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Application of the Concept of Exemption

Draft Safety Guide
DS499 (Revision of part of safety guide RSG 1.7)

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FOREWORD

By
Director General

[standard text to be added]

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PREFACE

In 2014, the Agency published the basic safety requirements; *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* (IAEA Safety Standards Series No. GSR Part 3) (the BSS), jointly sponsored by EURATOM, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP and WHO. That publication sets out the requirements that are designed to meet the fundamental safety objective and to apply the principles specified in the Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1).

The establishment of safety requirements and guidance on the concept of exemption is a major component of the support for radiation protection and safety provided by the IAEA to its Member States. The objective of this Safety Guide is to promote an internationally harmonized approach to the concept of exemption, through the development and application of standards for optimizing protection and safety, and to apply the graded approach to regulation.

Guidance on meeting the requirements of the BSS on the concepts of exclusion and exemption is provided in this Safety Guide. It updates part of the guidance given in the previous safety guide: Application of the concept of Exclusion, Exemption and Clearance (IAEA Safety Standards Series No. RS-G-1.7), which is hereby superseded along with a parallel safety guide (DS500) that updates part of the guidance relevant to the concept of clearance. The Safety Guide also provides some guidance to facilitate trade of commodities; however, additional more detailed technical information and guidance on radiation safety in the trade of commodities will be provided in a new Safety Report. In addition, the Safety Guide addresses exemption like approaches using screening levels to support decision making in few existing exposure situations.

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1. INTRODUCTION

BACKGROUND

1.1. The IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1] establishes requirements for protection and safety against exposure to ionizing radiation. These requirements are developed from widely accepted protection and safety principles. Three situations of exposure are identified: 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. There is provision for general requirements for protection and safety that apply, regardless of the type of exposure situation and include requirements concerning the legal and governmental framework. In accordance with these Standards, Exclusion, Exemption and Clearance are important concepts and components in regulatory functions.

1.2. 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 [1].

1.3. 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. Exemption refers to the determination by a regulatory body or government that a source or practice 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 regulatory aspects; or that exemption is the optimum option for protection irrespective of the actual level of the doses or risks. Clearance is the removal of regulatory control by the regulatory body or government from radioactive material or radioactive objects within notified or authorized practices.

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1.4. The 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 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:

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

Detailed guidance of the application of the values of these Tables for exemption purposes are provided in Section 4 and Section 5 of this Safety Guide.

1.5. The exemption values for natural and artificial radionuclides are derived from conservative exposure scenarios. As such, it is important that further conservativism in the application of these values in practice is avoided. It should be noted that scenario-based dose calculations underlying the derived 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 legislation and regulations should be avoided.

1.6. This Safety Guide, together with IAEA Safety Standards Series No. DS500, Application of the Concept of Clearance [2], supersedes the Safety Guide on Application of the Concepts of Exclusion, Exemption and Clearance, issued in 2004.[1]

[1] 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).

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OBJECTIVE

1.7. The 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 guidance on the application of the generic exemption levels contained in Schedule I of GSR Part 3 [1], the application of the concept of case by case exemption (hereinafter termed as specific exemption), as well as the guidance on exemption of surface contaminated commodities[2].

1.8. The Safety Guide also provides guidance on the concept of exclusion and on the application of screening levels for decision making in existing exposure situations including trade (see paragraph 2.11).

1.9. This Safety Guide is mainly intended for Governments and Regulatory Bodies to assist them in the application of the requirements of GSR Part 3 [1] related to the exemption of sources and practices from regulatory control. It will be useful to all those who intend to handle sources or materials containing radionuclides or radiation generators within an already existing or new practice. It will also be of interest to operating organizations.

SCOPE

1.10. This Safety Guide addresses the exemption of practices or sources within practices from regulatory control, as described in Schedule I of GSR Part 3 [1]. It is applicable to any facility or activity for which the concept of exemption is relevant. It also addresses the application of a graded approach to the concept of exemption (generic and specific exemption).

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

[2] Products generally used or consumed by the public, such as retail and wholesale goods, foodstuffs and construction materials, can contain radioactive substances. These products are generally termed 'commodities' in this Safety Guide (see para. 6.13).

1.12. This Safety Guide explains the use of screening levels for decision making in existing exposure situations, in particular, large scale post-accident remedial actions.

1.13. This Safety Guide provides guidance to a generic approach that should be followed relating to international trade of non-food commodities containing radionuclides. Additional detailed technical information on radiation safety in the trade of commodities will be provided in a supporting Safety Report [3].

1.14. This Safety Guide does not address the application of the concept of clearance, which is addressed separately in DS500 [2].

1.15. Recommendations on applying the provisions for exemption given in GSR Part 3 [1] to consumer products containing small amounts of radionuclides, radiation generators and consumer products containing radionuclides as activation products are provided in IAEA Safety Standards Series No. SSG-36, *Radiation Safety for Consumer Products* [4].

1.16. This Safety Guide primarily addresses exemption from regulatory control in planned exposure situations. Although, the use of the concept of exemption is exclusively applicable in planned exposure situations, guidance on the application of screening levels for decision making in managing particular cases of existing exposure situations is also provided. Emergency exposure situations are outside the scope of the Safety Guide, although the relationship between different exposure situations is explained.

1.17. 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 [5].

STRUCTURE

1.18. Following this introductory section, Section 2 gives an overview of the basic definitions and concepts of exclusion, exemption and clearance, with focus on a detailed explanation of the exemption concepts in planned exposure situations, and the application of screening levels for decision making in existing exposure situations. Section 3 addresses the responsibilities of government, regulatory bodies, applicant and other organizational and administrative arrangements.

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1.19. Section 4 and Section 5 provide guidance on the concepts of generic exemption and specific exemption, respectively. Finally, Section 6 addresses other exemption issues such as general practical aspects in monitoring and verification of values for compliance with exemption, revoking or revision of exemption and generic guidance on trade of commodities containing radionuclides.

1.20. Appendix I reproduces Table I.1. and Table I.2. from the GSR Part 3 [1]. Appendix II provides more detailed technical guidance on monitoring and verification of the values including uncertainties. Two annexes provide additional, more detailed information relating to the dosimetric modelling of surface contamination (Annex I) and example of a practical use of screening levels for decision making applied in the management of residual waste material in Japan after Fukushima Daiichi nuclear accident (Annex II).

2. THE CONCEPTS

GENERAL

2.1. The IAEA Safety Standards Series No. GSR Part 3 [1] establish requirements for protection and safety against the risks associated with ionizing radiation exposure. GSR Part 3 cover all exposure situations (para. 2.2) and present the concepts of exclusion, exemption and clearance. These concepts, with special emphasis on the exemption concept, and the relationship between them is put in context and briefly described in this section.

EXPOSURE SITUATIONS

2.2. The Standards [1] have evolved from the previous process-based protection approach using practices and interventions by moving to an approach based on exposure situation. They apply to all sources[3] emitting ionizing radiation that are amenable to control and to individuals exposed to ionizing radiation in the three different types of exposure situation: planned exposure situations, emergency exposure situations and existing exposure situations, as follows [1]:

[3] See the definition of 'Source' in GSR Part 3.

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"(i) 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.

"(ii) 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.

"(iii) 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. The system of radiological protection applies to radionuclides of natural origin and artificial radionuclides and covers all exposures to ionizing radiation from any source, regardless of its size and origin.

2.4. Artificial radionuclides are deliberately produced and/or used in the context of practices and therefore the requirements of planned exposure situations automatically apply. Such practices (or sources/materials within these practices) then enter in the scope of the regulatory system using the graded approach. Within this legal or regulatory framework for planned exposure situations, the concepts of **exemption** and **clearance** apply which further define the scope of the regulatory control.

2.5. For artificial radionuclides, there may, however, be some exceptions to the previous paragraph, e.g. existing exposure situation resulted after nuclear or radiological emergency or global fallout.

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2.6. If radionuclides of natural origin are intentionally used for their functional[4] properties, they should comply with the requirements for planned exposure situations, regardless of their total activity or activity concentration in the material or source. These include production, extraction, storage, and transport of such material. Typical examples of such situations are consumer products (deliberate incorporation) and uranium and thorium mining and processing.

2.7. For other situations, involving radionuclides of natural origin not covered in the previous paragraph, the requirements for planned exposure situation do not always apply. Such exposure situations are usually considered as "existing exposure situations". More specifically, the Standards state that "*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 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*" [GSR Part 3 [1], footnote 60]. Consequently, in these situations specified in para 3.1 of GSR Part 3 where exposures to materials or sources with 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 occur, requirements of planned exposure situations should be applied, based on a graded-approach framework [GSR part 3 [1], para 3.4(a)].

2.8. An exception to paragraph 2.7 is the situation of exposure due to radionuclides in everyday commodities such as food, feed, drinking water, agricultural fertilizer and soil amendments, construction materials and residual radioactive material in the environment. These are treated as existing exposure situations regardless of the type of radionuclide and the involved activity concentrations (GSR Part 3 [1], para 5.1(b), 5.1(c)(ii)).

2.9. Materials containing radionuclides of natural origin *outside* the regime of planned exposure situations (i.e., materials with no deliberate addition or incorporation of radionuclides of natural origin) and with individual radionuclide activity concentrations below 1 Bq/g for nuclides from the uranium and thorium series (separate or in secular equilibrium) and 10 Bq/g for ^{40}K, generally does

[4] Either functional properties of the radioactivity itself, or the functional, physical or chemical properties of the material.

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not require any actions on protection and safety, unless that, in some rare cases, the regulatory body considers that a significant exposure pathway may occur. These activity concentration values were derived on the basis of the concept of exclusion (see para.2.13–2.15), i.e. non-amenability to control exposures, and were selected by considering the upper end of the worldwide distribution of unmodified activity concentrations in soil. These cases should be considered as existing exposure situations and apply relevant requirements (see para 5.1 c(iii) of GSR Part 3). Any other unmodified primordial radionuclides present in nature at (considerably) low activity concentration levels whose contribution is negligible to human exposure (e.g. ^{87}Rb, ^{138}La, ^{147}Sm, ^{176}Lu) is excluded from the requirements of GSR Part 3 [1].

2.10. All aforementioned planned exposure situations within the regulatory framework should be subjected to a graded approach. Exemption defines the 'lowest level' of the graded approach and delineates the boundaries of the scope of regulatory control of planned exposures. Once not exempt, the practice or source within the practice falls within the scope of regulatory control which itself also follows a graded approach based on the (potential) radiological exposures and risks involved (see more in para. 2.25–2.28). Similarly, all aforementioned existing exposure situations described in para.2.5, 2.8 and 2.9 should be subjected to a graded approach and the source of exposure can either be removed from regulatory control via decision making based on screening levels or optimized on the basis of reference levels as appropriate.

2.11. Screening level is defined in this Safety Guide as a certain level (either a dose criterion or a derived (operational) quantity) applied for exemption like approaches in particular existing exposure situations. It is used for decision making above which additional actions from the viewpoint of radiation protection should be considered and below which no further actions are necessary. In this way, the screening level is a radiation-protection tool in existing exposure situations aiding in the decision-making processes in a similar way that exemption level in planned exposure situations.

2.12. Fig. 1 illustrates the concepts of exemption in planned exposure situations and the application of screening levels for decision making in existing exposure situations. In this figure, all information from para 2.1 to para. 2.10 is illustrated, within the scope of an overall regulatory system for planned exposure situation and existing exposure situation and indicated border lines for appropriate regulatory controls.

