuclides; low-energy gamma or X-ray detectors; solid state detectors for alpha spectrometric measurements; liquid scintillation counters for measurement of alpha and beta emitting radionuclides; and mass spectrometers. More information can be found in Ref. [20].

II.16. For materials containing mixtures of radionuclides, there could be information on the ratios of radionuclides in the ‘correlation factors’. Correlation factors can facilitate the estimation of activity concentrations of radionuclides that cannot be easily detected, such as low-energy beta emitters including ^{3}H, ^{63}Ni and ^{14}C. Monitoring of such radionuclides normally involves laboratory measurements and/or radiochemistry.

II.17. When selecting measurement equipment, considerations should be given on how the compliance with exemption criteria (e.g. in terms of activity concentration), relate to the equipment’s capabilities and to the material’s characteristics. This will depend on the radionuclide(s) and emitted radiation, the distribution of radionuclides within a material or item (throughout the volume or on the surface), and on whether correlation factors can be used. More detailed information on monitoring of surface activity and activity within a material is presented in Refs [18, 20].

MONITORING CHALLENGES IN THE VERIFICATION OF COMPLIANCE WITH EXEMPTION LEVELS

Uncertainties

II.18. Every measurement result should include an estimate of its overall uncertainty, which is based on a complete assessment of the sources of uncertainties. The need for an appropriate uncertainty evaluation is necessary to demonstrate compliance with exemption criteria. The following uncertainties, as appropriate, should be considered before making decisions on exemption:

(a) Uncertainties associated with sampling;
(b) Statistical uncertainties associated with counting, measurements and calibration;
(c) Uncertainties associated with variations in background radiation;
(d) Uncertainties associated with analytical methods;
(e) Uncertainties associated with the characteristics of the material (e.g. volume or mass, homogeneity, mixtures of radionuclides);
(f) Uncertainties associated with correlation factors between radionuclides.

More information can be found in Refs [20, 21].

Sampling

II.19. If a decision on exemption is based on activity concentration measurements on samples of the material, several issues should be addressed to ensure that the measurements provide the information necessary for the decision, such as the following:

(a) Sampling locations: Sampling should cover the regions where the radionuclides are expected to concentrate, while still ensuring that results are representative for exemption purposes.
(b) Number of samples: Increasing the number of samples provides a better estimate of the median value and the standard deviation of the activity concentrations in the material. The minimum number of samples needed for a selected statistical test depends on the type of test, the median value and standard deviation of the activity concentration, and the confidence intervals to be achieved.

(c) Sample size: The minimum sample size should be inferred from the analytical method(s) that will be used, with the aim being to ensure that the detection limit is well below the exemption levels (see para. II.20).

Detection limits

II.20. It should be ensured that monitoring techniques to verify exemption have a detection limit well below the corresponding exemption levels, for example, in terms of activity, activity concentration or dose rate. A detailed description of the concept of detection limits in the monitoring of radioactivity can be found in Ref. [22]. A practical derivation of detection limits, indicating the parameters of interest, is provided in Ref. [19].

Measurement of alpha emitters, beta emitters and low energy gamma emitters

II.21. Measurements of alpha emitters, beta emitters and low-energy gamma emitters are affected by self-absorption, which might lead to an incorrect conclusion that the exemption levels are met. Where self-absorption is expected to be significant, measurement techniques based on radiochemical separation should be used to determine the activity concentration in a material.

Inhomogeneity of radionuclides

II.22. If the presence of radionuclides is inhomogeneous within a material, determining the activity concentration of the material from a single measurement or sample will produce large uncertainties. These uncertainties can be reduced by mixing the material prior to monitoring or sampling, and by performing a larger number of measurements or taking a larger number of samples. The procedures used to identify and mitigate the effects on inhomogeneity should be documented.

II.23. As noted, in para. II.2, averaging procedures should be an integral part of the verification process. If inhomogeneities occur on a scale larger than the averaging mass, volume or area, average concentrations can be calculated relatively accurately, but care should then be taken to ensure that these large-scale variations are adequately identified.

Equipment calibration

II.24. Equipment used to verify compliance with exemption levels should be calibrated under well-defined and controlled conditions. However, conditions during actual monitoring (e.g. temperature, pressure, humidity) can differ from those under calibration conditions. Any such differences should be recognized and, where appropriate, the measurement results should be corrected. Information on the calibration of various types of monitoring equipment is provided in Refs [23–26].

