UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 23, 2021

ALL AGREEMENT STATES, CONNECTICUT, NON-AGREEMENT STATES AND STATE LIAISON OFFICERS

OPPORTUNITY TO REVIEW AND COMMENT ON INTERNATIONAL ATOMIC ENERGY AGENCY DRAFT SAFETY GUIDES DS499, "APPLICATION OF THE CONCEPT OF EXEMPTION" AND DS500, "APPLICATION OF THE CONCEPT OF CLEARANCE" (STC-21-022)

Purpose: To provide States with the opportunity to review and comment on the Draft Safety Guides DS499, "Application of the Concept of Exemption" and DS500, "Application of the Concept of Clearance"[1] by June 7, 2021, to the contact listed.

Background: The International Atomic Energy Agency (IAEA) has made available the Draft Safety Guide DS499, "Application of the Concept of Exemption" and DS500, "Application of the Concept of Clearance" for Member State review and comment. Proposed changes from Member State review will be taken into account in the finalization of the safety standards. The objective of Draft Safety Guide DS499 is to provide recommendations and guidance on the application of the concept of exemption within the framework of planned exposure situations in accordance with the requirements of Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards General Safety Requirements Part 3 (GSR Part 3). DS499 will be of particular value for regulatory bodies in applying the relevant requirements in GSR Part 3 relating to the exemption of a source or practice from regulatory control.

The objective of Draft Safety Guide DS500 is to provide recommendations and guidance on the application of the concept of clearance in accordance with the requirements of GSR Part 3 (e.g., clearance of materials, objects, and building from regulatory control). The drafts are part of the revision of the existing safety guide "Application of the Concepts of Exclusion, Exemption and Clearance" (RS-G-1.7) dealing with the concept of exemption (DS499) and clearance (DS500). The Draft Safety Guides DS499 and DS500 are being submitted in parallel for comment.

Discussion: The U.S. Nuclear Regulatory Commission (NRC) is coordinating the U.S. review of these safety guides. Consolidated comments will be submitted to the IAEA by the NRC through established official channels. Please provide your comments to Cindy Flannery (cindy.flannery@nrc.gov) by June 7, 2021. The attached IAEA comment template is provided

[1] This information request has been approved by OMB 3150-0029, expiration 7/31/2023 and 3150-0200, expiration 10/31/2021. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503, or by email to oira_submission@omb.eop.gov. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

for your use. Any comments provided should refer to the relevant paragraph number in the draft text being reviewed and should propose alternative text, as appropriate.

The review should focus on the following:

1. Are there any safety issues that may be inconsistent with States' regulations or common practices?
2. Relevance and usefulness of this document — Are the stated objectives appropriate, and are they met by the draft text? Do you have any suggestions to include in the document?
3. Scope and completeness — Is the stated scope appropriate and is it adequately covered by the draft text?
4. Quality and clarity — Does the guidance in the draft text represent the current consensus among specialists in the field, and is the guidance expressed clearly and coherently?

Comments of an editorial nature will be considered; however, it should be noted that the draft text will be comprehensively edited by the IAEA Secretariat.

Enclosed is: (1) communication from the IAEA concerning Draft Safety Guide DS499 and DS500 and its review, including an "Explanatory Note" regarding these documents; (2) Draft Safety Guide DS499, "Application of the Concept of Exemption," and Draft Safety Guide DS500, "Application of the Concept of Clearance;" and (3) blank templates for comment preparation.

If you have any questions regarding this communication, please contact the individual named below:

POINT OF CONTACT: Cindy Flannery E-MAIL: Cindy.Flannery@nrc.gov
TELEPHONE: 301-415-0223


Signed by Anderson, Brian
on 04/23/21

Brian C. Anderson, Branch Chief
State Agreement Liaison Programs
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. IAEA Explanatory Note for DS499
2. IAEA Explanatory Note for DS500
3. Draft Safety Guide DS499
4. Draft Safety Guide DS500
5. IAEA Comment Template for DS499
6. IAEA Comment Template for DS500

cc: David Crowley, OAS
Kim Steves, CRCPD

IAEA

Atoms for Peace and Development

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In reply please refer to: J5.03.01
Dial directly to extension: (+43 1) 2600-22744

The Secretariat of the International Atomic Energy Agency (IAEA) presents its compliments to the IAEA's Member States and has the honour to draw their attention to the following draft safety standard:

Application of the Concept of Exemption
(DS499)

Member States and their experts are hereby provided with an opportunity to review and evaluate this draft safety standard, which is available online at:

https://www.iaea.org/resources/safety-standards/draft-standards-for-ms-comment

A hard copy of the draft text will be sent out upon request.

Any proposed changes to this draft text resulting from the review by Member States will be taken into account in the finalization of the safety standard.

Member States are kindly requested to provide comments on the draft text following the guidance given in the attached Explanatory Note.

The Secretariat of the International Atomic Energy Agency avails itself of this opportunity to assure the IAEA's Member States of its highest consideration.

2021-03-05

Enclosures: Explanatory Note
Form for Comments
Statement by the Commission on Safety Standards

Explanatory Note

Application of the Concept of Exemption
(DS499)

The draft text for review, entitled ***Application of the Concept of Exemption***, was prepared as a draft Safety Guide to be issued in the IAEA Safety Standards Series**.**

The draft text has already been reviewed through consultants' meetings, as well as by the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC), and the Waste Safety Standards Committee (WASSC).

The objective of this draft text, as accepted by the Commission on Safety Standards (CSS), is to provide recommendations and guidance on the application of the concept of exemption within the framework of planned exposure situations in accordance with the requirements of GSR Part 3. The draft is part of the revision of the existing safety guide Application of the Concepts of Exclusion, Exemption and Clearance (RS-G-1.7) dealing with the concept of exemption (DS499). A second part, dealing with the concept of clearance (DS500), is also being submitted in parallel for comment.

The two draft safety guides cover similar subject matter to that in RS-G-1.7, but have been updated in line with the experiences of Member States and use the newer concepts and definitions, such as the different exposure situations, established in GSR Part 3. DS499 will be of particular value for regulatory bodies in Member States in applying the relevant requirements in GSR Part 3 relating to the exemption of a source or practice from regulatory control. The current draft also provides guidance on the concept of exclusion and on the application of an exemption approach using screening levels for decision making in existing exposure situations including trade.

The guidance in this publication is aimed primarily at Governments and Regulatory Bodies to assist them in the application of the requirements of GSR Part 3 related to the exemption of sources and practices from regulatory control. It will be of wide interest to all those who intend to handle sources or materials containing radionuclides or radiation generators as well as trade organizations.

Comments are requested in relation to:

- Relevance and usefulness: Are the stated objectives appropriate, and are they met by the draft text?
- Scope and completeness: Is the scope appropriate, and is it adequately covered by the draft text?
- Quality and clarity: Does the guidance in the draft text represent the current consensus among specialists in the field, and is this guidance expressed clearly and coherently?

Specific comments on the following two points are requested:

1. Feedback on the retention of the text dealing with existing exposure situations, including trade, in the draft safety guide DS499. (Agree/disagree)
2. Feedback on whether to merge both documents DS499 (exemption) and DS500 (clearance) or to continue with two separate guides as developed.

Comments of an editorial nature will be considered; however, it should be noted that the draft text will be comprehensively edited by the IAEA Secretariat.

Any comments should be made in English, should refer to the relevant paragraph number in the draft text being reviewed, and should propose alternative text where appropriate. Please use the attached Form for Comments to record all comments.

The responsible IAEA officer is Mr Haridasan Pappinisseri of the Department of Nuclear Safety and Security, who may be contacted for further information in connection with this subject by telephone at: +43 1 2600 22744 or via email at: H.Pappinisseri@iaea.org.

Any comments should be sent through the established official channels to the responsible IAEA officer by **6 July 2021**.

Form for Comments
Application of the Concept of Exemption
(DS499)

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Page.... of....							
Country/Organization: Date:							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

Statement by the Commission on Safety Standards

Publications in the IAEA Safety Standards Series are prepared and reviewed in accordance with a uniform process. To this end, the Commission on Safety Standards (CSS) and five committees with harmonized terms of reference — the Emergency Preparedness and Response Standards Committee (EPReSC), the Nuclear Safety Standards Committee (NUSSC), the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC) and the Waste Safety Standards Committee (WASSC) — have been established. The CSS has a special overview role with regard to the IAEA's safety standards and provides advice to the Director General on the IAEA's overall programme with regard to regulatory aspects of safety.

The uniform preparation and review process involves organizing expert group meetings; arranging at different stages of preparation for the internal review of draft texts; submitting the texts to the relevant Committee(s) for review; submitting draft texts to the IAEA's Member States for comment; and submitting the approved final draft of the safety standard[1] for endorsement by the CSS before publication.

The CSS stresses the importance of Member States' comments to the preparation and review process for safety standards. Publications in the IAEA Safety Standards Series not only should be of the requisite quality but also should represent the consensus view of the Member States and should address the issues of importance to the Member States. While the CSS, the Committees and the Secretariat strive to provide safety standards that satisfy these criteria, the review of draft standards by experts in the Member States is an essential stage in obtaining the broadest possible technical consensus and the highest possible quality and relevance.

Member States are also encouraged to provide the IAEA with feedback on their use of the safety standards. The status of safety standards extant and in preparation can be seen on the IAEA's website, where there are also links to electronic files for existing publications, including those in other official languages.[2] The responsible IAEA officer is Mr Dominique Delattre, Head of the Safety and Security Publications Unit of the Department of Nuclear Safety and Security. He may be contacted for further information in connection with this subject by telephone at: + 43 1 2600 22696 or via email at: D.Delattre@iaea.org.