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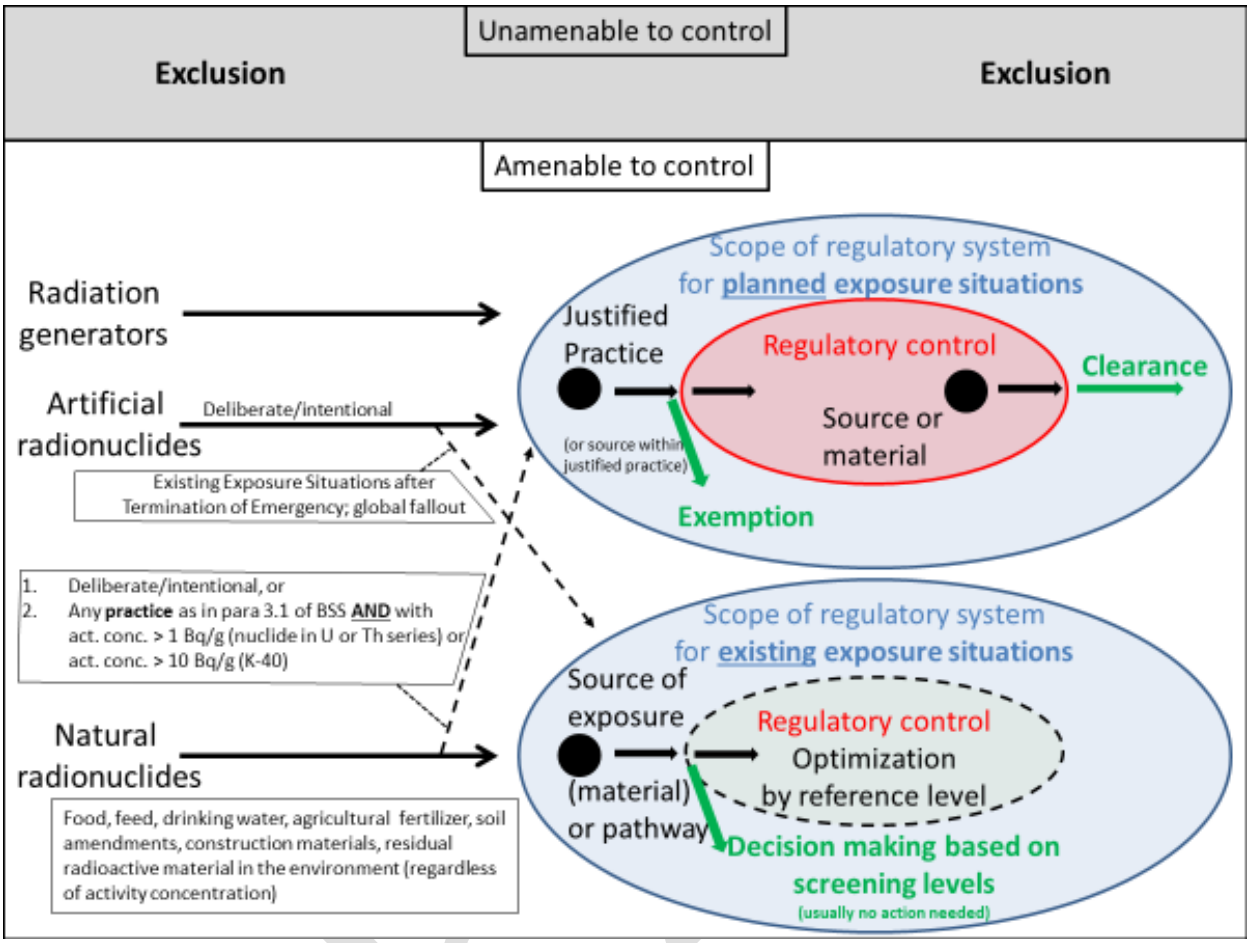

FIG. 1. The concepts of exclusion, exemption and clearance (See para 2.12).

CONCEPT OF EXCLUSION

2.13. According to paragraph 1.42 of GSR Part 3 [1], the requirements of GSR Part 3 apply to all situations involving radiation exposure that are amenable to control. Exposures deemed not to be amenable to control are excluded from the scope of GSR Part 3 and thereby from the scope of an instrument of regulatory control from a radiological point of view.

2.14. For example, it is not feasible or practical to control ^{40}K in the human body or cosmic radiation at the surface of the Earth [Footnote 8, GSR Part 3[1]]. Other examples of excluded exposures are: (a) unmodified soil concentrations (concentrations of radionuclides of natural origin in normal soil material), including unmodified soil concentrations in high natural background

radiation areas, and any other unmodified primordial radionuclides present in nature at (extremely) low activity concentration levels (e.g. ^{87}Rb, ^{138}La, ^{147}Sm, ^{176}Lu), and (b) global fallout resulting from past weapon testing (pre-1960s).

2.15. Excluded exposures are such that control measures are not possible to be taken by means of regulatory action, regardless of their magnitude. Therefore, sources leading to such exposures are, by their nature, excluded from regulatory control and are out of the scope of the requirements of the GSR Part 3 [1].

CONCEPT OF EXEMPTION

2.16. The GSR Part 3 [1] specifies the concept of exemption only in the context of practices within planned exposure situations and sources within these practices.

2.17. 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 on the basis of their meeting certain criteria. In essence, exemption may be considered an approval granted by the regulatory body which, once issued, releases the practice or source from some or all the requirements that would otherwise apply and, in particular, from the requirements related to notification, registration and licensing.

2.18. GSR Part 3, Schedule I, Para. I.1 provides the general criteria for exemption of a justified practice or a source within a justified practice from some or all the requirements of the Standards, as follows:

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."**

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2.19. Criterion (a) refers to both *normal exposures* (*e.g.*, expected exposures under normal operating conditions) and potential exposures (prospectively estimated exposures potentially resulting from an anticipated operational occurrence or accident). In criterion (b), regulatory control may not be justified since it would not lead to any further optimization of protection, irrespective of the actual level of the incurred doses or risks.

2.20. It is to be understood that, in this guidance, exemption from regulatory control solely refers to the radiological aspects of the justified practice or source(s) within the justified practice. This means that regulatory control on the basis of additional, non-radiological (environmental) requirements (and related legislation) may still apply.

CONCEPT OF CLEARANCE

2.21. While exemption is used as part of a process to determine the nature and extent of application of the system of regulatory control, clearance is intended to establish which material under regulatory control can be removed from this control. Therefore, a decision on granting clearance usually takes place *after* the planned activities with a source within a practice, while exemption refers to an a-priori decision instead (para. 2.17). Clearance thereby distinguishes itself from exemption, even though the general criteria on which such a decision is based are very similar (GSR Part 3, paras. I.1, I.10). As with exemption, clearance may be granted by the regulatory body for the release of radioactive or surface-contaminated materials or objects from a justified and (notified or) authorized practice.

2.22. Any *non-radioactive* and *non-contaminated* material, object or item within a notified or authorized practice that becomes or may (gradually) become radioactive or surface-contaminated during the operation of the activities within that practice are implicitly part of the notification and authorization. The release of these materials, objects or items either during the execution of the practice or after its discontinuation then becomes an issue of clearance, *not* exemption. Examples are the activation of materials (including building) and objects in accelerator facilities or in nuclear power plants, or the contamination of objects (*e.g.* at the surface) by handling or spillage of open sources. As the concept of clearance is out of the scope of this Safety Guide, detailed recommendations on clearance of materials and objects from a practice are described separately in the Safety Guide DS500 [2] and will not be discussed further in this guidance.

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Application of justification principle

2.23. 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 that:

"The operation of facilities or the conduct of activities that introduce a new source of radiation, that change exposures or that change the likelihood of exposures has to be justified in the sense that the detriments that may be caused are outweighed by the individual and societal benefits that are expected. 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".

In addition, para 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 over-rides the justification principle.

2.24. Practices deemed not to be justified include those involving the deliberate addition of radioactive substances to food and beverages, for instance, or those involving the unnecessary use of radiation or radioactive substances in commodities or products such as toys and personal jewellery or adornments [1, 6]. On the other hand, a device or manufactured item into which radionuclides have deliberately been incorporated and where the addition of radionuclides has been justified (consumer products) is included as a practice and the concept of exemption may be applicable.

Graded approach

2.25. Paragraph 2.12 of GSR Part 3 [1] provides the basis for the graded approach to the control of exposure:

"*The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.*"

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2.26. GSR Part 3 [1], Requirement 6 states that:

"*The application of the requirements of these Standards 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*".

States should benefit from the application of a graded approach to regulatory control, and with this end, para. 4.5 of IAEA Safety Standards Series GSR Part 1 (Rev 1) Governmental, Legal and Regulatory Framework for Safety [7] also stipulates that:

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

2.27. An important feature of the graded approach in planned exposure situations is the provision for exemption and clearance. 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."

2.28. A graded approach enables an effective use of the often-limited resources of the regulatory body in that greater attention and resources are focused on those practices that represent the more significant exposures and related risks. The graded approach for exemption purposes, is thus consistent with the optimization principle.

Generic and specific exemption

2.29. Activities and practices involving materials for which the generic exemption values (see Section 4) are exceeded need to be considered for placing under regulatory control by the regulatory body. In terms of a graded approach to regulation, however, the regulatory body may still decide that the optimum option is not to apply regulatory requirements. In other words, exemption can be applied generically without further consideration (generic exemption) or by the

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imposition of specific conditions pre-approved by the regulatory body (specific exemption). These conditions can refer to a specific type of practice, to specific requirements under which the activities can take place without further regulatory control, or to a combination of both (more guidance is included in paras. 2.29–2.34).

2.30. The concept of exemption is explained earlier in paras. 2.16–2.20 while the details and practical application of the *generic exemption* concept is described in Section 4.

2.31. Exemptions may also be granted subject to certain conditions established by the regulatory body. This is referred to as *specific exemption (case by case exemption)* in this Safety Guide. These conditions may for instance be related to the material's physical or chemical form, or they may impose restrictions on its use or on its disposal. Specific exemption is dealt with in para. I.6 of GSR Part 3 [1], for instance, for equipment containing radioactive material that is not otherwise automatically exempted without further consideration. There are several other cases of specific exemption, which are described in detail in Section 5, such as;

- Consumer products (para. 2.32 of IAEA Safety Standards Series No. SSG 36 [4]);
- Bulk amounts of solid material with radionuclides of natural origin;
- Surface contaminated commodities;
- Sealed sources, unsealed sources and type-approved equipment.

Regulatory approach for non-exempted justified practices

2.32. In case a justified practice or source within a justified practice does not comply with the generic exemption levels (Appendix I, Tables 1 and 2) and if it does not qualify for specific exemption either, it will enter the regime of regulatory control. Then, the next level of the graded approach is the requirement for the person or organization to submit a formal notification to the regulatory body. Notification could be sufficient for sources or practices where 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 (para. 3.7, GSR Part 3[1]). The conditions for a justified practice to be subject to notification are to be specified by the government or regulatory body. More guidance on the process of notification is

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given in IAEA Safety Standard Series No. GSG-13, Functions and Process of the Regulatory Body for Safety [8].

2.33. Where the level of exposures requires that further obligations need to be placed on the person or organization responsible for the intended practice (*i.e.*, the operator or authorized party), the GSR Part 3 [1] require the application for an authorization. In accordance with the graded approach, the authorization may take the form of either a registration or a license, the essential difference being the stringency of level of regulation and of imposed control measures.

2.34. Practices that pose or that are likely to pose low to moderate radiation risks should be subject to a system of authorization by means of registration [8]. Such authorizations should be accompanied by conditions or limitations (sometimes without any conditions depending on the case) with which the operator (the registrant) is required to comply, but they are unlikely to be as stringent as the conditions stated in licenses.