Background activity contribution

II.25. In the interpretation of measurements to verify compliance with exemption levels, the contribution of background radiation should be considered. For subtraction of a representative background, the levels of artificial radionuclides are usually negligible unless the material is from a radiologically contaminated site, and in any case are normally relatively easy to determine. For radionuclides of natural origin, there can be large variations in the local background, even within a specific site; consequently, care should be taken to ensure that any background subtraction is representative. More information is provided in Ref. [18].

Radioactive material with other hazardous properties

II.26. For materials that are radioactive and have other hazardous properties (e.g. radioactively contaminated asbestos), the verification of compliance with the radiological exemption criteria might not be sufficient to grant complete exemption from regulatory control. It may be necessary to involve other regulatory organizations, not just those associated with the radiation safety.

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ANNEX I

EXAMPLES OF DETERMINING EXEMPTION FOR MATERIALS CONTAINING MORE THAN ONE RADIONUCLIDE

I–1. The following two examples show how the exemption criteria can be determined when more than one radionuclide is involved.

EXAMPLE 1

10 kg of a liquid material containing 5×10^4 Bq ^{241}Pu and 9×10^3 Bq ^{241}Am.

The generic exemption levels for moderate amounts of material are specified in Table I.1 of GSR Part 3 [1]. and the weighted summation rules for the activity and activity concentration result in:

Method 1 (see para. 4.23)

Activity:

- $f(^{241}Pu) = 5x10^4/(5x10^4+9x10^3) = 0.85$
- $f(^{241}Am) = 9x10^3/(5x10^4+9x10^3) = 0.15$
- Thus, the derived exemption level for the mixture, $X_m = 1/((0.847/1x10^5)+(0.153/1x10^4)) = 4.2x10^4$ Bq.
- The total activity is $5x10^4 +9x10^3 = 5.9x10^4$ Bq. This exceeds $4.2x10^4$ Bq, thus the exemption level is exceeded.

Activity concentration:

- $f(^{241}Pu) = 5/(5+0.9) = 0.85$
- $f(^{241}Am) = 0.9/(5+0.9) =0.15$
- Thus, the derived exemption level for the mixture, $X_m = 1/((0.847/1x10^2)+(0.153/1x10^0)) = 6.2$ Bq/g.
- Total activity concentration = 5+0.9 = 5.9 Bq/g. This does not exceed 6.2 Bq/g, thus the exemption level is not exceeded.

Method 2 (see para. 4.23):

Activity:

- $5x10^4/1x10^5 + 9x10^3/1x10^4 = 0.5 + 0.9 = 1.4$. This exceeds 1, thus the exemption level is exceeded.

Activity concentration:

- $5/1x10^2 + 0.9/1x10^0 = 0.05 + 0.9 = 0.9$. This does not exceed 1, thus the exemption level is not exceeded.

In either method, one of the two criteria for exemption (i.e. total activity and activity concentration) is met; consequently, the material can be exempted without further consideration (i.e. generic exemption).

EXAMPLE 2

A bulk amount of a solid material containing ^{132}Te at an activity concentration of 0.9 Bq/g and ^{132}I at an activity concentration of 0.9 Bq/g.

For bulk amounts of solid material, the exemption levels are specified in Table I.2 of GSR Part 3 [1].

- Iodine-132 is the progeny of ^{132}Te and, as shown in footnote "a" of Table I.2 of GSR Part 3 [1], does not need to be considered separately. Consequently, only the activity concentration of the parent nuclide ^{132}Te has to be considered.
- The activity concentration of 0.9 Bq/g does not exceed the corresponding exemption level for ^{132}Te of 1 Bq/g from Table I.2. The material is, therefore, exempt without further consideration (i.e. generic exemption).

ANNEX II

EXAMPLES OF DOSIMETRIC MODELS FOR SURFACE CONTAMINATED ITEMS

II–1. This Annex briefly describes several dosimetric models that can be used to assess effective doses resulting from the use, direct handling, processing or machining of surface contaminated items.

European Commission dosimetric model

II–2. Reference [II−1] is a technical document describing the dosimetric model, exposure scenarios and parameters underlying the derivation of surface contamination clearance levels as recommended by the European Commission (Article 31 Group of Experts) and as published in Ref. [II−2]. Even though the methodology is for selecting clearance levels for residual surface contamination on metals (equipment, tools, scrap) arising from the dismantling of nuclear installations, it can be applied more generally to derive effective doses related to surface contamination, including contamination on other solid, non-metallic objects or items.