[1] Safety Guides are published under the authority of the Director General. Safety Fundamentals and Safety Requirements publications require the approval of the Board of Governors, after endorsement by the CSS.

[2] See http://www-ns.iaea.org/committees/files/CSS/205/status.pdf.

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The Secretariat of the International Atomic Energy Agency (IAEA) presents its compliments to the IAEA's Member States and has the honour to draw their attention to the following draft safety standard:

Application of the Concept of Clearance
(DS500)

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Any proposed changes to this draft text resulting from the review by Member States will be taken into account in the finalization of the safety standard.

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2021-03-05

Enclosures: Explanatory Note

Form for Comments

Statement by the Commission on Safety Standards

Explanatory Note

Application of the Concept of Clearance
(DS500)

The draft text for review, entitled ***Application of the Concept of clearance***, was prepared as a draft Safety Guide to be issued in the IAEA Safety Standards Series**.**

The draft text has already been reviewed through consultants' meetings, as well as by the Waste Safety Standards Committee (WASSC), the Radiation Safety Standards Committee (RASSC), and the Transport Safety Standards Committee (TRANSSC).

The objective of this draft text, as accepted by the Commission on Safety Standards (CSS), is to provide recommendations and guidance on the application of the concept of clearance in accordance with the requirements of GSR Part 3. The draft is part of the revision of the existing safety guide Application of the Concepts of Exclusion, Exemption and Clearance (RS-G-1.7), dealing with the concept of clearance (DS500). A second part, dealing with the concept of exemption (DS499), is also being submitted in parallel for comment.

The two draft safety guides cover similar subject matter to that in RS-G-1.7, but have been updated in line with the experiences of Member States and use the newer concepts and definitions, such as the different exposure situations, established in GSR Part 3. The guidance in the DS500 is aimed at authorized parties and regulatory bodies in Member States to assist them in the application of the requirements of GSR Part 3 on the clearance of materials, objects and buildings from regulatory control.

Comments are requested in relation to:

- Relevance and usefulness: Are the stated objectives appropriate, and are they met by the draft text?
- Scope and completeness: Is the scope appropriate, and is it adequately covered by the draft text?
- Quality and clarity: Does the guidance in the draft text represent the current consensus among specialists in the field, and is this guidance expressed clearly and coherently?

Specific comments are requested whether to merge the two draft documents DS499 (exemption) and DS500 (clearance) into a single Safety Guide or to continue the development and publication of two separate but consistent Safety Guides.

Comments of an editorial nature will be considered; however, it should be noted that the draft text will be comprehensively edited by the IAEA Secretariat.

Any comments should be made in English, should refer to the relevant paragraph number in the draft text being reviewed, and should propose alternative text where appropriate. Please use the attached Form for Comments to record all comments.

The responsible IAEA officer is Mr Vladan Ljubenov of the Department of Nuclear Safety and Security, who may be contacted for further information in connection with this subject by telephone at: +43 1 2600 22553 or via email at: V.Ljubenov@iaea.org.

Any comments should be sent through the established official channels to the responsible IAEA officer by **6 July 2021**.

Form for Comments
Application of the Concept of Clearance
(DS500)

COMMENTS BY REVIEWER Reviewer: Country/Organization:			Page.... of.... Date:	RESOLUTION			
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The CSS stresses the importance of Member States' comments to the preparation and review process for safety standards. Publications in the IAEA Safety Standards Series not only should be of the requisite quality but also should represent the consensus view of the Member States and should address the issues of importance to the Member States. While the CSS, the Committees and the Secretariat strive to provide safety standards that satisfy these criteria, the review of draft standards by experts in the Member States is an essential stage in obtaining the broadest possible technical consensus and the highest possible quality and relevance.

Member States are also encouraged to provide the IAEA with feedback on their use of the safety standards. The status of safety standards extant and in preparation can be seen on the IAEA's website, where there are also links to electronic files for existing publications, including those in other official languages.[2] The responsible IAEA officer is Mr Dominique Delattre, Head of the Safety and Security Publications Unit of the Department of Nuclear Safety and Security. He may be contacted for further information in connection with this subject by telephone at: + 43 1 2600 22696 or via email at: D.Delattre@iaea.org.

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[2] See http://www-ns.iaea.org/committees/files/CSS/205/status.pdf.

DS499
19 February 2021

IAEA SAFETY STANDARDS

For protecting people and the environment

STEP:8

Soliciting Comments from Member States (120 days comments period)

Review Committees: RASSC (lead), WASSC, and TRANSSC

Application of the Concept of Exemption

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

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IAEA
International Atomic Energy Agency

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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CONTENTS

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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.

DRAFT

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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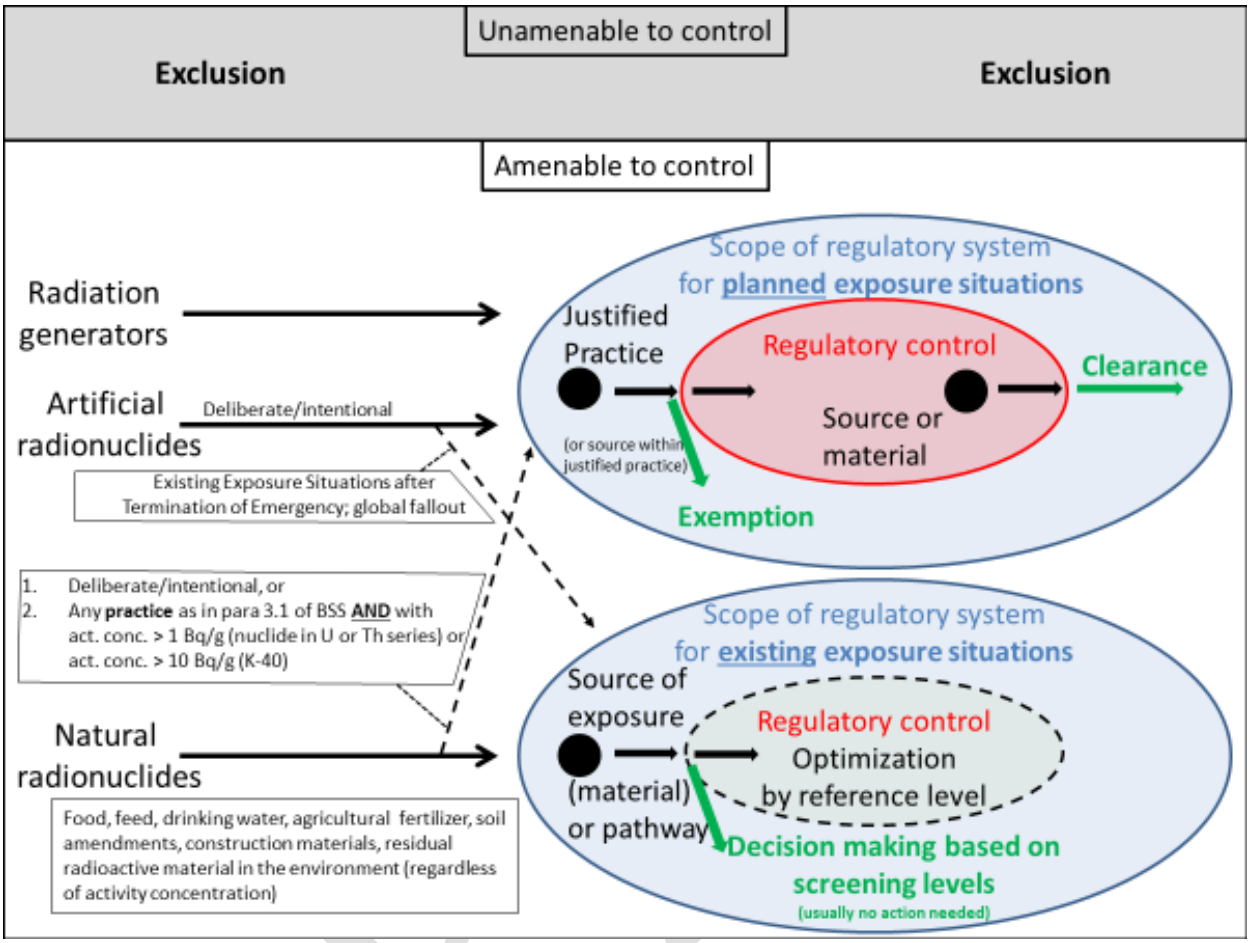

FIG. 1. The concepts of exclusion, exemption and clearance (See para 2.12).

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."**

DRAFT

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.

DRAFT

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.*"

DRAFT

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

DRAFT

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

DRAFT

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'.

DRAFT

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

DRAFT

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.

DRAFT

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

DRAFT

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.

DRAFT

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."

DRAFT

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.

DRAFT

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

DRAFT

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

DRAFT

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

DRAFT

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.

DRAFT

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]):

DRAFT

"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.

DRAFT

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

DRAFT

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.

DRAFT

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.

DRAFT

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

DRAFT

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.

DRAFT

– 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.

DRAFT

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.

DRAFT

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.

DRAFT

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

DRAFT

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

DRAFT

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

DRAFT

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.