2.35. Practices that pose or that are likely to pose relatively high radiation risks should be subject to a system of authorization by means of licensing [8]. This requires a detailed safety assessment (see paras. 5.7–5.10) to be carried out by the applicant and submitted to the regulatory body (or other relevant governmental body) [9].

3. ROLES AND RESPONSIBILITIES

GOVERNMENT

3.1. The responsibilities of the government[5] with regard to protection and safety are set out in Requirement 2 (paras. 2.13–2.28) of GSR Part 3 [1]. These include establishing an effective legal and regulatory framework for protection and safety in all exposure situations; establishing legislation that meets specified requirements; establishing an independent regulatory body with the

[5] 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'.

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necessary legal authority, competence and resources; establishing requirements for education and training in protection and safety; ensuring that arrangements are in place for the provision of technical services; education and training services; among others.

3.2. Particularly, for exemption, GSR Part 3 [1] require that "*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…*" (GSR Part 3 [1], Requirement 8).

REGULATORY BODY

3.3. The responsibilities of the regulatory body with regard to protection and safety are set out in Requirement 3 (paras. 2.29–2.38) of GSR Part 3 [1]. In particular, the responsibilities of the regulatory body with regard to exemption in planned exposure situations are set out in para. 3.10 of GSR Part 3 [1]. The Government or regulatory body is responsible for determining and verifying which practices or sources within practices are to be exempted from some or all of the requirements of GSR Part 3 [1] on the basis of the established exemption criteria (Schedule I of GSR Part 3 [1]).

3.4. To meet this requirement, the regulatory body should establish a framework for exemption in accordance with the criteria defined in GSR Part 3 [1]. Guidance for the establishment of this framework is included in this Safety Guide. The regulatory body should apply the graded approach in this framework as explained in paras. 2.25 – 2.28.

3.5. In general, the responsibility of the regulatory body is to ensure that, the derived, defined or imposed exemption levels, should not be in contradiction with other regulatory requirements of both radiological and non-radiological nature. Examples are the requirements laid down in the IAEA Safety Standards Series No.SSR-6 (Rev.1) Regulations for the Safe Transport of Radioactive Material 2018 Edition [10] or in other environmental regulations with corresponding exemption levels.

APPLICANT

3.6. The person or organization responsible for facilities and/or activities that (may) give rise to radiation risks should verify if the practice or source within the practice is automatically exempted

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from regulations or requirements of GSR Part 3 [1], and if not, apply to the regulatory body for possible specific exemption or for other forms of further regulation decided by the regulatory body. More specifically, it should follow Requirement 4 of GSR Part 3 [1] stating 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*" (the authorized party or applicant), and Requirement 9 of GSR Part 3 [1] stating that "*Registrants and licensees shall be responsible for protection and safety in planned exposure situations*".

3.7. In particular, the applicant has the following responsibilities in relation with exemption issues:

- Responsibility of compliance (and periodic verification of compliance) with the specific conditions under which exemption was granted;
- Responsibility for a proper safety assessment commensurate with the possible radiation risk of the intended practice when the generic-exemption instrument cannot be applied;
- Responsibility of assuring that an exempt practice remains exempt during its operation.
- Responsibility to inform the regulatory body about exempt practices or sources within such practices in case modifications or any changes are introduced that could affect the exemption conditions.

ORGANIZATIONAL AND ADMINISTRATIVE ARRANGEMENTS

3.8. The regulatory body should provide the criteria for generic exemption and additional information relevant to specific exemption (case by case exemption). While generic exemption is fulfilled automatically, in a specific exemption, interaction between the applicant and regulatory body may be required for the decision-making process. There may be exemptions where specific exemptions are granted to product types (see paragraphs 5.6 and 5.15).

3.9. Such interaction could vary from simple information provided by the applicant to a complete safety assessment depending on the characteristics of the practice and the requirements of the regulatory body.

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

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4. GENERIC EXEMPTION

INTRODUCTION

4.1. The general criteria for exemption of a practice or a source within a practice from some or all of the requirements of the Standards are set out in paras. I.1(a) and I.1(b) of GSR Part 3 [1].

4.2. The general criteria for exemption stated in GSR Part 3 [1] are subjective in nature and would require value judgements to be made by the regulatory body in establishing a regulatory framework for generic and specific exemption (case by case exemption) of intended practices or sources within practices. In this sense, the establishment of dose criteria for reaching a decision on exemption of a practice assists the regulatory body in achieving a consistent and harmonized approach to the protection of workers and the public from radiation risks.

4.3. GSR Part 3 [1] also require that under all reasonably foreseeable circumstances, the effective annual 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 must comply with the dose criteria specified in para I.2 of GSR Part 3 and explained in this Safety Guide. Although a labour-intensive and time-consuming safety assessment evaluating these annual effective doses would demonstrate compliance with these criteria, it may not always be necessary to undertake such safety assessments considering the low likelihood and small magnitude of exposures. Therefore, generic levels that will lead to automatic exemption of such practices are stipulated in para. I.3 of GSR Part 3 [1].

4.4. To provide quantitative guidance on exemption without further consideration, values of total activity (Bq) and/or activity concentrations (Bq/g) for a wide range of radionuclides have therefore been derived (see Tables I.1, I.2 and para. I.2 of GSR Part 3 [1]), transposing in a practical way the established dose criteria for generic exemption. These generic levels have been derived from dose evaluations based on a set of generalized exposure scenarios and conservative

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calculations [11, 12], taking into account the most relevant exposure pathways (external irradiation, dust inhalation, ingestion and skin contamination).

4.5. In the transposition of the selected dose criteria to total activities and/or activity concentrations, a distinction is made with respect to the amounts of material involved: a) moderate amounts of material, and b) bulk amounts of materials. Here, the term "moderate amount" refers to masses that "*are at the most of the order of a tonne*", and the term "bulk amounts of materials" can be taken as masses that are higher than of the order of 10 tonnes.

4.6. The phrase "of the order of" in para. 4.5 should be interpreted in a pragmatic way to allow flexibility for classification of the amount of material as moderate or bulk when considering the generic exemption levels.

4.7. From a regulatory viewpoint, the existence of derived exemption levels to be used for making decisions on granting exemption has obvious practical benefits in that they are easy to apply. The use of generic exemption levels by regulatory bodies not only leads to more consistency in decision making but also promotes a harmonized exemption approach between States.

4.8. The practical applications of the generic exemption levels for moderate and bulk amounts of material are provided in paras.4.13–4.27.

4.9. In case of surface-contaminated commodities, there are no generic exemption levels. By default, surface-contaminated commodities should be addressed as cases of specific exemption described in Section 5.

4.10. Also, in case of bulk materials with radionuclides of natural origin, there are no generic exemption levels and should be considered as stated in GSR Part 3 [1], para. I.4 "*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*" (see also paragraph 2.9).

4.11. Bulk amounts of materials cannot be interpreted as several moderate amounts for exemption purposes.

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4.12. 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 the other cases not covered in Table 1 (e.g., liquids and gases in bulk amounts, surface-contaminated commodities), specific exemption should be considered (see Section 5).

Table 1. Applicability of the generic exemption levels in GSR Part 3.

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 available (Specific exemption apply**)

* In rare cases, for bulk amounts of liquids and gases, specific exemption is necessarily considered on a case by case basis (see para. 5.28).

** Specific exemption 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 (para. I.4, GSR Part 3 [1]).

GENERIC EXEMPTION LEVELS FOR MODERATE AMOUNTS OF MATERIAL

4.13. For artificial radionuclides and also for radionuclides of natural origin deliberately added to or used in materials, the following dose criteria apply in accordance with para. I.2 of GSR Part 3 [1]:

"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."

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4.14. The phrase "of the order of 10 μSv or less in a year" in para. I.2 of GSR Part 3 should be considered as trivial dose in the context of explanations outlined in ICRP Publication 104 [13], which thus allows for an effective dose of "some tens of microsieverts per year" in justified cases. Although the trivial dose is considered in the range of 10 – 100 μSv/y, the lowest boundary was used for the derivation of generic exemption levels, since an individual may be exposed to several exposure sources over different pathways.

4.15. The generic exemption levels expressed in activity concentrations and total activity are presented in Table I.1 of GSR Part 3 [1] and have been calculated on the basis of scenarios involving moderate amounts of material [11]. The values were derived using conservative models based on the dose criteria described above and rounded following the logarithmic approach (i.e., values rounded to exponents of 10). The scenarios cover solids, liquids, and gases [12].

4.16. According to para. I.3(a) of GSR Part 3 [1], generic exemption applies 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.

Here, the total activity on the premises at any one time should be considered as stated in para. 3.7 "the applicant has the responsibility to inform the regulatory body about exempt practices or sources within such practices in case modifications or any changes are introduced that could affect the exemption conditions". For instance, if there are several workplaces in a single authorized facility, one should consider the premise as the facility itself and should not consider each workplace as one premise. At the same time, if a single owner has multiple facilities operating at different sites below the exemption levels but taken together, they may exceed exemption levels. In this case considering two different exposed populations they can be regarded separately.

4.17. When materials involving mixtures of radionuclides are considered, the exemption levels in Table I.1 should be used following the weighted summation rule and the approaches as described in para. 4.28.

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4.18. In cases where the generic exemption levels in Tables I.1 and I.2 cannot be met, the practice or source could still be eligible for exemption on a case by case basis (see Section 5 for Specific Exemption).

GENERIC EXEMPTION LEVELS FOR BULK AMOUNTS OF SOLID MATERIAL

4.19. According to Paragraph I.3(b) of GSR Part 3 [1], generic exemption applies to: (footnotes omitted)

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.

4.20. The practical application of the exemption criteria for bulk amounts of solid material (and the exemption levels provided in Table I.2) is exclusively applicable for artificial radionuclides. As stated in para. 4.10, there are no generic exemption levels in case of bulk materials with radionuclides of natural origin (i.e., specific exemption (case by case exemption) should be applied, see Section 5).

4.21. For bulk amounts of materials containing artificial radionuclides, the same dose criteria as stated in para. 4.13 for moderate amounts apply.

4.22. In the case of an intended practice involving a bulk amount of material containing artificial radionuclides, exemption *without further consideration* proceeds by means of applying the corresponding activity-concentration values of Table I.2. Since the intended practice now involves bulk amounts of materials, exemption cannot be granted anymore based on compliance with total-activity values (as in Table I.1, column 3). Exemption can thus be granted automatically if the activity concentration of a radionuclide is less than or equal to the corresponding exemption level (Bq/g) in Table I.2.

4.23. For mixtures of radionuclides, the approach how to use the values in Table I.2 is described in para 4.28, following the weighted summation rule.

4.24. The activity-concentration values in Table I.2 for bulk amounts of solids also apply to decisions on granting clearance (from regulatory control) without further consideration. In this

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way, such unconditionally cleared materials do not automatically enter the system of regulatory control again.

4.25. The activity-concentration values for the artificial radionuclides in Table I.2 of GSR Part 3 [1] are derived using a scenario-based approach as described in Safety Reports Series 44 [11]. Generalized, conservative exposure scenarios for both workers and members of the public were constructed to cover all conceivable situations worldwide. The activity-concentration values included in Table I.2 have been determined by the dose criteria as stated in para. 4.13.

4.26. When instances arise in rare cases where materials containing radionuclides for which exemption levels are not available in Tables I.1 and I.2, the applicant and/or regulatory body may refer to the available literature (such as Ref. [14]) that provide values for additional radionuclides extending the calculations following the methodologies provided in Radiation Protection 65 [12] and Safety Report Series 44 [11].

4.27. In the case of bulk amounts of liquids and gases, exemption should be applied on a case-by-case analysis as specific exemption (See Section 5).