II–3. The methodology evaluates the effective dose incurred by persons due to total surface contamination (fixed and removable) in two exposure scenarios: the processing of cleared scrap (transport, automated and manual processing); and the reuse of cleared items. The first scenario considers the transport, handling and sorting of cleared scrap, as well as its automated or manual processing and machining, such as pressing, shredding, milling and segmenting (e.g. thermal, sawing, grinding). The second scenario considers exposures from the continued reuse of cleared equipment from an authorized facility, including exposures due to inhalation of radionuclides from cleaning, sanding or scrapping (thermal segmentation) this equipment.

II–4. The exposure scenarios in Ref. [II–1] are constructed such that only the dominating exposure pathway is considered in each conservatively defined sub scenario. This means that the corresponding annual effective dose contributions are considered separately and are not summed to yield a total effective dose (i.e. in contrast to other dosimetric models for surface contamination).

The maximum dose contribution (from all sub scenarios) then determines the limiting value of the surface contamination clearance level. The exposure pathways considered are the skin dose from beta emitters, the external effective dose from gamma emitters, the committed effective dose from inadvertent ingestion, and the committed effective dose from inhalation.

IAEA-CRP dosimetric model

II–5. In 2001, the IAEA initiated a Coordinated Research Project with the objective to review the scientific basis of the limits for removable surface contamination specified in the IAEA Transport Regulations [II−3]. These limits are based on a simple dosimetric model: see paras 580.1 and 580.2 of [II−4]. The findings and conclusions of the project, which also had the task "to develop guidance material for evaluating the radiological significance of surface contamination to workers and the public in the light of state-of-the-art research and technical developments and current transport practices", were published in Ref. [II−5].

II–6. The model in Ref. [II–5] evaluates the occupational dose incurred by transport workers handling various types of surface contaminated package[6], as well as the possible doses received by members of the public during transport operations. The model calculates the total annual effective dose per unit of non-fixed surface contamination (μSv/a per Bq/cm^2) with contributions from skin contamination (transfer of contamination), external exposure from the package surface, inhalation of resuspended activity, and ingestion of activity transferred to the hands (secondary, hand-to-mouth ingestion). The model evaluations are considered to be conservative. The model has since been modified and extended for further use outside the domain of transport [II−6, II−7, II−8].

Dosimetric model by Ogino and Hattori

II–7. The model by Ogino and Hattori [II−8] is based on the IAEA model that was originally developed for transport safety [II−6]. The model was further developed by classifying surface contaminated objects into three general categories with independent flat square areas (m^2): manually handled objects (0.1 m^2); closely handled objects (1 m^2); and remotely handled objects

[6] Packages used for the transport of radioactive material; however, only the exposures from the surface contamination on the outside of these packages are calculated.

(10 m^2). Two scenarios are considered: in the realistic scenario, the surface contamination is assumed to be distributed over one-tenth of the central surface area of each object; in the low probability scenario, the entire surface of the objects is contaminated. The effects of uncertainty associated with the exposure scenarios were also examined using a probabilistic calculation [II−9].

RIVM-SUDOQU dosimetric model

II–8. The RIVM-SUDOQU model [II−6], [II−7] was developed with the aim to assess public exposure and occupational exposure from scenarios related to the handling and use of surface contaminated retail products, items and objects in indoor and outdoor environments. Since consumers may use the same product throughout the year, the removal of activity by resuspension and abrasion is explicitly considered by the dosimetric model. Surface contamination levels thus become time-dependent, being reduced through product use as well as radioactive decay. This is incorporated into the RIVM-SUDOQU model by the use of mass balance equations. The model evaluates the total annual individual effective dose from all exposure pathways per unit of surface contamination (i.e. microSieverts/a per Bq/cm^2) based on the main exposure pathways (external exposure, inhalation, ingestion and skin contamination) for removable, fixed and total contamination levels.