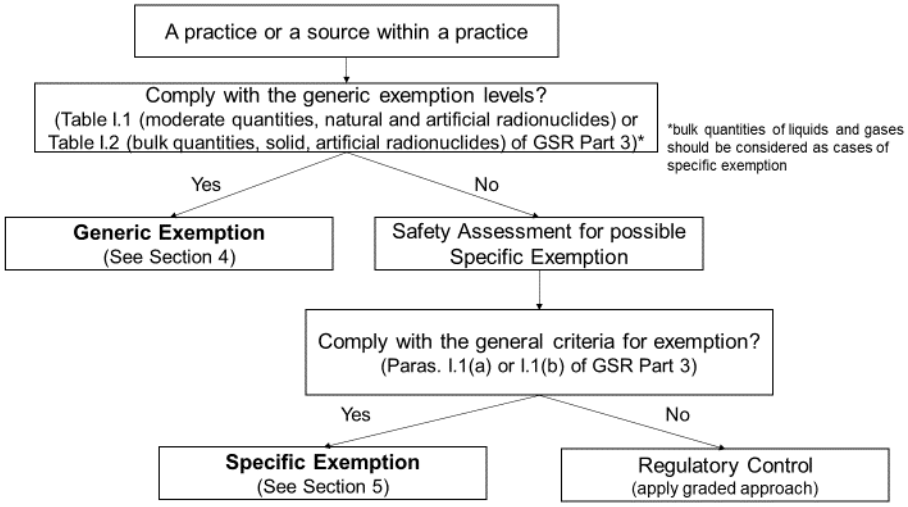

FIG. 2. Flow chart of granting generic exemption and specific exemption.

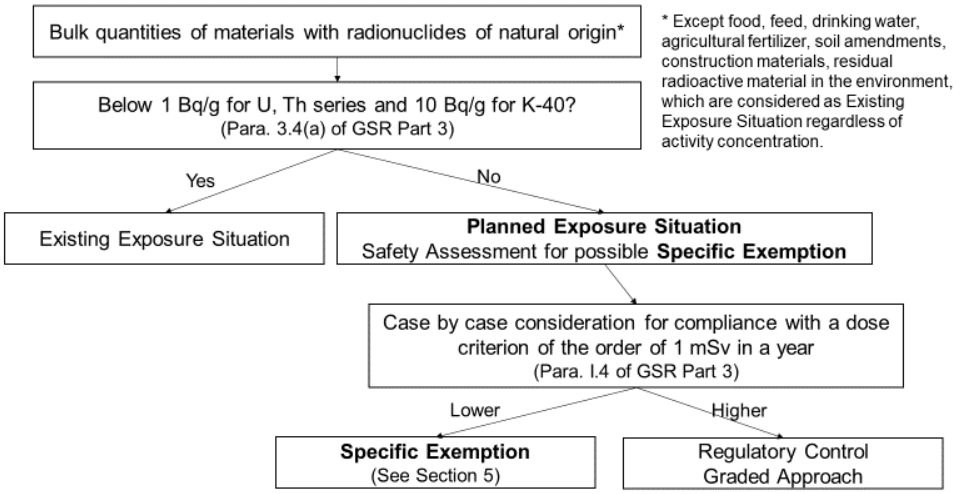

FIG. 3. Flow chart of granting specific exemption for bulk materials with radionuclides of natural origin.

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.

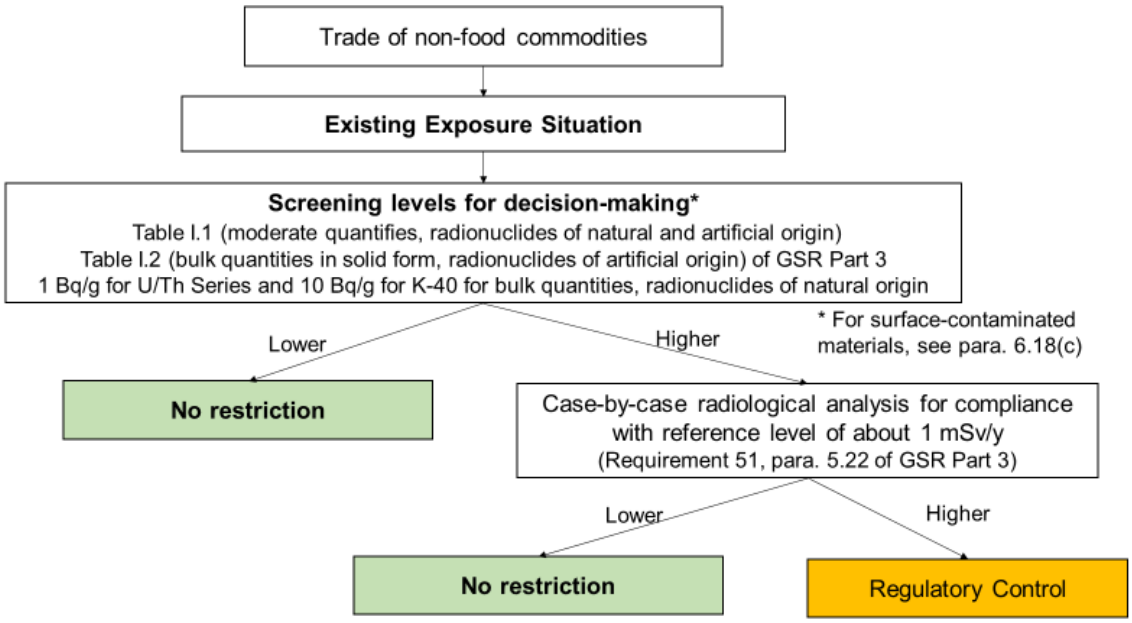

FIG. 4. Flow chart illustrating the use of screening levels for decision-making in trade of non-food commodities.

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.

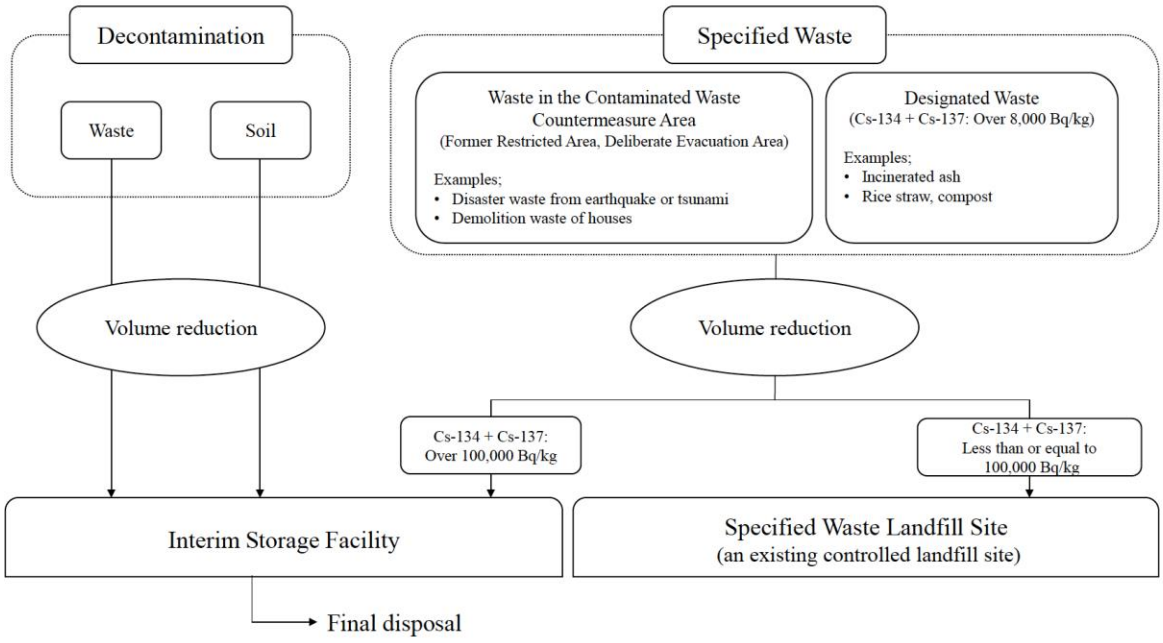

Fig. II–1. Flow diagram for treatment of decontamination waste and soil and Specified Waste based on the Act on Special Measures in Fukushima Prefecture (modified from MOE Decontamination Report 2014 [II–5] with permission).

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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for protecting people and the environment

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Application of the Concept of Clearance

Draft Safety Guide
DS500 (Revision of Safety Guide RS-G-1.7)

IAEA
International Atomic Energy Agency

FOREWORD

By
Director General

[standard text to be added]

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PREFACE

In 2014, the Agency published the 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 application of the concepts of exemption and clearance 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 clearance, through detailed guidance on clearance levels and their application in practices, which is aimed to contribute to optimizing protection and safety and to application of the graded approach to regulation of materials, waste and objects containing radionuclides with low activity concentrations.

This Safety Guide updates part of the guidance related to clearance, that was provided 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 (DS499) that updates part of the guidance relevant to the concept of exemption.

The IAEA would like to express its appreciation to the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) who contributed the Annex IV “Example of the Application of the Clearance Concept in Small Medical Facilities” and to the International Radiation Protection Association (IRPA) who contributed the Annex V “Illustration of Typical Conservatism in the Clearance Process”.

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CONTENTS

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1. INTRODUCTION

BACKGROUND

1.1. Exclusion, exemption and clearance are used as part of the process to determine the nature and extent of regulatory control as it applies to all exposure situations, including planned exposure situations, as part of the optimisation process. Exclusion applies to those exposures that are not deemed amenable to control, regardless of the magnitude of the exposures in question. Exemption refers to the determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control. Clearance is the removal of radiological regulatory control from radioactive material or radioactive objects within notified or authorized practices. The concept of clearance is also relevant to remediation works (that occur to correct an existing exposure situation), since the remediation is a planned activity subject to regulatory control. Graphical illustration of the concepts is provided in Figure 1.