GENERIC EXEMPTION LEVELS FOR MIXTURE OF RADIONUCLIDES

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

For exemption of radioactive material containing more than one radionuclide, on the basis of the levels given in Tables I.1 and I.2 of BSS Schedule I, and when these tables are applicable, the condition for exemption from some or all of the requirements of these Standards 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:

$$X_{\mathrm{m}} = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}}$$

where

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

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

As an alternative to the equation above, the following formula can also be used (weighted summation rule).

$$\sum_{i=1}^{n} \frac{C_i}{EL_i} \leq 1 \quad \text{(Eq. 2)}$$

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.

4.29. A decision on generic exemption of a (justified practice with a) material comprising more than one type of radionuclide should take account of the weighted summation rule for the entire mixture of radionuclides in case the exemption levels for the individual radionuclides are based on exposure scenario calculations and dose criteria. The latter is the case for the exemption levels (in Bq and Bq/g) of artificial radionuclides and radionuclides of natural origin listed in Table I.1 (moderate amounts) and of artificial radionuclides listed in Table I.2 (bulk amounts). Compliance with the weighted summation rule ensures that the dose criteria are also met in the case of a mixture of radionuclides. In the case of bulk amounts of solid materials with a mixture of natural and artificial radionuclides, the summation rule cannot be applied, and therefore a specific exemption based on safety assessment should be considered. The dose criteria to be complied with are those given in para. I.2 of GSR Part 3 [1] for artificial radionuclides and para. I.4 of GSR Part 3 [1] for radionuclides of natural origin independently.

4.30. In applying these equations, adequate consideration should be given on footnotes of Table I.1 and Table I.2 GSR Part 3 [1] regarding how to deal with radioactive progeny.

4.31. In Eq. 2, from a practical point of view, a radionuclide whose contribution to the weighted summation is marginal can be neglected [15] in determining exemption level of the material

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containing mixture of radionuclides. For example, radionuclides that together contribute to the weighted summation by less than 0.1 could be excluded.

Examples

4.32. The following two examples provide how the exemption criteria can be determined when more than one radionuclide is involved.

1) A moderate amount (10 kg) of a liquid material containing $5x10^4$ Bq ^{241}Pu at an activity concentration of 5 Bq/g and $9x10^3$ Bq ^{241}Am at an activity concentration of 0.9 Bq/g.

   For moderate amounts the exemption levels can be found in Table I.1, and the weighted summation rules for the activity and activity concentration result in:

   Method-1

   Activity:

   $f(^{241}Pu) = 5x10^4/(5x10^4+9x10^3) = 0.847$, and $f(^{241}Am) = 9x10^3/(5x10^4+9x10^3) = 0.153$

   $X_m = 1/((0.847/1x10^5)+(0.153/1x10^4)) = 4.2x10^4$ Bq exemption level for the mixture.

   Total activity = $5x10^4+9x10^3 = 5.9x10^4$ Bq > $4.2x10^4$ Bq, thus exemption level exceeded.

   Activity concentration:

   $f(^{241}Pu) = 5/(5+0.9) = 0.847$, and $f(^{241}Am) = 0.9/(5+0.9) = 0.153$

   $X_m = 1/((0.847/1x10^2)+(0.153/1x10^0)) = 6.2$ Bq/g = exemption level for the mixture.

   Total activity concentration = 5+0.9 = 5.9 Bq/g < 6.2 Bq/g, thus exemption level not exceeded.

   Method-2:

   Activity: $5x10^4/1x10^5 + 9x10^3/1x10^4 = 0.5 + 0.9 = 1.4 > 1$, thus exceeded.

   Activity concentration: $5/1x10^2 + 0.9/1x10^0 = 0.05 + 0.9 = 0.95 < 1$, not exceeded.

   Conclusion: As one of the two criteria (i.e., total activity, activity concentration) is fulfilled, the materials can be generically exempted.

   Method 1 and 2 are different approaches to the same calculation.

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.

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For bulk amounts of solid materials, the exemption levels can be found in Table I.2. ^{132}Te is the parent nuclide of ^{132}I and from Table I.2 it follows that, for this parent-daughter combination, the daughter nuclide ^{132}I does not need to be considered separately (see footnote "a" of Table I.2 of GSR Part 3 [1] for ^{132}Te). This means that we only have to consider the activity concentration of parent nuclide ^{132}Te. This concentration has a value of 0.9 Bq/g which does not exceed the corresponding exemption level of 1 Bq/g from Table I.2. The material is, therefore, exempt without further consideration.

LIMITATIONS OF APPLICABILITY OF GENERIC EXEMPTION LEVELS

4.33. The values in Tables I.1 and I.2 cannot be automatically applied to existing exposure situations because the concept of exemption is only related to planned exposure situations. Furthermore, these values do not apply to the following cases:

- Material in transport in accordance with the IAEA Transport Regulations SSR-6 (Rev.1) [10];
- Control of radioactive discharges of liquid and airborne effluents (GSR Part 3 [1], para. I.9).

However, the values of Tables I.1 and I.2 can be used as screening levels in particular situations of trade as described in Section 6.

DILUTION

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

GENERIC EXEMPTION OF PRACTICES USING RADIATION GENERATORS

4.35. The following equipment within justified practices are automatically exempted without further consideration from the requirements of the Standards (para. I.3(c) of GSR Part 3 [1]):

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"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.*

4.36. 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 etc. Additional related technical information can be found in ICRP Publication 104 [13].

4.37. Radiation generators that do not fulfill the conditions in para. 4.35, as well as other equipment containing radioactive materials, are either authorized by the regulatory body or the applicant can apply for a specific exemption (case by case) (see Section 5).

5. SPECIFIC EXEMPTION

INTRODUCTION

5.1. In terms of para. I.3 and sub-sections (a), (b) and (c) of GSR Part 3 [1], certain sources within justified practices are automatically exempted without further consideration from the requirements of GSR Part 3, i.e., generic exemption. In case a practice or source within a practice does not comply with these generic automatic exemptions, or they cannot be applied, the applicant can still apply to the regulatory body for a case by case exemption termed as specific exemption. Examples of specific exemption cases include, but are not limited to, bulk amounts of materials with radionuclides of natural origin, surface-contaminated commodities, and certain consumer products.

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5.2. To qualify for specific exemption, a person or organization should demonstrate that the intended practice: (1) is justified and (2) complies with the criteria for general exemption (para. I.1, GSR Part 3 [1]).

5.3. 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 for instance, para I.4 of GSR Part 3[1].

5.4. If a practice or a source within a practice does not qualify for generic nor for specific exemption, it would enter into the domain of regulatory control applying a graded approach.

5.5. Granting specific exemption should be based on a safety assessment for demonstration of compliance with the general exemption criteria (para. I.1, GSR Part 3 [1]).

5.6. There may be instances where no exchange is required between the applicant and the regulator, for example where consumer products meeting the exemption criteria have been available for many years and exemption can be included into the regulatory framework without the need for interaction.

SAFETY ASSESSMENT

5.7. A safety assessment is an evaluation and critical review of all safety-related components of a (intended) practice that influence the protection of humans and the environment. It thus covers the overall evaluation of the safety of a certain practice, facility or activity in terms of, e.g., the magnitude of hazards, radiation risks, or the performance and adequacy of safety barriers or safety measures. Assessment of radiation risks in terms of expected likelihood and magnitude of exposure should not only cover 'normal operation' but should also include foreseeable, potential exposures. The relevant requirements are established in paras. 3.29 to 3.36 of GSR Part 3 [1], describing the various aspects and criteria that should be covered in an appropriate safety assessment.

5.8. A safety assessment by definition is *"An assessment of all aspects of a practice that are relevant to protection and safety; for an authorized facility, this includes siting, design and operation of the facility."* [1]. Safety assessment is typically required when a person or organization applies for a license for a (intended) practice with a relatively high (potential) level of radiation risk. However, a safety assessment is required in case a decision on specific exemption is to be

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made when generic exemption cannot be applied. In addition to the general criteria for exemption (para I.1 of GSR Part 3) with which the safety assessment must comply, the regulatory body may impose certain additional requirements on the underlying safety-evaluation components or on the structure of the assessment. Examples of this could be: complete characterization and description of the device (item description, function, radionuclides, activities, half-lives, chemical and physical form, number of items), a description of the safety barriers (shielding, containment), demonstration of the integrity of the device, description of the operating conditions and maintenance, dose assessment in normal and potential/incident scenarios.

5.9. In specific cases of consumer products, the recommendations on a safety assessment are described in paras. 3.30 to 3.35 of SSG-36 [4]. In such cases, the scope of the safety assessment should cover the full life cycle of the consumer products including their production, storage, transport, and use, as well as their disposal. Even though exemption of the products is granted for their actual use — inasmuch as the general criteria for exemption are met — this does not necessarily imply that the entire chain is exempted automatically. The manufacturing of the products could still be under regulatory control, or regulatory control may still be required if the number of consumer products exceeds a certain amount (for instance for storage, transport, or disposal). There may thus be several limitations or conditions also to the exemption of consumer products. These limitations and conditions will be based on the underlying safety assessment.

5.10. In general, the safety assessment for specific exemption of an intended practice should evaluate and review the safety-related components of all the stages in the chain of the practice. Based on the results presented in the safety assessment, the regulatory body (from their interpretation of the assessment) should then decide (1) to grant unconditional exemption for the intended practice without further consideration, (2) to grant exemption under specific conditions (e.g., the number of consumer products), (3) to exempt only part of the chain of the practice, or (4) to refuse exemption and impose some form of regulatory control. Such a decision should be based on the fulfillment of the general criteria for exemption (para. I.1, or I.4 of GSR Part 3 [1]).

SPECIFIC EXEMPTION CASES

5.11. The following subsections provide guidance on different cases of specific exemptions when generic exemption does not apply.

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Consumer products

5.12. A consumer product is defined in GSR Part 3 as [1]:

"*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*".

5.13. The Safety Guide SSG-36 [4] provides guidance on how the provisions for exemption given in GSR Part 3 [1] are to be applied to consumer products. In para 1.1 of SSG-36 [4], 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 which, as a result of being intentionally exposed to radiation, contain activation products.

5.14. Some of the examples of consumer products are:

- Ionization chamber smoke detectors;
- Gaseous tritium light devices;
- Luminous clocks and watches;
- Certain lamps and lamp starters;
- Irradiated gemstones;
- Thoriated tungsten welding electrodes.

More examples and appropriate regulatory guidance can be found in the Safety Guide SSG-36 [4].

5.15. As some consumer products have been available for many years, the regulatory body may grant specific exemption for certain consumer product types without the need for interaction in every case, and assuming that an overarching safety assessment has been carried out and is applicable to all relevant consumer products.

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Bulk amounts of solid material with radionuclides of natural origin

5.16. As mentioned in para. 2.7, practices involving bulk amounts of solid materials with activity concentration of any radionuclide in the Uranium or Thorium series above 1 Bq/g or activity concentrations of ^{40}K above 10 Bq/g should be treated as planned exposure situations.

5.17. Paragraph I.4 of GSR Part 3 [1] states that:

"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."

5.18. This dose criterion should be interpreted as being dose increment as a result of the practice, over the local background radiation doses. In addition, the dose criterion of the order of 1 mSv in a year takes into account the dose contributions from the progeny radionuclides of U and Th series as appropriate but does not take into account the dose contribution from radon inhalation. The protection and safety against radon inhalation are dealt separately in GSR Part 3 [1].

5.19. The term "of the order of 1 mSv in a year" should be interpreted taking into consideration *"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."* as stated in para. I.1(b) of GSR Part 3 [1].