II–9. The RIVM-SUDOQU model can also bypass the mass balance equations, by which it converges towards the IAEA-CRP method in Ref. [II−5]. In this mode, the model can also assess occupational exposure scenarios that are usually characterized by the continuous flow of newly contaminated items for which the mass balance framework is redundant. Furthermore, a small adaptation of the RIVM-SUDOQU model produces the same approach as used in the Ogino and Hattori model [II−8, II−9]. Consequently, the RIVM-SUDOQU model can be used as a benchmark in dosimetric modelling.

II–10. A pilot project also revealed the applicability of the RIVM-SUDOQU model in the derivation of radionuclide-specific surface contamination clearance levels based on deterministic calculations and reuse scenarios relevant to nuclear installations [II−10, II−11]. In a corresponding benchmarking study, several results were compared with those from other dosimetric models for surface contamination, such as the EC model described in paras II–2–II–4. Further development of

the RIVM-SUDOQU model allowed for detailed parameter sensitivity analyses and probabilistic dose evaluations.

RESRAD-BUILD dosimetric model

II–11. The RESRAD-BUILD model [II−12] evaluates the potential radiation doses incurred while working or living inside buildings contaminated with residual radioactivity: on surfaces of floors, walls and ceilings; within building materials (e.g. drywall, concrete, pipes); or accumulated inside the building (e.g. equipment, objects, filters). RESRAD-BUILD is a multi-compartment[7] pathway analysis model that considers two specific types of exposure scenario: building occupancy scenarios; and building renovation scenarios. The first type of scenario usually involves long term, chronic exposures, for example of residents, office workers and industrial workers. In these scenarios, contaminants may become airborne due to normal use and cleaning of the building. In the second type of scenario, involving building decontamination and renovation, exposure to higher contamination levels typically occurs over shorter timescales (compared to building occupancy scenarios) but under controlled conditions. These scenarios include activities such as sanding a floor, chipping concrete and removing or installing drywall.

II–12. A model run can contain up to ten different sources whose geometry can be a volume, surface area, line or a point. By mechanical removal or erosion, source activity becomes airborne and is further analysed by an air quality compartment model. The model run can contain up to ten receptor points for which the total effective dose equivalent is calculated. The exposure pathways considered are: external exposure to radiation from the source; external exposure to radiation from deposited activity on the floor; external exposure from submersion in airborne activity; inhalation of airborne activity; inhalation of radon decay products and tritiated water vapour; inadvertent ingestion of removable activity directly from the source; and inadvertent ingestion of activity deposited on building surfaces. The RESRAD-BUILD computer code can perform both deterministic and probabilistic dose analyses. It has been successfully applied to assess the potential

[7] The building can contain up to three rooms.

dose distribution resulting from surface contamination using indoor occupational exposure scenarios [II−13].

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ANNEX III

EXAMPLES OF SCREENING VALUES APPLIED IN CASES OF EXISTING EXPOSURE SITUATIONS

EXAMPLE 1: SCREENING VALUES APPLIED AFTER THE FUKUSHIMA DIIACHI ACCIDENT

Introduction

III–1. IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [III–1] uses the concept of exemption only within the context of planned exposure situations. However, within the context of the existing exposure situation after the Fukushima Daiichi accident in Japan, certain screening values have been applied for decision making with regard to the management of waste contaminated with radioactive material.

III–2. Following the Fukushima Daiichi accident, the Nuclear Safety Commission of Japan (NSC) issued more than 200 technical advice documents up to 10 September 2012, based on the Act on Special Measures Concerning Nuclear Emergency Preparedness [III–2] that came into effect in 1999 after the JCO criticality accident in Japan. These technical advice documents were developed taking into account ICRP recommendations and the IAEA safety standards.

III–3. For the optimization of protection for a member of the public in the existing exposure situation after the Fukushima Daiichi accident, NSC advised to select an appropriate reference level from the lower part of the 1–20 mSv/a band with the long term objective of a 1 mSv/a reference level, as recommended by ICRP [III–3]. Following this advice, the Government of Japan has set 1 mSv/a as the long term objective for the additional dose to a member of the public.

III–4. With respect to the treatment of contaminated waste generated from the accident, workers at the treatment facility and a member of the public around the facility have been managed so as to keep the additional dose below 1 mSv/a, based on the advice of NSC. Furthermore, NSC has advised to keep the additional dose to a member of the public who lives in the vicinity of the disposal facility after the termination of the institutional control to below 10 μSv/a.