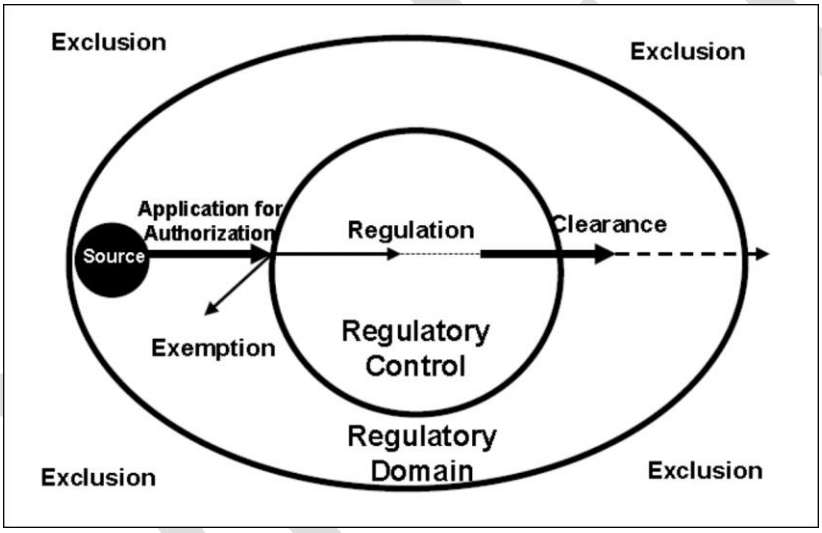

Figure 1. Relation of exclusion, exemption and clearance to the regulatory domain

1.2. 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. Clearance thereby distinguishes itself from exemption, even though the general criteria on which such a decision is based are very similar (paras. I.1, I.10 of the IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1]).

1.3. 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 conduct

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 conduct of the practice or after its discontinuation then becomes an issue of clearance. 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.

1.4. The process of clearance is a regulated activity and is carried out in accordance with the regulatory regime for the authorized activity and, hence, the procedures and processes leading to the act of clearance need to be well defined.

1.5. Requirement 8 of GSR Part 3 [1] makes provision for exemption and for the clearance of sources within notified or authorized practices, consistent with the use of a graded approach as specified in requirement 6 of [1]. The concepts of exemption and clearance are based on the same dose criteria.

1.6. This Safety Guide provides guidance on the clearance process and on the application of the clearance levels, in particular on the organisation and regulation of the process, and its verification. It contains guidance on:

- clearance process;
- establishment of national regulations;
- planning, organization and implementation; technical and safety implications; and resources needed to implement the clearance process;
- conditional (specific) clearance;
- use of surface contamination levels;
- clearance for liquids and gases (explaining the boundary between clearance and discharges, discussing whether the existing clearance levels for solid material could be relevant to liquids and gases);
- involvement of interested parties and enhancement of public understanding.

1.7. This Safety Guide is one of the documents supporting the GSR Part 3 [1] and IAEA Safety Standards Series No. GSR Part 6 Decommissioning of Facilities [2]. This safety guide addresses application of the concept of clearance. The Safety Guide on the Application of the Concept of Exemption (DS499) [3] addresses application of the concept of exemption and the concept of exclusion. Together,

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these two Safety Guides supersede the Safety Guide on Application of the Concepts of Exclusion, Exemption and Clearance, issued in 2004.[1]

1.8. GSR Part 3 [1] provides activity concentrations (mass specific values in Bq/g) that can be used for clearance of bulk quantities of solid material. Values are provided for both radionuclides of natural origin and artificial radionuclides and these are the values originally provided in 2004[1]. The models used in the calculations of individual dose for artificial radionuclides are described in the IAEA Safety Report SRS-44 [4].

1.9. The calculation scenarios and models described in the Ref. [4] are still valid and therefore there is no need to repeat this information in this guidance document.

1.10. It is recognized that the general clearance levels for artificial radionuclides are based on exposure scenarios that are highly conservative compared with the exposure that generally can be expected after clearance. This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build-up of unnecessary additional layers of conservatism. It also reflects the use of the graded approach, in the light of the conservative nature of the values.

OBJECTIVE

1.11. The objective of this Safety Guide is to provide detailed guidance on the application of the concept of clearance for materials, objects and buildings that are to be released from regulatory control in the framework of planned exposure situations, as specified in GSR Part 3 [1]. That requirements address regulatory framework for clearance, clearance process, process of derivation of clearance levels, application of clearance to solid, liquid and gaseous materials, unconditional (general) clearance and conditional (specific) clearance for both mass specific and surface specific clearance criteria. It also provides guidance on involvement of interested parties. The Safety Guide discusses the application of screening levels for recycle/disposal of materials and waste after the early and intermediate phases of a nuclear emergency.

1.12. This safety Guide is intended for authorized parties and regulatory bodies in Member States to assist them in the application of the requirements of GSR Part 3 on the clearance of materials, objects and buildings from regulatory control.

[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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SCOPE

1.13. The scope of this Safety Guide covers the following aspects:

(a) Responsibilities of the authorized party (registrant or licensee) and the regulatory body;

(b) All relevant steps of the clearance process including characterization, determination of the nuclide vector[2], sampling, measurement techniques, monitoring and management of the clearance process;

(c) Mass specific and surface specific clearance levels for unconditional clearance;

(d) Concept of conditional (specific) clearance and guidance on its application;

(e) Examples of derivation of mass specific and surface specific clearance levels for conditional (specific) clearance (actual values would depend on specific conditions applied, so no universal set of values could be proposed);

(f) Case-by-case approach which can be used for small quantities of material (i.e., of the order of one ton or less), or for other situations where the assumptions for the generic derivation of clearance levels do not apply (e.g. where the water pathway is not relevant), or for radionuclides for which clearance values have not been given in the GSR Part 3 [1], or for cases where it is proposed that the rounding procedure or other features from the model in Ref. [4] are not applied or are modified;

(g) Clearance of material and waste associated with planned activities in an area affected by consequences of a nuclear or radiological emergency;

(h) Considerations of clearance of liquids;

(i) Consideration of clearance of gases;

(j) Considerations of averaging masses and averaging areas;

(k) Discussion of the scenarios underpinning calculation of the clearance levels and the implications for application of the clearance levels;

(l) Involvement of interested parties.

1.14. The guidance provided in this Safety Guide is applicable during decommissioning of facilities, to assist in the minimization of waste that will require disposal as radioactive waste, and. for removal of

[2] Nuclide vector is a list of relevant radionuclides together with their activity percentages.

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regulatory control by the regulatory body from other radioactive material or radioactive objects within other notified or authorized facilities and activities, such as releasing material for unconditional or conditional reuse/recycling or for disposal as non-radioactive waste at conventional disposal site during operation of a facility. The guidance is applicable to solid and liquid materials. For gaseous materials only a brief discussion of key aspects to be taken into consideration is provided in section 6. It is also applicable to clearance of sealed radioactive sources, if such practice is applied in a Member State.

1.15. The information presented in this Safety Guide is applicable to facilities that use, manufacture, process or store radioactive material. The types of facilities considered include nuclear power plants, research reactors, other nuclear fuel cycle facilities, facilities for the management of radioactive waste, industrial plants, medical facilities, research facilities, educational facilities and accelerators. It also applies to industries processing material containing radionuclides of natural origin (NORM industries) and to products from such industries (e.g. products containing thorium). NORM industries are industries where these materials are processed but not for their radioactive, fertile or fissile properties. Examples of NORM industries are production of oil and gas, manufacture of titanium dioxide pigments, extraction of rare earth elements and alloys, production of metals (aluminium, iron, steel) and use of thorium in gas mantles. The information also applies to the management of material originating from remediation activities or from post-emergency situations.

1.16. The aspects of exemption are outside the scope of this Safety Guide, as they are addressed in the Safety Guide DS499 [3]. The concept of exclusion is described in section 2, as well as in DS499.

1.17. The aspects related to the control of contaminated non-food commodities that can be traded freely are outside the scope of this Safety Guide and will be addressed in a separate publication.

1.18. The aspects related to release of sites from regulatory control are outside the scope of this Safety Guide, as they are addressed in the IAEA Safety Standards Series No. WS-G-5.1, Release of Sites from Regulatory Control on Termination of Practices [5]. Buildings on a nuclear site can be cleared according to the guidance provided in this Safety Guide. It should be noted that different concepts and criteria apply for clearance of buildings versus release of sites.

1.19. The aspects related to managing radioactive waste in an emergency are outside the scope of this Safety Guide, as they are addressed in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [6] and No. GSG-11, Arrangements for the Termination of a Nuclear Radiological Emergency [7].

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STRUCTURE

1.20. Section 2 gives an overview of the regulatory framework for clearance, including basic definitions and concepts of exemption and clearance, general clearance criteria, and the responsibilities of different parties involved. Section 3 addresses the general aspects of clearance, such as the overall process and its management. Section 4 deals with clearance of solid material, discussing mass specific and surface specific levels for clearance, case-by-case approach, averaging masses and areas, implementation of clearance measurements, uncertainty considerations and aspects related to use of mixing and dilution, as well as to the general level of conservatism applied in deriving clearance levels. Sections 5 and 6 provide considerations related to clearance of liquid and gaseous materials, respectively. Concept of conditional clearance is introduced in Section 2 and discussed in Section 7. Section 8 addresses the involvement of interested parties and the enhancement of public understanding in relation to clearance.

1.21. The Appendix 1 provides an example of application of screening levels for recycling or disposal on conventional landfills of material and waste generated in a post-emergency situation.

1.22. Annex I discusses the dosimetric modelling for derivation of radionuclide specific values for clearance based on surface contamination measurements. Annex II provides examples of surface specific values for unconditional clearance. Annex III provides examples of mass specific values for conditional clearance. Annex IV provides an example of the application of clearance in small medical facilities. Annex V addresses typical levels of conservatism applied in the derivation of clearance levels as well as in the implementation of the clearance process.