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

Surface contaminated items

5.21. In cases where contamination occurs near or at a well-defined surface of an item, the health detriment might not be represented well by the exemption levels for the activity in Bq and the activity concentration in Bq/g (Schedule I of GSR Part 3 [1],). Since the exposure pathways for the direct handling, machining and processing of surface-contaminated items may differ significantly

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from those of volumetric contaminations with the activity inside the material, compliance with the mass-based exemption levels (i.e., in Bq/g) does not necessarily guarantee that the general exemption criteria (GSR Part 3 [1], paras. I.1 and I.2) are met. In those cases, it would be more appropriate to grant specific exemption based on surface contamination levels rather than on the mass-based exemption levels.

5.22. Planned activities with surface-contaminated items in intended practices, and hence also their exemption, are not very common and are not expected to occur frequently. However, in the rare case that planned activities with surface-contaminated items with artificial and/or natural radionuclides are intended, *specific* exemption should be granted on a *case-by-case* basis, for which compliance with the general exemption criteria (GSR Part 3 [1], paras. I.1 and I.2) is to be demonstrated by an appropriate safety assessment. This safety assessment should take into account the following:

- An evaluation of the radiological exposures and hazards should be performed using a dosimetric model that is dedicated to or capable of assessing the effective doses resulting from direct handling, processing or machining of radioactively surface-contaminated items. Annex–I briefly describes examples of dosimetric models for surface contamination that can be used for the assessment;
- Proper account should be taken of both fixed and non-fixed (removable) contamination, i.e., the *total* contamination level associated with a certain removable fraction;
- All relevant exposure pathways possibly leading to a significant radiological dose should be taken into account, for instance:
  - external exposure from radiation emitted from the surface of the contaminated items;
  - internal contamination by inhalation of airborne activity resulting from resuspension driven by handling, processing or machining the items;
  - internal contamination by secondary, inadvertent ingestion of activity transferred to hands as a result of handling the items (hand-to-mouth);
  - external exposure by contamination transferred to (and spread over) the skin by handling the items;
  - external exposure of the skin during direct contact with the items.

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– internal contamination from direct ingestion of activity residing on the item's surface (item-to-mouth).

5.23. For a mix of radionuclides, the annual effective dose contributions of all radionuclides are to be regarded and summed to yield the total annual effective dose. In addition, proper or at least conservative account should be taken of the ingrowth of radioactive progeny.

5.24. Surface-contamination values from the IAEA Transport Regulations 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 not constructed for exemption purposes. Therefore, an appropriate safety assessment (see para. 5.22) is needed on the applicability of these surface-contamination values for specific exemption other than for radioactive material transport. For many radionuclides and exposure scenarios, most of the existing dosimetric models (see Annex I) support that these surface-contamination values comply with the general exemption criteria (para. I.2 of Schedule I, GSR Part 3 [1]).

Sealed source, Unsealed source, Type approved equipment

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

"*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."

5.26. A safety assessment should be performed to categorize as "a type approved equipment" for the first time, but there is no need to be performed in subsequent cases of the similar type. The fulfillment of the requirements in para. 5.25 simplifies the process of granting specific exemption without the need to perform an additional safety assessment. Typical examples are equipment used in medicine, industry and research such as radioimmunoassay equipment, radiometric detectors, x-ray fluorescence etc.

Other specific exemption cases

5.27. Any other case not described in paras. 5.12–5.26 should be considered on a case-by-case basis for specific exemption based on a safety assessment. Some examples are:

(a) materials with radionuclides not listed in Tables I.1 and I.2;

(b) in rare cases, liquids and gases in bulk amounts.

5.28. Such safety assessment should be carried out taking into account all the relevant exposure pathways to verify the compliance with the general exemption criteria (Schedule I, GSR Part 3 [1]).

6. VERIFICATION OF COMPLIANCE AND APPROACHES IN EXISTING EXPOSURE SITUATIONS

INTRODUCTION

6.1. This Section provides guidance on other issues relevant to the concept of exemption such as verification of compliance with exemption levels, revoking or revision of exemption and application of an exemption-like approach in existing exposure situations.

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6.2. As per the GSR Part 3 requirements, the exemption concept is applicable in planned exposure situations. However, there are many cases of existing exposure situations where decision on control needs to be taken using the concept of Reference levels (annual effective dose to the representative person in the range of 1 – 20 mSv) (para 5.8 of GSR Part 3[1]). Therefore, an exemption-like approach using screening levels are recommended in this Safety Guide for managing certain cases of existing exposure situations. Examples include a) for supporting decision making in the longer term in an existing exposure situation after the termination of a nuclear or radiological emergency; b) trade of commodities; c) construction materials within the framework of existing exposure situation etc.

6.3. In existing exposure situations, the concept of reference level should be used for a protection strategy in conjunction with the implementation of the optimisation process for exposures. They should be used as tools for optimization in defining, selecting, analysing or benchmarking a certain protection strategy. If an exemption-like process in such situations is necessary, any derived screening level should be based on an underlying, case specific effective dose criterion whose numerical value is smaller than or equal to the selected reference level for the existing exposure situation under consideration. In such cases a value of the order of 1 mSv/y or less is recommended for such dose criterion, considering the band of reference levels for existing exposure situations and adhering to the general criteria for exemption as specified in Schedule I, para I.1 (a) and (b), I.2, I.4 and para 5.22 of GSR Part 3, below which no further optimisation or protective actions may be necessary. The basis for selecting this value of annual dose considers the dose criteria for low-probability scenarios for artificial radionuclides and the dose criteria for specific exemption of bulk amounts of materials containing radionuclides of natural origin where no further protective actions may be necessary as it would yield no net benefit. Hence for practical application, to support decision making, an approach using screening levels of measurable quantities, derived from the above mentioned dose criterion, is recommended. Those screening levels should be defined by the regulatory body based on the existing exposure situation of application.

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PRACTICAL ASPECTS IN THE VERIFICATION OF COMPLIANCE WITH EXEMPTION LEVELS

6.4. Before taking any decision on granting exemption, appropriate measurements should be undertaken. These measurements should enable reliable comparison (i.e., verification of values) with the established exemptions levels or the general exemption criteria. With this aim, it is required that: (a) representative samples are collected; (b) the correct measurement and analytical methods are employed; (c) the desired accuracy and precision of measurements are reached; (d) the measurement results are assigned to proper material, location, weight, length or sample; and (e) the results are evaluated according to established standards.

6.5. In the verification process, averaging procedures in determining representative values of activity or activity concentration should be an integral part of every step and they need to be selected according to the type and amount of material. Consideration should also be given to locations of concentrated activity within or on the surface of the material.

6.6. Verification should also be done on any other conditions and environment specified in which the exemption applies.

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

REVOKING OR REVISION OF EXEMPTION

6.8. Revoking or revision of exemption occurs when an initially exempted practice or source within a practice is either no longer deemed justified or no longer meets the general criteria for exemption (GSR Part 3 [1], Schedule I). The regulatory body can revoke (cancel) or revise the exemption of the practice or source within the practice. In case exemption is revoked, the practice or source within the practice may lose its state of being outside the scope of regulatory control or even be prohibited if no longer justified. Revision of generic or specific exemption refers to a change in the requirements imposed on the practice or source within the practice under which it may remain exempted.

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6.9. Revoking or revision of exemption may for instance occur if verification of the values demonstrates noncompliance with the aforementioned general exemption criteria. This could be the result of an intended or unintended/unforeseen modification of the existing practice or source within the existing practice. If exemption was originally granted under specific conditions, its discontinuation may be avoided by complying to a change in the conditions, i.e., revision of exemption instead of revoking.

SCREENING LEVELS IN SPECIAL CASES

6.10. Although the concept of exemption applies only to planned exposure situations, in some cases within the framework of existing exposure situations, it could be of help for the regulatory body to use some screening levels for decision-making with the same approach as of exemption concept.

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

6.11. For example, in the aftermath of large-scale nuclear or radiological emergency involving significant release of radioactive material to the environment, this would result in contamination of large territories, a large number of contaminated objects (e.g. houses) and radioactive waste as well as conventional waste. In this case it would be appropriate to manage exemptions based on operational screening levels established in terms of measured quantity, for example specific activity (Bq/g), count rate (cpm or cps) or ambient dose equivalent rate (μSv/h). Annex−II provides details of the application of the screening levels for supporting decision making with regard to the management of residual waste generated in Japan after the Fukushima Daiichi accident.

Construction materials

6.12. Similar approach can be used for decision making on the use of construction materials containing radionuclides of natural origin. In this case, an activity concentration index is used as a screening tool for identifying construction materials that might need to be subject to restriction (para. 4.19 of the Safety Guide SSG-32 [16]).

Trade of commodities

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6.13. Products generally used or consumed by the public, such as retail and wholesale goods, foodstuffs and construction materials, can contain radioactive substances. These products are generally termed 'commodities' in this Safety Guide.

6.14. According to para. 5.1 of GSR Part 3 [1], exposures to commodities with presence of artificial radionuclides and radionuclides of natural origin should be managed as existing exposure situations.

6.15. Paragraph 5.22 of GSR Part 3 (Requirement 51) [1] states that:

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.

6.16. In this Safety Guide, general guidance on the trade of non-food commodities is provided, and further supporting technical information will be given in a Safety Report [3]. In line with para 6.14, the radiation protection framework for trade of non-food commodities should be managed as an existing exposure situation irrespective of the origin of the radionuclides in such commodities. In the case of everyday commodities such as food and drinking water, the criteria for radionuclide activity concentrations are provided in the Ref. [17].

6.17. Guidance on adaptation or lifting of restrictions on non-food commodities implemented during the emergency response phase including guidance on adaptation and lifting of restrictions on international trade of such commodities is provided in GSG-11 [18].

6.18. For non-food commodities, radionuclides can either reside on the surface or be distributed throughout the volume of the commodities. Guidance on the management of trade in these commodities using a screening-based approach for decision making is provided as follows.

(a) As a starting point, the values in Table I.1 for moderate amounts of materials with artificial and natural radionuclides and those in Table I.2 for bulk amounts of solid materials with artificial radionuclides may also serve as corresponding screening levels for trade. If measurements are below these levels, trade of non-food commodities can be permitted without further radiological

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consideration. If measurements are above the levels established in Table I.1 and Table I.2, this does not necessarily mean that the trade should be restricted. Further, a case-by-case analysis can be performed at the first point of entry into trade to comply with Requirement 51 (para. 5.22) of GSR Part 3 [1] taking into account 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 screening purposes. If measurements are above these screening levels, Requirement 51 (para. 5.22) of GSR Part 3 [1] should be considered.

(c) In the case of non-food commodities with the presence of radioactivity on the surface, a case-by-case analysis has to be performed at the first point of entry into trade to comply with Requirement 51 (para. 5.22) of GSR Part 3 [1], taking into account realistic exposure scenarios and adequate dosimetric models (e.g., see Annex II). The surface contamination values from the IAEA Transport Regulations (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 for removable surface contamination) may be used as screening levels, where no other options are available, as in many occasions trade requires prompt decisions.

6.19. Confirmation that the screening levels of para. 6.18 are not exceeded 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 States, but authorities in exporting States should ensure that a system is in place 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 set up its own routine measurement programme solely for the purpose of monitoring commodities, particularly if there is confidence in the controls exercised by the exporting state.

6.20. In cases where there are reasonable grounds for believing that the annual effective dose to the representative person (para. 5.22 of GSR Part 3 [1]) exceeds 1 mSv, the Government can still consider facilitation of trade based on societal, economic and other relevant factors, adhering to the requirements in national regulations as well as the flexibility allowed in the Requirement 51 of GSR Part 3. In general, to avoid unnecessary hindrances to trade at boundary transfer points, States should co-ordinate their regulatory strategies and their implementation, including strategies for

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monitoring commodities, with neighbouring States. Arrangements should be made to determine the actual activity levels in commodities either by obtaining the information from the supplier or by monitoring organized by the regulatory body. Any measurements should be made by appropriate techniques and with equipment capable of measuring activity levels at the values specified (see Appendix II).