Management of large amounts of contaminated waste

III–5. The Great East Japan Earthquake was one of the most disastrous catastrophes. A large amount of waste was generated by the earthquake and tsunami, and a part of the waste was contaminated by radionuclides released from the Fukushima Daiichi nuclear power plant. To effectively and safely treat the waste, the Ministry of the Environment of Japan set a screening value, in terms of radionuclide activity concentration, to distinguish the waste that can be treated under the conventional law on waste management (i.e. below the screening value) [III–4], from the waste that involves additional radiation protection regulation (i.e. exceeding the screening value), as prescribed by the Act on Special Measures promulgated on 30 August 2011 [III–5].

III–6. In the Act on Special Measures [III–5], the screening value has been set at 8,000 Bq/kg for ^{134}Cs plus ^{137}Cs. It is based on the criterion that the additional dose to a member of the public or a worker will be less than 1 mSv/a. If this screening value is exceeded, the waste is specified as 'Designated Waste', and additional treatment for radiation protection purposes is applied, such as the cement solidification of soot and dust, and periodic measurements of radioactivity in gas and liquids discharged from the facility, in accordance with the Act on Special Measures [III–5]. If below the screening value, the waste is subject to normal waste treatment by local authorities or operators under the conventional law on waste management [III–4]. Fig. III–1 shows the flow diagram for the management of decontamination waste and soil and 'Specified Waste', based on the Act on Special Measures [III–5].

Application of screening values in an existing exposure situation

III–7. GSR Part 3 [III–1] uses the concept of exemption only within the context of planned exposure situations. However, the screening values described in paras II–5 and II–6 can be considered as an example of similar decision making in the context of the existing exposure situation after the Fukushima Daiichi accident. A large amount of waste contaminated with radioactive material already existed when a decision on control had to be taken, and under the prevailing circumstance the screening value for waste (i.e., 8,000 Bq/kg for ^{134}Cs + ^{137}Cs) was set by the regulatory body.

III–8. The IAEA safety standards emphasize the importance of a graded approach in the regulation of facilities and activities. In particular, para. 4.5 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) Governmental, Legal and Regulatory Framework for Safety [III–6] states:

> "The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control".

The screening values applied to the specification of Designated Waste is an example of the implementation of the graded approach using an appropriate activity concentration level for waste.

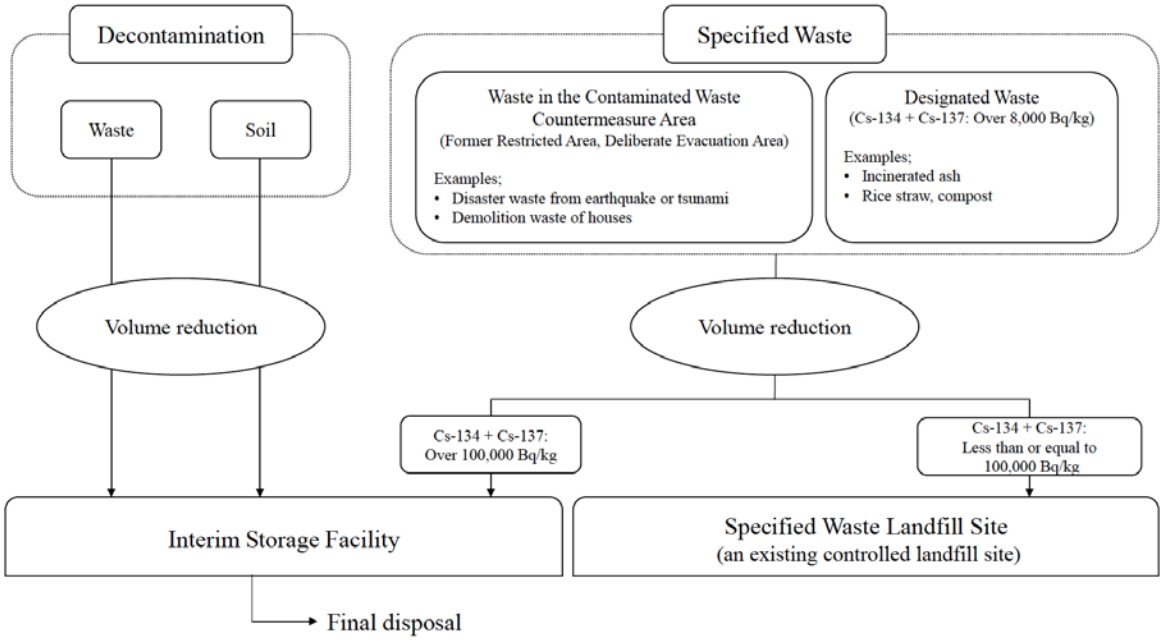

Fig. III–1. Flow diagram for treatment of decontamination waste and soil and Specified Waste based on the Act on Special Measures in Fukushima Prefecture (modified from Ref. [III–7] with permission).