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2. REGULATORY FRAMEWORK FOR CLEARANCE

GENERAL

2.1. In this Safety Guide term "clearance" is used in accordance with the definition from the IAEA Safety Glossary[8]: "*Removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized facilities and activities. Removal from regulatory control in this context refers to regulatory control applied for radiation protection purposes.*". The term "clearance" is used in relation to materials, waste and movable objects including vehicles, buildings or parts of buildings (e.g., rooms or labs within a building), while for removal of regulatory control from sites, the term "release from regulatory control" is used. In some Member States the term "clearance of sites" is also in use. The terms "characterization" and "monitoring" related to the clearance process in this Safety Guide, are also used in accordance with the definition from the IAEA Safety Glossary [7].

2.2. Reference [9 SS 89] described the original basis for exemption and the derivation of a dose criterion of the order of 10 μSv per year and the collective dose criterion of 1 man Sv per year of operation. This concept was taken forward in 1996[3] as a basis for exemption and clearance.

2.3. In 2014, GSR Part 3 [1] introduced generic clearance levels based on general criteria for either sufficiently low radiation risks or considerations of net benefit in continuing regulatory control. The collective dose criterion, mentioned in para. 2.2, is no longer considered as part of the clearance and exemption concepts.

2.4. GSR Part 3 [1] defines the concept of clearance as

> "*The removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices*", where a practice refers to "*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.*"

[3] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

The concept of specific clearance which is called "conditional clearance"[4] herewith, is also introduced in GSR Part 3, Schedule 1, section I.13. The radiological basis for conditional clearance is the same as for clearance, namely those specified in Schedule 1, sections I.10 and I.11, see paragraph 2.7.

2.5. Requirement 10 (Justification of practices) of GSR Part 3 [1] states that:

"The government or the regulatory body shall ensure that only justified practices are authorized".

So, it is implicit that a practice has to be justified[5] in order to be subject to notification or authorisation.

2.6. In addition, GSR Part 3 [1] defines a clearance level as "*A value, established by a regulatory body and expressed in terms of activity concentration, at or below which regulatory control may be removed from a source of radiation within a notified or authorized practice."* However, it has to be noted that values for specific (conditional) clearance can be proposed (derived) by the authorised parties and then they become a subject of authorisation by the regulatory body (see also para. 2.21). Therefore, the process of clearance has to be a regulated process, in accordance with a framework, established by the regulatory body. The clearance levels could be expressed in terms of activity concentration (Bq/g) and in terms of specific surface activity (Bq/cm^2).

2.7. The clearance criteria are described in Schedule I of the GSR Part 3 [1]. Para I.10 states as a general rule that:

(a) "Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks."

The general criteria for clearance should include the concept trivial dose of the order of 10 μSv in a year. The value of 10 μSv in a year was used for the derivation of the generic clearance levels.

[4] The term used in the GSR Part 3 is "specific clearance". However, in this Safety Guide the well-established term "conditional clearance" is used with the same meaning, in order to avoid a need for constructions such as "radionuclide-specific surface-specific specific clearance levels".

[5] Definition of **justification** [1]: The process of determining for a planned exposure situation whether a practice is, overall, beneficial; i.e. whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

Para. I.11 of GSR Part 3 states that radioactive material may be cleared without further consideration provided that the expected effective dose incurred by any individual is of the order of 10 μSv or less in a year for a realistic exposure scenario and does not exceed 1 mSv in a year for scenarios that address bounding exposure situations (which are termed "low probability scenarios" in GSR Part 3). This concept of using two sets of scenarios ("realistic" and "low probability") is discussed further in Section 4.

2.8. The corresponding clearance levels (derived limits of activity concentration) for solid material with radionuclides of artificial origin are listed in Table I.2 of GSR Part 3 [1] and for solid material with radionuclides of natural origin in Table I.3 of GSR Part 3 [1]. These values also apply to radionuclides of natural origin used for their radioactive, fertile or fissile properties because these radionuclides arise from an authorised practice in a planned exposure situation, see para. 3.10. Criterion (b) is applied to solid material with radionuclides of natural origin not used for their radioactive, fertile or fissile properties, e.g. in NORM industries, and the corresponding clearance levels are listed in Table I.3 of GSR Part 3 [1].

2.9. The clearance levels in Tables I.2 and I.3 of GSR Part 3 are based on the dose criteria provided in para. I.11 of GSR Part 3, and are derived using generic models. Compliance with these clearance levels may be taken without further consideration to indicate compliance with the dose criteria for clearance in para. I.11 of GSR Part 3. Where appropriate, different clearance levels corresponding to the dose criteria in para. I.11 of GSR Part 3 may be derived using more specific, e.g. less conservative, models, or specific materials may be cleared on consideration of specific circumstances and the qualitative criteria in para. I.10 of GSR Part 3.

2.10. For radionuclides of natural origin in residues that might be recycled into construction materials, or for which the disposal may present a risk of contamination of drinking water supplies, the activity concentration in the residues should not exceed specific values derived to meet a dose criterion of the order of 1 mSv in a year [1]. This means that the values in Table I.3 of GSR Part 3 [1] are not relevant in these cases. The regulatory body will therefore need to stipulate appropriate values taking into account these considerations, including values for those primordial nuclides not included in Table I.3 of [1]. Further guidance is given in Section 4, paragraphs 4.6-4.9. Examples for building materials are provided in Refs [10,11 EC BSS (2013/59/EURATOM)/EC RP112)]. The drinking water exposure pathway is addressed in Ref. [12 EC RP122 Part 2]. The guidance given in both EC recommendations can be used as guidance for modelling in situations where disposal of material could cause contamination of water supplies that could be used for private local supply of drinking water and water for agricultural purposes, although the values recommended in Ref. [12 RP122 Part 2] have been superseded by those in Table I.3 of [1].

DRAFT

2.11. Conditional clearance may be granted by the regulatory body for specific situations (para I.13 of GSR Part 3[1]), on the basis of the dose criteria listed in para 2.7. Further details are developed in Section 7 of this Safety Guide.

2.12. Clearance is, in principle, applicable to solid, liquid and gaseous materials. Once the clearance process has taken place, the waste or material that meets the clearance levels is no longer considered radioactive material and can be used, recycled or disposed of without further regulatory consideration regarding the radiological aspects. Hence, the procedures and processes leading to the act of clearance should be well defined in the national regulatory framework and in the facility's license basis. In particular, the respective responsibilities of the regulatory body and of the authorized party should be clearly established.

2.13. According to para 3.12 of GSR Part 3 [1] (Requirement 8: Exemption and clearance)

> "The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies."

This means clearance regulations should be embedded into a regulatory framework specifying that cleared materials are no longer radioactive in a legal sense or, equivalently, that the residual activity of cleared materials may be disregarded. In this way, any discrepancy between the fact that cleared material may still bear activity in a physical sense, and the fact that this activity does not play any role in a legal sense can be avoided. This applies to both the materials released under either unconditional clearance or conditional clearance (discussed in Section 7).

2.14. Clearance is also applicable to management of material originating from remediation activities or from post-emergency situations. If the concept of clearance is applied to material arising from such situations, the dose criterion remains the same as for application of clearance to material from planned exposure situations, as specified in paras I.10 – I.12 of GSR Part 3 [1]. Other approaches can also be taken, based on reference levels for existing exposure situations [13 DS468], but since these approaches use dose criteria that are different to the clearance criterion specified in para I.10-I.12 of GSR Part 3, then the process is not termed clearance. More detailed explanation and examples are given in the Appendix 1.

DRAFT

EXCLUSION

2.15. According to paragraph 1.42 of the GSR Part 3 [1], the requirements of the 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 the GSR Part 3 and thereby from the scope of an instrument of regulatory control from a radiological point-of-view. Excluded exposures are such that control measures are not possible to be taken by means of regulatory action, regardless of their magnitude.

2.16. 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 of the GSR Part 3 [1]). Other examples of excluded exposures include: (a) unmodified concentrations of radionuclides of natural origin in normal soil material, including those in high natural background radiation areas, and 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 coming from weapon testing (pre-1960s).

RESPONSIBILITIES OF THE REGULATORY BODY

2.17. To meet the Requirement 8 of the GSR Part 3 [1], described in para 2.11 of this Safety Guide, the regulatory body should put in place a framework for clearance of material, including clearance levels to be used, in agreement with the clearance criteria defined in the GSR Part 3 [1].

2.18. Depending on the national framework, the regulatory body should review the results of the characterisation programme implemented by the authorized party (described in para. 2.35) to define the radionuclide inventory subject to clearance.

2.19. For clearance of bulk material from regulatory control, the regulatory body should refer to the derived clearance levels for solid material with radionuclides of artificial origin and of natural origin, listed in the Table I.2 and Table I.3 of GSR Part 3 [1].

2.20. For clearance of surface contaminated material, the regulatory body should promote the use of radionuclide specific clearance levels, derived in an analogous way as the clearance levels for bulk materials. This topic is discussed further in section 4, paras 4.18-4.27.

2.21. When establishing clearance levels, the regulatory body should be aware of other regulatory requirements that could also apply, such as non-radiological limits and, to the extent possible, harmonize these requirements.

2.22. If the regulatory body allows authorized parties to propose their own derived clearance levels on the basis of the clearance criteria defined in GSR part 3 [1], the regulatory body should require authorized

parties to demonstrate that their own derived clearance levels will provide an equivalent level of protection and safety, and should approve these levels. This is an example of case-by case clearance levels. In that case, the implications of the derived levels should also be explained to the relevant interested parties and verified against other regulatory requirements, e.g. those dealing with non-radiological limits (to avoid situations that derived clearance levels are higher than limits derived on the basis of chemical toxicity, or if such situation arises, to manage it properly). The implication in terms of harmonisation and the potential for the material to come back into regulatory control also need to be considered and managed properly. If conditions are specified on the type of material, amount or destination then this is conditional clearance, see section 7 for further discussion.