SUMMARY FLOW CHART

6.21. Fig. 2 and Fig. 3 summarize the key aspects and simple steps in granting generic and specific exemption. Relevant paragraphs should be referred for further understandings.

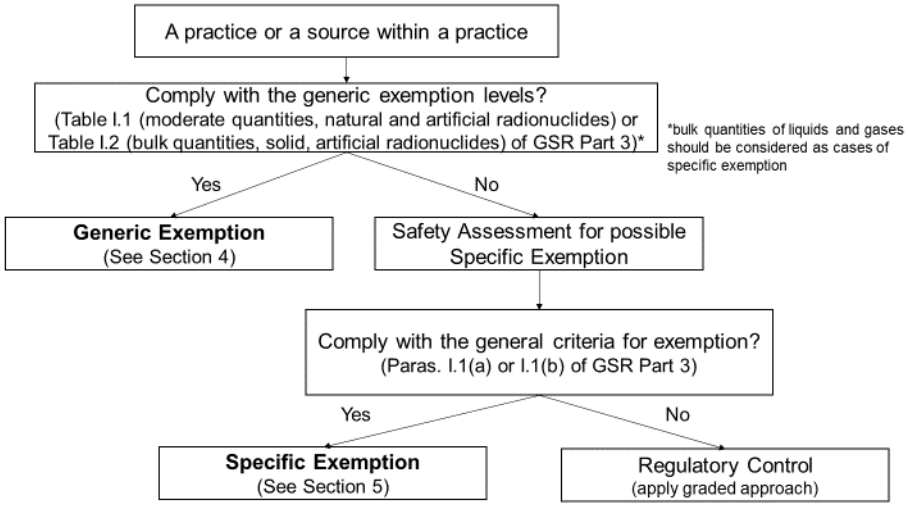

FIG. 2. Flow chart of granting generic exemption and specific exemption.

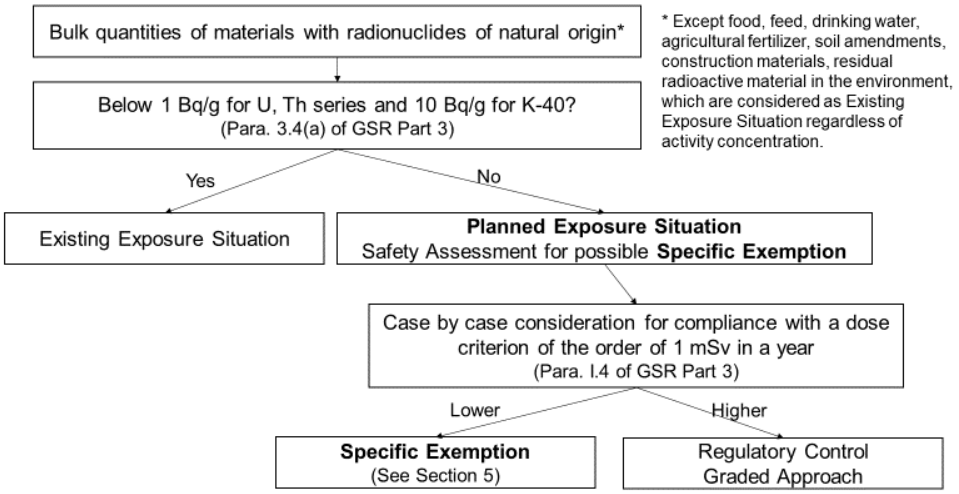

FIG. 3. Flow chart of granting specific exemption for bulk materials with radionuclides of natural origin.

6.22. Fig. 4 summarizes the key aspects and simple steps in the use of screening levels for decision-making in trade of non-food commodities. Relevant paragraphs should be referred for further understandings.

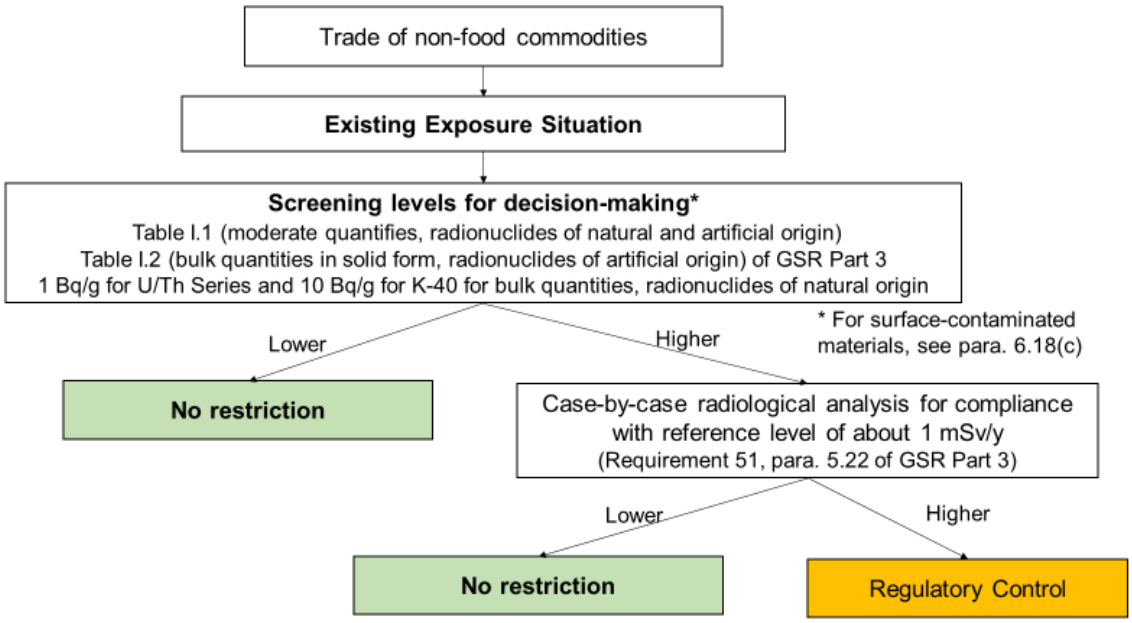

FIG. 4. Flow chart illustrating the use of screening levels for decision-making in trade of non-food commodities.

Appendix I

TABLES OF EXEMPTION

I.1. This Appendix reproduces the Table I.1 and Table I.2 of GSR Part 3 [1]. (pages 111-128 from GSR Part 3)

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)

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Appendix II

VERIFICATION OF COMPLIANCE WITH EXEMPTION LEVELS

GENERAL APPROACH

II.1. For any justified practice or material, adequate monitoring can demonstrate compliance with the exemption criteria. As the generic exemption levels in Tables I.1 and I.2 assume that radionuclides are homogeneously distributed within materials, for compliance with these levels, monitoring should take into account averaging or representativeness of the samples and analysis. Averaging procedures in determining representative values of activity or activity concentration should be an integral part of every step in a verification process and they should be selected according to the type and amount of material under evaluation. Consideration should also be given to locations or areas of concentrated activity.

II.2. Verification of compliance with the exemption criteria should be based on a procedure that may include a) direct measurements on the material, b) laboratory measurements on representative samples, c) the use of properly derived radionuclide relationships, d) adequate traceability of material, including its origin, and e) other means that are acceptable to the regulatory body, by prior approval or by application.

II.3. Consistent with the principle of optimization, a graded approach should be applied to the monitoring of materials for compliance with the exemption criteria. This approach will generally depend on the volume, complexity and homogeneity of the material, and on the type and level of radionuclides.

II.4. In deciding on a measurement strategy, the following steps should be considered:

— to optimize the number of samples by grouping materials. This should be done as uniformly as possible, with samples in a group being representative of the material for which a decision on exemption is to be made;
— to quantitatively assess the mixture of radionuclides, present in the representative material, taking into account the available information about the history of the material.

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II.5. The optimum monitoring strategy then follows from the selection of a proper measurement method using appropriately calibrated techniques and instruments, including any necessary pre-treatment of the samples prior to its analysis.

Management approach

II.6. To plan and conduct monitoring for compliance in a timely and effective manner, the establishment of an organizational structure with clear allocation of responsibilities and adequate resources is required. Corresponding management issues to be considered include:

a) Inventory of available and required resources: financial and human resources, monitoring instruments and organizational structure of the monitoring programme;
b) Establishment of a quality management programme;
c) Establishment of conditions on personnel and/or the contribution of contractors with respect to required expertise and level of training.

II.7. The following activities should be performed to assist the process of verification of compliance with criteria for exemption: specification of number of samples required, estimated number of measurements, measurement locations required to demonstrate compliance, approach to deal with mixtures of radionuclides and how to establish correlation factors and approaches for dealing with uncertainties and detection limits for all measurement techniques.

Deciding on the optimum strategy

II.8. 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 monitoring costs, selection of appropriate methods, and optimization of protection measures.

II.9. Use of statistically based methods that consider carefully defined parameters regarding the homogeneity of the contamination and the instrument-measurement characteristics can significantly reduce monitoring costs. Material with radionuclides that is unlikely to exceed the exemption levels could be subjected to a simplified monitoring scheme, whereas those at levels that may approach or exceed these levels usually require further extended monitoring [19].

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II.10. For verification of compliance, it is needed that: , a) the samples are collected properly, b) correct measurement and analytical methods are employed, c) the required accuracy and precision of measurements are met, d) the results are assigned to proper material, location, weight, length or sample, evaluated according to established standards [20], and consequently, the results of measurements are reliable for proper comparison with the established exemption levels.

QUALITY MANAGEMENT

II.11. Quality management is an integral part of the decision-making process for exemption of materials from regulatory control. Assurance of quality of results ensures and demonstrates that the established criteria have been met, and provides confidence in the obtained data, employed techniques and equipment, monitoring strategy, sampling and measurement method, and analysis and interpretation of results. The degree of quality-management implementation should follow a graded approach, i.e., being commensurate with the scope and complexity of the monitoring process. More details on quality management programs are presented in SRS-67 [19] and NUREG-1576 [21].

SELECTION OF MONITORING TECHNIQUES AND INSTRUMENTS

II.12. A monitoring technique is a tool used in the monitoring strategy to facilitate the process of verification of compliance with exemption levels. It consists of a selected monitoring instrument and a corresponding protocol describing its use in both direct and indirect measurements. For direct methods, the instrument is used to directly measure the material, while for indirect methods measurements are performed on secondary media or samples (e.g. swipes), transferred or taken from the material.

II.13. Generally, three techniques are selected for monitoring purposes: surface scan, bulk measurement and sample collection with subsequent laboratory analysis. The first two, direct techniques are relatively low-cost and may involve reasonably precise methods if the composition of radionuclides is known and if they are readily measurable. The third, indirect technique is usually more expensive but also more precise, enabling the determination of the radionuclide composition.

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II.14. First, a material should be scanned directly to determine which fractions of material are clearly above or below the exemption levels. For any fraction of material that cannot be confirmed by the direct measurements, further indirect monitoring techniques can be employed to characterize the material. A monitoring strategy could thus comprise more than one technique [19].

II.15. Indirect laboratory analyses of samples taken as part of the monitoring program should always be conducted within an appropriate quality management system to assure traceable, accurate, representative, reproducible and defensible results.

II.16. Typical radioanalytical laboratories will usually be equipped with some or all of the following instruments [20]: 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 both alpha and beta emitting radionuclides; and Mass spectrometers. More information can be found in NUREG-1576 (MARLAP) [21].