Public perception

III–9. The screening value for waste was derived from a conservative scenario to ensure that the additional exposure remains below 1 mSv/a for a member of the public or a worker during the

treatment of waste, and remains below 10 μSv/a for a member of the public after the termination of institutional control. However, it has not always been accepted that waste at or below the screening value can be treated safely under the relevant standards set by the regulatory body. Some waste treatment operators have set their own waste acceptance criteria below the screening value in consideration of the anxiety expressed local residents, and to help facilitate the treatment of waste.

Screening values for the control of surface contamination

III–10. Large amounts of removed soil and waste generated from decontamination activities have been regulated under the Act on Special Measures [III–5] and safely stored at the Temporary Storage Sites before being transported to the Interim Storage Facility (see Fig. III–1). When the transport vehicle departs daily from the Temporary Storage Sites after unloading the removed soil and waste, the Ordinance by the Ministry of Health, Labour and Welfare of Japan [III–8] requires that the surface contamination level on the vehicle does not exceed 40 Bq/cm^2, which corresponds to 13,000 counts per minute (cpm) assuming the use of a typical Geiger Muller (GM) survey meter with a 50-mm bore, which is widely used in Japan. If the survey meter reading exceeds 13,000 cpm, the surface is decontaminated. Thus, this is an example of a screening value being applied in decision making for the management of surface contamination in an existing exposure situation.

III–11. With respect to the control of surface contaminated objects, guidelines for planned exposure situations, emergency exposure situations and existing exposure situations have been developed by the Standardization Committee on Radiation Protection of the Japan Health Physics Society [III–9]. Table III–1 summarizes the main points of the guidelines. Objects are defined as valuable solid goods for which reuse or recycling has been justified (e.g. vehicles, equipment and the other items), noting that the term commodities is used in the translation of the guideline [III–9]. For the existing exposure situation, the guideline recommends an individual effective dose criteria of less than 1–10 mSv/a, depending on the prevailing circumstance, and gives an example of readings of the typical GM survey meter of 21,000 cpm, corresponding to an annual effective dose criterion of 1 mSv. Therefore, the screening value for the transport vehicle in the Temporary Storage Sites described in para. III–10 satisfies the guideline (i.e. 13,000 cpm < 21,000 cpm), which implies that the additional dose to a member of the public and to workers remains below 1 mSv/a.

TABLE III–1. SUMMARY OF GUIDELINES FOR MOVING OUT OBJECTS CONTAMINATED WITH RADIOACTIVE MATERIAL IN PLANNED EXPOSURE SITUATIONS, EMERGENCY EXPOSURE SITUATIONS AND EXISTING EXPOSURE SITUATIONS (MODIFIED FROM REF. [III–9] WITH PERMISSION).

	Planned Exposure Situation	Emergency Exposure Situation	Existing Exposure Situation
Dose criteria (effective dose)	Order of 10 μSv/a or less	Less than 10 mSv/a	Less than 1–10 mSv/a
Referred concept	Clearance	Generic criterion from IAEA GSR Part 7 [II–10]	Intervention
Basic purpose and concepts	• Moving out from controlled area to general area • Application of the concept of clearance of many relatively small objects moved out	• Moving out from the area where affected by radioactive material released in a nuclear or radiological emergency • Justification and optimization • One tenth of the maximum reference level of 20–100 mSv/a for an emergency exposure situation • An upper bound of 1 mSv/a effective dose for international export	• Moving out from the area affected by a nuclear or radiological emergency or an area in recovery from an accident to a less affected or ordinary area • Justification and optimization • The lower part of 1–20 mSv/a band which is the reference level in existing exposure situation • An upper bound of 1 mSv/a effective dose for international export
Exposure Scenarios	Handling of small packages [II–11] Handling of general objects [II–12]	Handling of spent fuel casks [II–11] Handling of general objects [II–12]	Handling of spent fuel casks [II–11] Handling of general objects [II–12]
Examples of readings of typical GM survey meter widely used in Japan	• 1,000 cpm (10 Bq/cm^2 of ^{60}Co) • 2,300 cpm (10 Bq/cm^2 of ^{137}Cs)	460,000 cpm (1,900 Bq/cm^2 of ^{131}I +19 Bq/cm^2 of ^{134}Cs + 19 Bq/cm^2 of ^{137}Cs)	21,000 cpm (0.44 Bq/cm^2 of ^{131}I + 44 Bq/cm^2 of ^{134}Cs + 44 Bq/cm^2 of ^{137}Cs), corresponding to the annual effective dose criterion of 1 mSv.