2.23. In addition to defining clearance levels in terms of activity concentration, the regulatory body should also specify averaging masses, volumes or areas of material to be monitored for clearance or to approve parameters proposed by an authorized party. The regulatory body should also approve or specify additional monitoring criteria to identify presence of "hotspots" (a non-uniform distribution of activity concentration with some values above the clearance levels) in the material considered for clearance. Further details are discussed in section on averaging masses and areas (Section 4, paras 4.35-4.44).

2.24. The regulatory body should specify that deliberate dilution and/or mixing with clean material to reach the activity concentration values prior to release of material from regulatory control is not an acceptable practice, unless a permission is obtained from the regulatory body for such an action. More detailed explanation on this point is provided in section 4 (paras 4.92-4.97).

2.25. According to para. 3.37 of GSR Part3 [1] (Requirement 14: Monitoring for verification of compliance):

> "The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."

The regulatory body should have competence and resources to review and supervise the clearance procedures of the authorized party, including capacity of making independent verification measurements.

2.26. According to the national framework, the regulatory body should agree / approve the appropriateness of the monitoring process of the authorized party (registrant and licensee) for verification of compliance with clearance levels. Based on the results of the monitoring process, the authorized party should decide whether material complies with the clearance levels. For the decision as to whether specific material is suitable for clearance, the regulatory body should base its approval on the monitoring results,

DRAFT

according to the national framework. In case of the use of statistically based methods by the authorized party, the approach should be fully documented and approved by the regulatory body prior to its implementation. In addition, in case of specific (conditional) clearance, the regulatory body should be provided assurances for compliance with all the conditions attached to the clearance process, such as destination for the material and its further processing or reuse).

2.27. Since decisions made on the basis of the monitoring results have important regulatory, public health and societal implications, the quality management system implemented and used by the authorized party should satisfy the requirements established by the regulatory body and international standards. The regulatory body should also undertake its own independent verification programme, as additional assurance that the monitoring programme is being carried out adequately.

2.28. In the case of conditional clearance (specific clearance), the regulatory body should establish a mechanism to demonstrate compliance with the conditions attached to the process, e.g. that the metal will only go to a recycling facility and will be melted rather than reused directly. In addition, the regulatory body should allocate responsibilities for the process and consequences in case of non-compliance.

2.29. According to para. 2.35 of GSR Part3 [1] (Requirement 3: Responsibilities of the regulatory body):

> "The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to facilities and activities."

2.30. In the case of clearance of material from regulatory control, the regulatory body should define the required content of the key records and the documentation that demonstrates compliance of the clearance process with the requirements.

2.31. In addition, the regulatory body should define the period of time required for keeping the records and documentation (depending on the history, hazard and characteristics of the material) after the material has been cleared.

2.32. Material cleared from radiological regulatory control could still be subject to other non-radiological regulatory controls. Therefore, the relevant regulatory bodies should coordinate their activities, share their concerns, and communicate their regulatory strategies and their implementation in order to build confidence in the clearance process and to ensure smooth management of the material after clearance. In the case of transboundary movement, this coordination should involve regulatory bodies from the involved countries. This can be accomplished through transparency, disclosure and use of international standards and procedures.

2.33. The regulatory body should consult with interested parties in developing the regulatory framework for clearance and in enhancing public understanding.

RESPONSIBILITIES OF THE AUTHORIZED PARTY

2.34. According to para. 2.35 of GSR Part 3 (Requirement 14: Monitoring for verification of compliance):

"Registrants and licensees and employers shall ensure that:

(a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of these Standards;
(b) Suitable equipment is provided and procedures for verification are implemented;
(c) Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;
(d) Records are maintained of the results of monitoring and verification of compliance, as required by the regulatory body, including records of the tests and calibrations carried out in accordance with these Standards;
(e) The results of monitoring and verification of compliance are shared with the regulatory body as required."

2.35. As part of the clearance process, the authorized party should perform a radiological characterisation of the material to be cleared, comprising the determination of the radionuclide vector (fraction of the activity concentration contributed by each present radionuclide) to be considered and the spatial distribution of the activity. Depending on the national framework, the results should be submitted to the regulatory body.

2.36. The authorized party should set up the clearance process, making the measurements and verifying compliance with the clearance criteria, including selecting proper equipment and place for clearance measurements, calibration of equipment, establishment of organisation with clear responsibilities, hiring of competent people, training of staff, promotion of safety culture, development of procedures and documentation, and interfacing with the regulator and interested parties, according to the national framework.

2.37. The process of clearance of material from regulatory control should be an integral part of the integrated management system. The assurance of the quality of results obtained and used during the clearance process is critical for ensuring and demonstrating that the established activity values have been met and to build confidence in the use of the data, the equipment and the methodology. The authorized party should develop and implement a quality management programme during monitoring for compliance with clearance levels through formally documented and controlled procedures and working instructions.

DRAFT

This quality management should satisfy the recognized standards established by the regulatory body and international standards.

2.38. The authorized party is responsible for the reliability of the results of the monitoring programme and should not rely on the regulatory body to point out unexpected deficiencies in their work. Any verification programme carried out by the regulatory body should not be considered as a substitute for the quality control/assurance programme within the management system established by the authorized party.

2.39. The authorized party should communicate the results of its clearance and monitoring programme to the regulatory body in a transparent way to obtain regulatory approval for the clearance of material.

2.40. The authorized party is responsible for the clearance activity and should retain key records from the monitoring to demonstrate that clearance has been carried out appropriately. These records should be developed and preserved in the appropriate formats, as defined by the regulatory body. Documentation should be stored for a defined period of time, as specified by the regulatory body.

2.41. The authorized party should engage with interested parties to explain the application of the concept of clearance and seek acceptance from receivers of waste and materials. Interested parties may include professional associations (e.g., a national association of metal recyclers), non-governmental organizations, and the party that is requested to receive the cleared material. Guidance on this topic is provided in Section 8.

ORGANIZATION AND IMPLEMENTATION OF THE CLEARANCE PROCESS

2.42. The organisation and implementation of the clearance process will be dependent on the chosen approach of the regulatory body for this matter. The minimal set of requirements for the clearance process should consist of:

(a) Defining roles and responsibilities of authorized party, contractors and regulatory bodies and establishing adequate personnel resources (in number and competence);

(b) Establishing an appropriate quality management programme;

(c) Organizing involvement of interested parties (receivers of waste and materials) prior to implementation of the process in accordance with existing national law on public involvement and with graded approach (paragraphs 2.47-2.54).

2.43. The clearance levels to be used could either be defined by the regulatory body (e.g. generic clearance levels as defined in the GSR Part 3 Tables I.2 and I.3 [1]), or proposed by the authorized party and approved by the regulatory body, or a combination of the two approaches in case of multiple

radionuclides present in the material to be cleared. Such combination may involve use of generic clearance levels for some radionuclides (that are provided by the regulatory body), together with use of clearance levels that are derived and proposed by the authorized party for the radionuclides not included in the list of generic clearance levels or considered not adequate (for example, too conservative) for the specific clearance case.

2.44. In any case, the overall clearance process requires a structured approach both by the regulatory body and by the authorized party. The regulatory body should clearly define the different steps in the process and specify hold points if applicable. Arrangements should be put in place for timely discussions between regulator and authorized party as an important part of the clearance process. In the cases where authorisation or licensing for clearance is required, the requested data and the level of detail should be specified by the regulatory body.

2.45. In order to verify compliance with clearance levels, the authorized party should put in place an appropriate monitoring programme, based on a reliable characterisation and a good definition of the source term (list of radionuclides and their expected activities in the material). The monitoring programme should be submitted to the regulatory body for approval, according to the national framework, before the start of the clearance process.

2.46. Clearance occurs at the point at which regulatory control due to radioactivity of the material is removed. This might involve independent verifications by the regulatory body. Additional considerations for the point at which clearance occurs in case of conditional clearance are addressed in section 7.

GRADED APPROACH

2.47. The clearance process provides an opportunity to apply a graded approach to management of material and waste, by applying the level of regulatory control that is commensurate to the level of radiological risks associated with the material and its intended use. Para 2.31 (Requirement 3: Responsibility of the Regulatory Body) and Requirement 6 of the GSR Part 3 [1] state that:

> "The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."
>
> "**Requirement 6: Graded approach**
>
> **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.**"

2.48. The application and implementation of the clearance concept relates to a large range of authorized activities, for example, operation of facilities, decommissioning, and management of radioactive waste. International consensus has been achieved on activity concentration values (Bq/g) below which material does not require regulatory control [1]. The practical implementation of these clearance levels should also consider a graded approach, which depends on the national regulatory framework and decision by regulatory body.

2.49. The application of the graded approach to the clearance process should take into account aspects such as the size and complexity of the facility or project (e.g. nuclear power plant versus research laboratory, decommissioning versus operational activities), the amount of material to be cleared, operational history, the national regulatory framework and general social and economic factors.

2.50. In the case where the history and provenance of the material is well known and shows evidence for no activation and low levels of contamination, the complexity of the monitoring process (number of samples and measurements, type of analyses) should be in an agreement with this information. In any case, the reasoning for the selected approach needs to be firm and well documented. In the case where the history and provenance of the material is well known and shows no indications for activation or contamination, the clearance procedure should not be applied. Instead, it should be sufficient to state that the material has not been radiologically impacted by the practice. If any doubt exists, a few confirming measurements should be made to confirm the non-existence of activation or contamination.

2.51. Also, if it is verified that the material has a consistent radionuclide vector or a uniform level of contamination, then fewer measurements are required to characterise it and conduct the clearance process.