Mixtures of radionuclides

II.17. For some materials there could be information on the ratios of radionuclides in the corresponding mixture, the so-called correlation factors. Correlation factors can allow the estimation of activity concentrations of radionuclides that cannot be easily detected. These include low-energy beta emitters that neither emit energetic beta particles nor photons in their nuclear transformations (e.g., ^{3}H, ^{63}Ni, ^{14}C). Monitoring of such radionuclides normally requires laboratory measurements and/or radiochemistry.

Selection of instrument

II.18. When selecting an appropriate monitoring instrument and technique, considerations should be given on how the compliance with exemption criteria that are to be verified (e.g. the activity-concentration values), relate to the instruments' capabilities and to the material's characteristics. This will depend on e.g. the type of radionuclide(s) and emitted radiation, the type of contamination

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(volume/bulk or surface), and on whether correlation factors can be used. More detailed information on monitoring of surface or mass concentration is presented in references [19, 21].

MONITORING CHALLENGES

Uncertainties

II.19. Every measurement result should include an estimate of its overall uncertainty, which is based on a complete assessment of sources of uncertainties. The need for an appropriate uncertainty evaluation is crucial to comply with the exemption criteria.

II.20. Monitoring of material for exemption purposes is inherently accompanied by many sources of uncertainty that need to be taken into account. The following uncertainties, not limited to, should be practically considered while making decisions on granting exemption:

a) Sampling;
b) Statistical uncertainties in counting, measurements and calibration;
c) Variation in background radiation;
d) Uncertainties in analytical methods;
e) Characteristics of the material (e.g., material volumes or masses, homogeneity, mix of radionuclides);
f) Uncertainties associated with correlation factors between radionuclides, if needed.

More information can be found in NUREG-1576 (MARLAP) [21] and ISO/IEC Guide 98-3 [22].

Sampling

II.21. If a decision on exemption is based on the assessment of activity concentrations by performing measurements on samples of the material (indirect technique), several issues should be addressed to ensure that they provide the information necessary for the decision, such as:

a) Sampling positions: Sampling should cover the regions where the radionuclides are expected to concentrate, and should be representative;

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 required for a statistical compliance test depends on the type

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of test, the median value and the standard deviation of the activity concentration and the imposed confidence levels (limits on the decision errors);

c) Sample size: The minimum sample size is inferred from the analytical method(s) that will be used, with the requirement to provide a signal in the detection system well above the detection limit.

Minimum detectable activity

II.22. It should be demonstrated that the employed instrument and monitoring technique has a minimum detectable activity (MDA) well below the corresponding exemption value(s), for example, activity concentration values. Only then, the instrument and monitoring technique together are capable of demonstrating, with an acceptable level of confidence, that the material meets the criteria for exemption. Consequently, MDA values should be determined for any instrument and monitoring technique. A detailed description of the concept of detection limits in the monitoring of radioactivity can be found in ISO 11929 [23] and SRS-64 [20]. A practical derivation of detection limits, indicating the parameters of interest are described in SRS-64 [20].

Alpha, beta and low energy gamma emitters

II.23. Alpha, beta and low-energy gamma emitters may be difficult to measure if their presence does not reside at the surface of the material. This is caused by the fact that radiation emitted from within the material is shielded by the material itself (self-absorption) and thereby remains undetected. The significance of this effect is most pronounced for alpha and low-energy beta particles due to their very short range in the material. If the presence of radionuclides is entrained within a material or within particles or fragments, only the activity on or close to the surface can be detected efficiently (if the surface is clean of dust, dirt, grease and grime) which may lead to the incorrect conclusion that the exemption levels are met.

Non-homogeneity

II.24. If the presence of radionuclides is non-homogeneous within the averaging mass, volume or area, average activity concentrations determined from any single measurement can lead to (large) uncertainties as the outcome may strongly depend on how the measurement was performed. These

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uncertainties can be reduced by homogenizing by physical mixing of the material prior to monitoring; performing a larger number of measurements to partially account for non-homogeneity of the material; and using longer counting times.

II.25. If non-homogeneities occur on a scale (much) larger than the averaging mass, volume or area, average concentrations can be calculated relatively accurately, but care must then be taken that these large-scale variations in the activity concentrations are adequately detected.

Instrumental calibration

II.26. Instruments are typically calibrated under well-defined, specific and controlled circumstances. However, conditions during actual monitoring can differ significantly from these calibration conditions. Depending on the instrument, the radionuclide of interest, the source's geometry, the prevailing ambient conditions (temperature, pressure) and potentially other factors, instrument readings during monitoring could therefore differ significantly from those under calibration conditions. Such differences should be recognized and understood for a correct interpretation and evaluation of the monitoring results.

II.27. Information on proper calibration of various types of instrumentation can be found in SRS-16 [24], ISO 7503-2 [25], DOE guide [26] and ISO-17025 [27].

Background activity contribution

II.28. In the interpretation of the output of the measurement, the contribution of the background radiation should be considered. More information can be found in SRS-67 [19].

Mixed hazardous and radioactive material

II.29. Materials with the presence of both radioactive and other hazardous substances, e.g. radioactively contaminated asbestos, require special attention. Consequently, verification of compliance with the radiological exemption criteria then may not be sufficient to grant exemption (without further consideration) of the practice. This requires the involvement of all relevant regulatory bodies, not just those associated with the radioactive aspects. Monitoring of such materials, including the corresponding strategy to protect personnel, should recognize and take

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account of all involved health hazards, which imposes conditions on training, education and equipment to work safely with these materials. In general, the radiological aspects of the protection strategy may be integrated in the overall protection strategy.

Representativeness of results

II.30. In conclusion, for measurement results to be representative of the situation, several conditions such as sufficient number of samples, adequate sampling methods, appropriate monitoring locations and monitoring techniques that are able to characterize the radionuclides of interest should be satisfied with basis on an appropriate quality assurance program.

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Annex I

EXAMPLES OF DOSIMETRIC MODELS FOR SURFACE CONTAMINATION

INTRODUCTION

I–1. As mentioned in para 5.22 of this safety guide, an evaluation of the radiological exposures and hazards — for the benefit of a safety assessment — should be carried out using a dosimetric model that is dedicated to or capable of assessing effective doses resulting from the use, direct handling, processing or machining of items or objects with a surface contamination. The applicant may develop its own dosimetric methodology, or instead, use one of the existing models to perform these evaluations. This Annex briefly describes several such models.

Dosimetric model from Radiation Protection 101

I–2. Publication "Radiation Protection 101" (RP101) [I−1] is a technical document describing the dosimetric model, exposure scenarios and parameters underlying the derivation of surface-clearance levels as recommended by the European Commission (Article 31 Group of Experts) and as published in "Radiation Protection 89" [I−2]. Even though the methodology lays the foundation for selecting limiting values for the residual surface activity of metals arising from the dismantling of nuclear installations (equipment, tools, scrap), it can be applied more generally to derive effective doses related to surface contamination, i.e., including other solid, non-metallic objects or items.

I–3. The methodology allows evaluating the effective dose incurred by the total surface activity (fixed and removable) within two main types of exposure scenarios: (1) the processing of cleared scrap (transport, automated and manual processing), and (2) the reuse of cleared items. The first type of scenario not only considers the transport, handling and sorting of cleared scrap, but also its automated or manual processing and machining, e.g. pressing, shredding, milling and segmenting (thermal, sawing, grinding). The second type of scenario considers relevant dose contributions from the continued reuse of cleared equipment from an authorized facility, as well as the enhanced inhalation-dose contribution from cleaning, sanding or scrapping (thermal segmentation) this equipment.

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I–4. Exposure scenarios in the RP101 methodology 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, as opposed to several other dosimetric models for surface contamination. The maximum dose contribution (from all sub scenarios) then determines the limiting value of the surface clearance level. The considered contributions are the beta-skin dose, the external gamma dose, the committed effective dose from inadvertent ingestion, and the committed effective dose from inhalation. The level of conservatism of the deterministic approach can be assessed separately by the implementation of a stochastic model.

Basic IAEA TECDOC-1449 (IAEA-CRP) model

I–5. In 2001, the IAEA initiated a Coordinated Research Project (CRP) with the objective to review the scientific basis of the regulatory limits for removable surface contamination as laid down in the IAEA Transport Regulations in force at the time [I–3]. The fundamental principles of these limits were already established in 1961 [I–4] and are based on a simple dosimetric model [I–5]. The CRP, 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*', published the findings and conclusions in a final report in 2005, in TECDOC-1449 [I–6]. In this publication, a basic radiological model (the IAEA-CRP model) is presented for non-fixed surface contamination, which enables the assessment of the effective annual dose incurred under routine transport conditions.

I–6. The model evaluates the occupational dose incurred by transport workers handling various types of surface-contaminated packages[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/year per Bq/cm^2) with contributions from skin contamination (transfer of contamination), external exposure from package's surface, inhalation of

[6] Packages for the transport of radioactive material, but doses are only calculated for the exposure to the surface contamination residing on these packages.

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resuspended activity and ingestion of activity transferred to the hands (secondary, hand-to-mouth ingestion). The model evaluations are rather conservative, e.g. since physical decay is not taken into account. After its publication, the basic IAEA-CRP model has been modified and extended for further use outside the domain of transportation [I–7], [I–8], [I–9].

Dosimetric model by Ogino and Hattori

I–7. The model by Ogino and Hattori [I–9] is based on the IAEA-CRP model [I–6] developed for transport safety. Since there may be practical problems if the IAEA-CRP model were to be used for deriving exemption levels for surface contamination for application in the field of radiation and waste safety, the model was further developed by classifying the surface-contaminated objects into three general categories with independent flat square areas (m^2); namely, (i) manually handled objects (0.1 m^2), (ii) closely handled objects (1 m^2), and (iii) remotely handled objects (10 m^2). The surface contamination is assumed to be distributed over one-tenth of the central surface area of each object in the realistic scenario, and a situation in which the entire surface of the objects is contaminated is assessed by the low-probability scenario. Effects of uncertainty associated to exposure parameters were also examined by the probabilistic calculation [I–10].

RIVM-SUDOQU model (SUrface DOse QUantification)

I–8. The RIVM-SUDOQU model [I–7], [I–8] was developed with the aim to assess public and occupational exposure 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 wipe-off should be regarded explicitly by the dosimetric model. Surface-contamination levels thus become time-dependent by the product use itself and not just by radioactive decay. This is incorporated into the RIVM-SUDOQU model by the consideration of mass/activity-balance equations. The model evaluates the total[7] annual individual effective dose per unit of surface contamination (i.e., microSv/year per Bq/cm^2) based on the main exposure pathways (external gamma-radiation exposure, inhalation, ingestion and skin contamination) for removable, fixed or total contamination

[7] "Total": dose contributions from all considered pathways are summed to yield the total effective dose.

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levels. The concept of the Limiting Effective Surface Dose (LESD) is introduced to target issues related to conservatism of dose evaluations.

I–9. The RIVM-SUDOQU model can also bypass the mass-balance equations, by which it converges to the basic IAEA-CRP methodology from TECDOC-1449 [I−6]. In this mode, it can also assess occupational exposure scenarios that are usually characterized by the continuous flow of freshly contaminated items for which the mass-balance framework is redundant. Furthermore, a small adaptation of the RIVM-SUDOQU model will result in the model by Ogino and Hattori [I−9, I−10]. SUDOQU can therefore be used as a benchmark in dosimetric modeling.

I–10. A pilot project also revealed the applicability of the methodology in the derivation of nuclide-specific surface-clearance levels based on deterministic calculations with reuse scenarios related to nuclear facilities [I−11, I−12]. In a corresponding benchmarking study, several results were compared with those from other dosimetric models for surface contamination, such as the RP101-model described above [I−2]. Further development of the RIVM-SUDOQU model will enable dose evaluations related to the processing or machining of surface-contaminated items and will allow for detailed parameter-sensitivity analyses and probabilistic dose evaluations.