EXAMPLE 2: SCREENING VALUES APPLIED FOR CONSTRUCTION MATERIALS

III–13. Building materials[8] and construction materials (hereinafter referred to collectively as construction materials) generally contain some levels of natural or artificial radionuclides. Radionuclide concentrations can depend on the geological origin of the materials and/or can result from (residual) contamination from either authorized or past practices, or from a nuclear or radiological emergency. Identification of construction materials and verification of compliance with Requirement No. 51 of GSR Part 3 [III–1] is not always straightforward. Therefore, the government and the regulatory body can apply certain screening values to aid the decision-making process, as explained in Ref. [III–13].

III–14. Producers and manufacturers of construction materials, and importers, traders and construction companies could be considered the responsible parties at different stages of the life cycle of such materials, and therefore will be responsible for demonstrating compliance with regulations.

III–15. States have adopted various methods to deal with the regulation of construction materials. In accordance with a graded approach, restrictions on the use of construction materials for residential, public, industrial or other purposes could, for instance, be defined on the basis of activity concentration measurements.

III–16. Relevant guidance to characterize and control radioactivity in construction materials can be issued by an appropriate regulatory body or other competent authority in the areas of radiation protection or public health, or as building codes. The guidance needs to establish a means of identifying those construction materials that could lead to doses to members of the public that are higher than the relevant reference level. In addition, the regulations and guidance need to include provisions for measurement quality, record keeping of measurement results and the form and frequency of reporting.

III–17. Paragraph 5.22 of GSR Part 3 [III–1] specifies a reference level in terms of an annual effective dose of about 1 mSv for exposure due to radionuclides in construction materials. The

[8] ‘Building materials’ are construction materials that are used for the construction of buildings such as dwellings, offices, industrial premises and other workplaces.

reference level of about 1 mSv applies only to the dose received from exposure to gamma radiation from the construction materials (i.e. it excludes any additional dose from ^{222}Rn or ^{220}Rn released from these materials into indoor air) [III–14]. Realistic estimation of the annual effective dose to the representative person is complex and generally needs to be performed by radiation protection experts. Therefore, it is common practice to include the use of screening values in the guidance for practical purposes to provide a simpler means of demonstrating compliance with the reference level. Such screening values could involve the establishment and use of the following:

(a) Derived activity concentrations for the radionuclides of interest;

(b) A method for applying an 'activity index' (see para. III–18);

(c) Derived, operational levels expressed in terms of gamma dose rates.

III–18. An activity index is a dimensionless quantity that is derived from measured activity concentrations of radionuclides that might be present in building and construction materials, typically ^{40}K, ^{226}Ra and ^{232}Th. Additional artificial radionuclides might also need to be considered, where appropriate. Screening values can be expressed as an activity index against which the calculated index is to be compared to estimate whether the material complies with the dose reference level. Annexes I and II of Ref. [III–13] provide more guidance on the calculation of the activity index, as well as on measurement methods and dose calculation and modelling, deriving screening values, and on the use of gamma dose rates as operational screening values. (See also section 4 of Ref. [III–14]).

III–19. Where construction materials are not used as a bulk material but, for instance, as a superficial or decorative material, such as in tiles, gypsum board, or granite decorations, a different screening value for the activity index may be applicable. For example, in China, the Czech Republic and Finland, the activity index for such superficial materials differs from the activity index for bulk materials.

III–20. Construction materials exceeding the relevant screening value for the measured or calculated quantity may still be used in a restricted manner or with certain conditions, in accordance with a graded approach. Examples of such conditional provisions in national regulations are provided in annex IV of Ref. [III–13].

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