2.52. Regardless of the size of the project, adequate monitoring of the material to be released is required to demonstrate that the requirements of the regulatory body are met, but the level of effort put into quality management, documentation and record keeping should be commensurate with the scope and complexity of the monitoring process.

2.53. Further discussion on the management of the uncertainties in the clearance process is given in section 4.

2.54. The concept of conditional clearance, otherwise referred to in GSR Part 3 [1] as *"clearance granted by the regulatory body for specific situations"*, is also an example of a graded approach. This is described further in the section 7.

DRAFT

3. GENERAL ASPECTS OF CLEARANCE

OVERVIEW

3.1. The operation and decommissioning of facilities, remediation activities or post-emergency situations generate certain amounts of radioactive waste or material. Some material and waste will be radiologically clean but are considered potentially radioactive due to their origin from the controlled area of the facilities. Significant amounts of the waste or material from operation and decommissioning will have a sufficiently low activity concentration that meets the criteria for clearance as described in Paras I.10-I.12 of the GSR Part 3 [1] and is therefore suitable for clearance. Most of the radioactive waste and material with low activity concentrations will be solid, but there are situations when liquids (and even gases) may also be suitable for clearance. The discussion on general aspects of clearance therefore focuses on aspects relevant to solids, which are addressed in Section 4. If not specified otherwise, it is also applicable to liquids. Specific considerations for liquids are addressed in Section 5 and for gases are addressed in Section 6.

3.2. The clearance process results in a decision as to whether the waste or material can be released from further regulatory control regarding its radiological properties. Only very short lived radioactive waste [14 GSG-1] can be cleared after storage, when its activity falls below the clearance levels. Other properties, e.g. the hazardous properties of the waste or material, will determine whether other controls remain or become appropriate.

3.3. As part of the clearance process, the radionuclide content of the material should be determined through a process of characterisation (more detailed guidance is provided in the following sub-section). The resulting list of the radionuclides present and the fraction, or percentage, of the activity concentration contributed by each radionuclide is known as the radionuclide vector. The different processes that have contributed to the presence of radionuclides in the waste (e.g. fission, activation, contamination, fuel fabrication) should be identified in order to ensure that the radionuclide vector is comprehensive.

CONSIDERATION OF CLEARANCE FOR MATERIALS CONTAINING MORE THAN ONE RADIONUCLIDE

3.4. GSR Part 3 [1] specifies clearance levels for solid material. The clearance levels in terms of mass specific activity concentrations (in Bq/g) for individual radionuclides of artificial origin are listed in Table I.2 and the clearance levels for individual radionuclides of natural origin are listed in Table I.3 of GSR Part 3.

DRAFT

3.5. The clearance levels specified in GSR Part 3 [1] apply to individual radionuclides. If wastes or material contain more than one radionuclide, the process of clearance should take into account the contribution of each of the radionuclides to the dose. Therefore, a clearance level should be determined for the specific radionuclide vector in the material that is being considered for clearance. The approach for materials containing more than one radionuclide depends on whether the radionuclide is of artificial or of natural origin.

3.6. The approach for materials containing more than one radionuclide of artificial origin is often referred to as the 'sum of fractions' approach and the summation rule is described in para I.14 of GSR Part 3 [1]:

> "For clearance of radioactive material containing more than one radionuclide of artificial origin, on the basis of the levels given in Table I.2 (p. 124), the condition for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (*Xm*), determined as follows:
>
> $$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}} \qquad \text{(I.2)}$$
>
> where
>
> *f(i)* is the fraction of activity concentration of radionuclide i in the mixture;
>
> *X(i)* is the applicable level for radionuclide i as given in 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).

$$\sum_{i=1}^{n} \frac{C_i}{CL_i} \leq 1 \qquad (1)$$

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

The sum of fractions should always be used for artificial radionuclides, regardless of the number of radionuclides in the summation or the choice of the monitoring technique (see para 4.55).

3.7. The mass specific clearance levels for radionuclides of artificial origin, given in Schedule I, Table I.2 of [1], also take into account dose contributions from relevant progeny radionuclides. The weighting factors applied for the activity concentrations of the progeny are given in Table II-1 of the Appendix II of

SRS-44 [3]. Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculations in SRS-44 (thus requiring only the clearance level of the parent radionuclide to be considered), are listed in the footnote to Table I.2 in GSR Part 3 [1]. The weighting factors account for secular equilibrium and also for the relevant contribution of longer-lived progeny to the exposure resulting from the parent radionuclide.

3.8. Therefore, a progeny radionuclide that is listed in the footnote to Table I.2 in GSR Part 3 [1] should not be included in the summation rule if it is present at an activity concentration that is equal to or lower than that corresponding to the weighting factor from Table II-1 of Appendix II of Ref. [3] multiplied by the activity concentration of the parent radionuclide. If this is not the case, the activity concentrations of parents and progeny radionuclides should be considered (unmodified) in the summation rule.

3.9. The mass specific clearance levels for radionuclides of natural origin apply to each individual radionuclide of the decay chain of ^{238}U and ^{232}Th or parts thereof, regardless whether the decay chains are in secular equilibrium or not. Hence, the sum of fractions approach is not appropriate for clearance of materials containing only radionuclides of natural origin. GSR Part 3 [1] specifies in para. I.12(b) that the material can be cleared provided that the activity concentrations of radionuclides of natural origin do not exceed the relevant level given in Table I.3. The activity concentration of each radionuclide of natural origin should therefore be compared with the clearance level and, if each one is less than or equal to the clearance level then the material can be cleared. For example, for wastes containing radionuclides from the ^{238}U- decay chain, the mass specific clearance level of 1 Bq/g would apply to each member of the ^{238}U- decay chain present in the waste. Where the secular equilibrium is significantly disturbed (e.g. due to thermal processes) or only parts of the decay chain are present, use of the levels given in Table I.3 of GSR Part 3 may be found too restrictive. In this case, the competent authority might derive appropriate values on the basis of model considerations.

3.10. Contamination with radionuclides of natural origin, where these result from authorised practices in which natural radionuclides are processed for their radioactive, fissile or fertile properties, such as uranium extraction, conversion, enrichment, fuel fabrication and fuel reprocessing, are treated in the same way as artificial radionuclides. In this case, the fact that these radionuclides arise from an authorised practice in a planned exposure situation according to Section 3.1 of GSR Part 3 [1] is decisive, not the origin of the radionuclides. Hence, the mass specific clearance levels from the Table I.3 of GSR Part 3 [1] (1 Bq/g) do not automatically apply in cases of clearance of materials containing naturally-occurring radionuclides.

3.11. For clearance of solid bulk material containing a mixture of radionuclides of natural origin and radionuclides of artificial origin, GSR Part 3 [1] specifies that the conditions given in paras I.12(b) and

I.14 of [1] both have to be satisfied. Therefore, the radionuclides of artificial origin in the waste or solid material should be considered separately from the radionuclides of natural origin when making the decision as to whether the waste can be cleared. The clearance decision should therefore contain the following steps:

(a) apply the summation rule to the radionuclides of artificial origin in the waste or material;
(b) apply the clearance levels for radionuclides of natural origin to the radionuclides of natural origin individually;
(c) if both the radionuclides of artificial origin and the radionuclides of natural origin meet the clearance criteria then the material can be cleared;
(d) if either the radionuclides of artificial origin or the radionuclides of natural origin fail to meet the clearance criteria, then the material cannot be cleared.

3.12. Note that radionuclides of natural origin that arise as a result of a practice, where these radionuclides are processed for their radioactive, fertile or fissile properties, are included in the summation rule under (a), as discussed in paras 4.8-4.10. Radionuclides of natural origin not arising from a practice, e.g. present in construction materials, are considered under (b) above.

CHARACTERISATION OF THE MATERIAL TO BE CLEARED

3.13. The objective of radiological characterisation of the material to be cleared is to provide a reliable database of information on quantity and type of radionuclides, their spatial distribution and their physical and chemical states. The characterisation results should then be used by the authorized party to clearly define the material to be cleared, and to select the optimum monitoring strategy (compliance monitoring) for the clearance process. The characterisation results should also be used to assess various options for the clearance process and their consequences, for example, batch monitoring tools and techniques, destinations for the cleared material, conditional clearance or unconditional clearance, radiological protection of workers, general public and environment, and resulting costs. The level of detail and the implementation of the different proposed steps should be proportional to the complexity of the situation in accordance with the graded approach.

3.14. Characterisation requires a logical and systematic approach. A comprehensive characterisation programme comprises the following steps [15 TRS389]: (a) review of historical information including process knowledge of the material; (b) activation and decay calculations; (c) preparation of the sampling and analysis plan based on an appropriate statistical approach; (d) performance of measurements, sampling and analyses; (e) review and evaluation of the data obtained; and (f) comparison of calculated results and measured data. Characterization should be considered as an iterative process, taking into

account possible alterations in the radionuclide vector due to e.g. chemical decontamination or dismantling activities. The iterative character of the process is further discussed below.

3.15. The characterisation process should collect information on the following aspects: origin of the material within the facility, location of the originating facility, type of originating facility, period of operation, operational history (including incidents and post-incident remediation) and radionuclides associated with operations; size, type and quantities (total and rate of production) of material; radionuclides present in the material; expected levels of contamination or activation of each type of material; type of contaminant (fixed or non-fixed surface contamination, bulk contamination); homogeneity of contamination (identification of hotspots on the surface or within the volume); other hazards associated with the material; time frame for the clearance process and clearance monitoring throughput required. Further information on characterisation is provided in Ref. [16 SRS67].

3.16. The characterisation process will generate a large amount of data in different formats (e.g. paper, digital) and therefore the authorized party should have a suitable records and data management system, which should be integrated with the overall information management system of the facility. Examples of such systems to support decommissioning are described in the refs [17,18].