RESRAD- BUILD computer code

I–11. The RESRAD-BUILD computer code [I−13], member of the RESRAD Family of Codes, is developed by Argonne National Laboratory with financial support from the U.S. Department of Energy (DoE). The aim of this code is to evaluate 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[8] pathway analysis model that considers two specific types of exposure scenarios: (1) building-occupancy scenarios, and (2) building-renovation scenarios. The first type of scenario usually involves long-term, chronic exposures of e.g. residents, office workers and industrial workers. In these scenarios contaminants may become airborne due to normal use and cleaning of the building.

[8] The building can contain up to three rooms

In the second type of scenario, involving building decontamination and renovation, exposure to higher contamination levels typically occurs at shorter time scales (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 [I–13].

I–12. A model run can contain up to ten different sources whose geometry can vary between a volume, *surface area,* line or a point. By mechanical removal or erosion, source activity becomes airborne which is further analyzed by the underlying air-quality compartment model. The model run can contain up to ten receptor points for which the total effective dose equivalent (TEDE) is calculated. The considered exposure pathways are (1) external exposure to radiation from the source, (2) external exposure to radiation from deposited activity on the floor, (3) external exposure from submersion, (4) inhalation of airborne activity, (5) inhalation of radon decay products and tritiated water vapor, (6) inadvertent ingestion of removable activity directly from the source and (7) 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 dose distribution resulting from radioactive surface contamination using indoor occupational exposure scenarios [I–14].

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Annex II

SCREENING LEVELS APPLIED AFTER FUKUSHIMA DAIICHI NUCLEAR ACCIDENT

INTRODUCTION

II–1. GSR Part 3 [II–1] uses the concept of exemption only within the context of the planned exposure situation. However, after the Fukushima nuclear accident in Japan, screening levels have been applied in decision making in the existing exposure situation for the management of waste contaminated with radioactive materials resulted from the Fukushima-Daiichi nuclear power plant. This Annex provides such examples.

II–2. Following the Fukushima nuclear accident, the Nuclear Safety Commission of Japan (NSC) issued more than 200 technical advice until September 10, 2012, based on the Act on Special Measures Concerning Nuclear Emergency Preparedness that came into effect in 1999 after the JCO criticality accident in Japan. The technical advice by NSC were developed taking into account the ICRP recommendations and IAEA Safety Standards.

II–3. For the optimization of radiation protection for a member of the public in the existing exposure situation after the Fukushima nuclear accident, NSC advised to select an appropriate reference level from the lower part of 1–20 mSv/y band with the long-term objective of 1 mSv/y as recommended by ICRP in its Publication 111. Following the advice, the Government of Japan has set 1 mSv/y as the long-term objective of the additional exposure dose for a member of the public.

II–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 to keep the additional exposure dose below 1 mSv/y, based on the advice by NSC. Furthermore, NSC advised to keep the additional exposure dose below 10 μSv/y for a member of the public who lives in the vicinity of the disposal facility after the termination of the institutional control.

TREATMENT OF LARGE AMOUNT OF CONTAMINATED WASTE

II–5. The Great East Japan Earthquake was one of the most disastrous catastrophes. Large amount of waste was generated by the earthquake and tsunami, and a part of the waste become

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contaminated by the Fukushima nuclear accident. To effectively and safely treat the waste, Ministry of the Environment of Japan (MOE) has set a screening level of radioactivity concentration to distinguish the waste that can be treated under the conventional law on waste management (i.e., below the screening level) [II–2] from the waste that requires the additional regulation from the viewpoint of radiation protection prescribed by the Act on Special Measures promulgated on August 30, 2011 (i.e., exceeding the screening level)[II–3].

II–6. In the Act on Special Measures [II–3], the screening level of radioactivity concentration for waste has been set as 8,000 Bq/kg for ^{134}Cs and ^{137}Cs. It is based on the scenario assessment that the additional dose to a member of the public and worker is less than 1 mSv/y. When exceeding 8,000 Bq/kg, the waste is specified as "Designated Waste", and additional treatment standards from the viewpoint of radiation protection are applied such as the cement solidification of soot and dust, periodical measurement of radioactivity concentration in discharged gas and liquids from the facility under the Act on Special Measures [II–3]. When not exceeding 8,000 Bq/kg, the waste is subject to the normal waste treatment by local authorities or business operators under the conventional law on waste management [II–2].

II–7. Fig. I–1 shows the flow diagram for treatment of decontamination waste and soil and Specified Waste based on the Act on Special Measures [II–3] in Fukushima Prefecture.

APPLICATION OF SCREENING LEVELS IN EXISTING EXPOSURE SITUATION

II–8. GSR Part 3 [II–1] uses the concept of exemption only within the context of the planned exposure situation. However, the aforementioned screening level for waste can be considered as an example of the similar decision making in the existing exposure situation after the Fukushima nuclear accident. Large amount of waste contaminated with radioactive materials discharged from the accident already existed when a decision on control had to be taken, and under the prevailing circumstance the screening level for waste (i.e., 8,000 Bq/kg for ^{134}Cs + ^{137}Cs) was set by the regulatory body.

II–9. The IAEA Safety Standards emphasizes the importance of a graded approach in the regulation of facilities and activities. In particular, the GSR Part 1 [II–4] requires in para. 4.5 that *"The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach", adding that "for the lowest*

associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control". The screening levels applied to the specification of Designated Waste is an example of the implementation of the graded approach using the appropriate level of radioactivity concentration for waste.

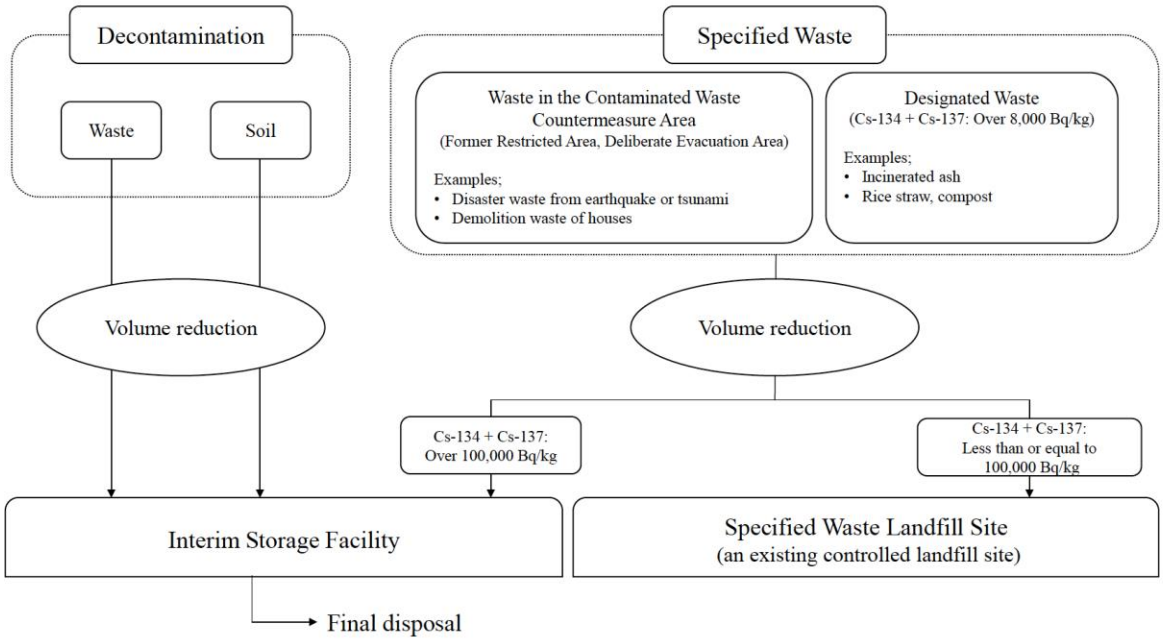

Fig. II–1. Flow diagram for treatment of decontamination waste and soil and Specified Waste based on the Act on Special Measures in Fukushima Prefecture (modified from MOE Decontamination Report 2014 [II–5] with permission).

PUBLIC PERCEPTION

II–10. The screening level for waste was derived from a conservative scenario assessment to ensure that the additional exposure remains below 1 mSv/y for a member of the public and worker during the treatment of waste and remains below 10 µSv/y for a member of the public after the termination of institutional control. However, it is not always accepted that the waste at or below the screening level can be treated safely with relevant standards set by the regulatory body. Some waste-treatment business operators have set a lower criterion below the screening level for their facilities to accept

commissions of treatment in consideration of the anxiety of local residents, which sometimes prevents the smooth treatment of waste.

SURFACE CONTAMINATION CONTROL OF TRANSPORT VEHICLE

II–11. Large amount of removed soil and waste generated from the decontamination activities have been regulated under the Act on Special Measures [II–3] and safely stored at the Temporary Storage Sites before transporting to the Interim Storage Facility (see Fig. II–1). When the transport vehicle departs daily from the Temporary Storage Sites after unloading the removed soil and waste, the Ordinance by Ministry of Health, Labour and Welfare of Japan (MHLW) [II–6] requires that the surface contamination level on the vehicle should not be exceeding 40 Bq/cm^2, which corresponds to 13,000 counts per minute (cpm) assuming the use of typical Geiger Muller (GM) survey meter with a 50-mm bore widely used in Japan (i.e., ALOKA TGS-136). When exceeding 13,000 cpm, the additional requirement of surface decontamination has been required from the viewpoint of radiation protection. The screening level has been applied in decision making for the management of surface decontamination in the existing exposure situation.

II–12. With respect to the surface contamination control of contaminated objects, Guidelines have been developed by the Standardization Committee on Radiation Protection of the Japan Health Physics Society for planned, emergency and existing exposure situations [II–7]. Table II–1 summarizes the main points of the guidelines. Here, the objects are defined as solid-state valuable goods justified for the reuse or recycle when moving out (e.g., vehicles, equipment and the other items), noting that the term commodities is used in the translation of the guideline [II–7]. As for the existing exposure situation, the guideline recommends to use the individual effective dose criteria of less than 1–10 mSv/y 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 aforementioned screening level for the transportation vehicle in the Temporary Storage Sites satisfies the guideline (i.e., 13,000 cpm < 21,000 cpm), which implies that the additional dose to a member of the public and the worker remains below 1 mSv/y.

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Table II–1. Summary of guidelines for moving out objects contaminated with radioactive materials in planned, emergency and existing exposure situations by Standardization Committee on Radiation Protection of Japan Health Physics Society (modified from Ref [II–7] with permission).

	Planned Exposure Situation	Emergency Exposure Situation	Existing Exposure Situation
Dose criteria (effective dose)	Order of 10 μSv/y or less	Less than 10 mSv	Less than 1–10 mSv
Referred concept	Clearance	Generic criterion of IAEA GSR Part 7[II–8]	Intervention
Basic point of view	• Moving out from controlled area to general • Application of the concept of clearance of many relatively small objects moved out	• Moving out from the area where affected by radioactive materials released significantly in nuclear or radiological emergency • Justification and optimization • A tithe of the maximum of the reference level of 20–100 mSv in emergency exposure situation • Upper bound of 1 mSv of annual effective dose for international export	• Moving out from the area where affected by nuclear or radiological emergency or area where in recovery from accident to less affected or ordinary area • Justification and optimization • The lower part of 1–20 mSv band which is the reference level in existing exposure situation • Upper bound of 1 mSv of annual effective dose for international export
Exposure Scenarios	Handling of small packages [II–9] Handling of general objects [II–10]	Handling of bulk spent fuel cask [II–9] Handling of general objects [II–10]	Handling of bulk spent fuel cask [II–9] Handling of general objects [II–10]
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.

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