Historical information

3.17. Detailed information on the history of the material to be cleared should be collected as the first step in the characterisation process. This information should then be used to develop the other steps in the characterisation process. Information should be obtained from various sources such as: historical records; knowledge of the types of processes involving the material; experience gained elsewhere; public or institutional memory; recollections from workers.

3.18. This detailed history should include information on: the processes or activities during the operation of the facility; location of controlled and supervised areas; description of the facility and equipment; type and form of the radioactive material used during operations; whether the radioactive contaminants have been enclosed within specific areas; whether the material has been potentially activated by neutron exposure; whether the material has been contaminated as a consequence of an accident or spill; whether the building or equipment has been refurbished or modified; whether the building, equipment and areas have been decontaminated; time at which contamination or activation of the material occurred; results of any past characterisation or monitoring of the material.

3.19. Establishing the historical information relevant to the material to be cleared should be straightforward for most of the facilities, such as nuclear power plants, but might be more complicated for nuclear research facilities where different types of activities, such as experiments, chemical processes

DRAFT

and others, were carried out, or for novel nuclear power plants, because information on the plant history may often be lacking and there are no or few similar facilities which can be used as reference. Where detailed historical information is not available, for example in the case of remediation activities or for old facilities, a greater emphasis will need to be placed on the characterisation programme.

3.20. The detailed information on the history of the material to be cleared should be used to determine an initial estimate of the radionuclide vector for the material, and this initial estimate should be used to develop and implement steps (b), (c) and (d) described in para. 3.14 (calculation, sampling plan, measurements, sampling and analysis). Initial measurements provide useful information that can be used to guide the sampling plan, e.g. by defining zones.

Sampling of material

3.21. Steps (e) and (f) (review and evaluation of data, and comparison of calculated and measured results) should be carried out as early as possible and continue during sampling and analysis. Characterization plans may change as a result of these ongoing assessments, for example, where contamination is more (or less) extensive than originally anticipated or where trends in measurements made indicate that the sampling plan in use will not give the required information for planning. The historical information may also need to be revisited if additional radionuclides are identified in steps b), c) and d) and thus the characterisation process should be viewed as an iterative process. One of the important outputs from the characterisation process is a credible radionuclide vector or vectors for the materials to be cleared.

3.22. Two main types of measurement are relevant for characterization of solids for clearance: measurements of the surface contamination (fixed or removable), and bulk activity measurements, generally based on gamma spectrometry or total gamma measurements, but also including alpha and beta measurements. In each case, particular attention should be paid to ensure that the methods of measurement take into account the geometry, the surface conditions and the nature and extent of the radioactive contaminants. It is unlikely that dose rate measurements unsupported by spectrometry will provide useful information for characterization for clearance. Further information on in situ measurement techniques is available [16,19,20].

3.23. The sampling and analysis programme should ensure that representative samples are taken from the material to be characterized. The sampling and analysis techniques determine the constituents and their radioactivity in selected locations. Further information on sampling and analysis techniques is available [15,16,19,20,21] (TRS389, SRS67, MARSSIM, MARSAME, ISO21238). The sampling and analysis techniques should be selected and applied in accordance with the graded approach.

Establishing the nuclide vector selecting from all radionuclides that have been identified

3.24. Material for clearance usually contains more than one radionuclide, and some of these radionuclides may be difficult to measure routinely during the clearance process. The information obtained from the historical review and the calculations can be used to determine an initial estimate of the radionuclides expected and the ratios (also called scaling factors[6]) between the different radionuclides that are used in derivation of radionuclide vectors. Then, a limited number of thorough measurements can be used to determine whether difficult-to-measure (DTM) radionuclides are found to be roughly in a fixed ratio with easy-to-measure (ETM) radionuclides. If this is the case, then a stable radionuclide composition exists and the measured scaling factors could be used to estimate the activity of the DTM radionuclides, in the material to be cleared, from the measurements on ETM radionuclides. An example is the use of ^{60}Co to monitor the wide range of DTM radionuclides associated with activation products and corrosion products associated with the operation of reactors.

3.25. Scaling factors for DTM radionuclides should be used carefully and the stability of the radionuclide vector should be reviewed frequently. In some facilities, one set of scaling factors can apply over a large area, whereas in other facilities the radionuclide composition may vary considerably over space and time, and for different materials, particularly where chemical processes or decontamination procedures have taken place. Radionuclide composition will also vary where the radioactivity is generated by neutron activation and the concentration of impurities in the material play a significant role (e.g. variations in the cobalt content of steel).

3.26. The selection of the significant radionuclides to be evaluated for clearance is a kind of screening process and is based on an initial estimate of the activity concentration (C) of the radionuclides in the material. Since the uncertainty of the initial estimation of the activity concentration C is usually larger than the uncertainty in the final process for clearance through the compliance measurements, the uncertainty of C in the screening process should be addressed by selecting a larger number of significant radionuclides.

3.27. In practice, all radiation monitoring equipment has a response which depends on radiation type, energy and material geometry. The response of the equipment that will be used will have to be calculated for the mix of radionuclides and their relative proportions. This involves selection of key radionuclides to be measured based on their emission properties, the ease and efficiency of detection (particularly whether the required detection limit can be achieved) and considering their contribution to the summation rule. Although selection of radionuclides which contribute a higher fraction towards the clearance level (CL)

[6] Factors or parameters determined from sampling and analysis data and used in calculating the activity of difficult-to-measure radionuclides on the basis of measured radioactivity of easy-to-measure radionuclides.

of the material, i.e. a high value of *C*/*CL*, would be preferable, in many cases it will be necessary to select a radionuclide which contributes a lower fraction because it is easier to measure. An example for the selection method for solid materials consists of two steps is provided in Figure 3.1 [16 SRS67]:

(a) The first step determines which radionuclides should be included in the overall evaluation and refers to the boxes in the upper part of the Figure 3.1.A key radionuclide is selected among the easy-to-measure (ETM) radionuclides, which gives relatively high value of *C*/*CL*. Then a measure of significance is introduced as the relative ratio $(C_j/CL_j)/(C/CL)_{key}$, where $(C/CL)_{key}$ is the ratio for the key radionuclide, and select significant radionuclides that satisfy the condition $(C_j/CL_j)/(C/CL)_{key} > 0.01$.

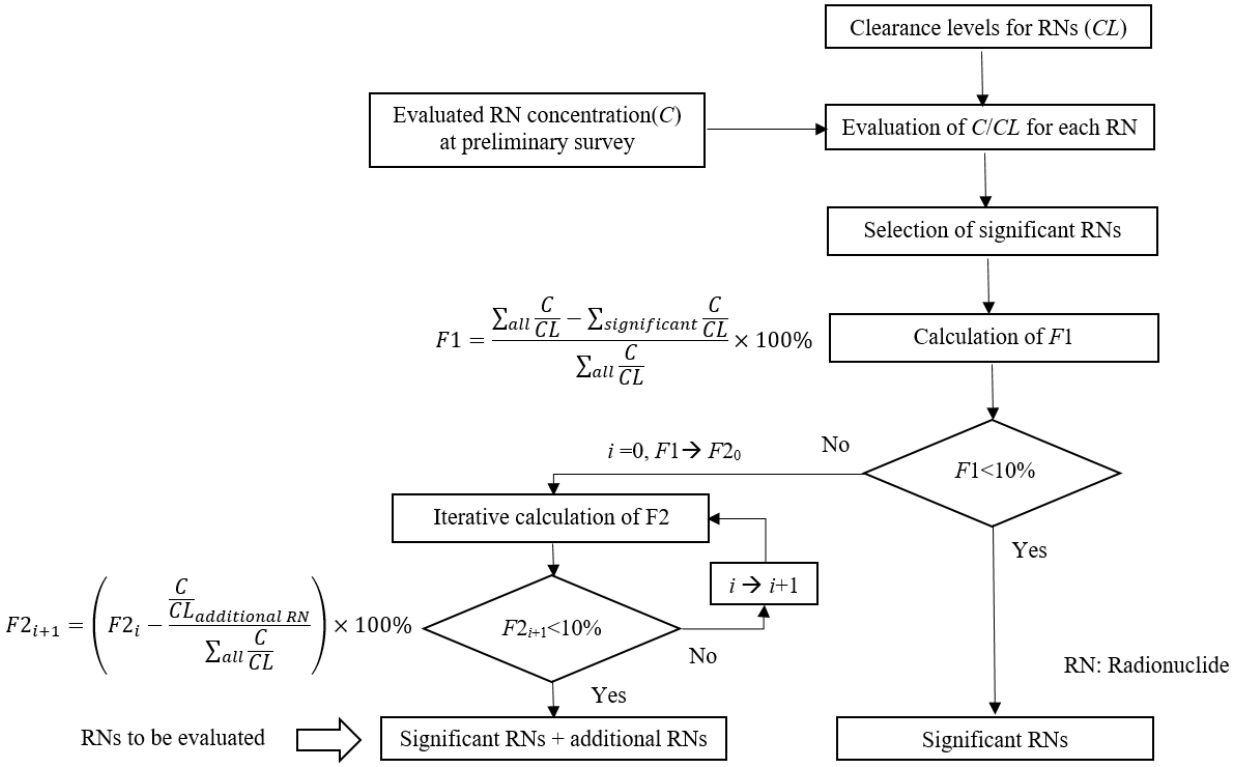

Fig. 3.1. An approach to selection of significant radionuclides to be evaluated (based on [16 SRS67]).

(b) In the second step, selection of radionuclides is done so that with the smallest possible number of selected radionuclides, the sum of *C*/*CL* for that selection corresponds to >90% of the sum of *C*/*CL* of all radionuclides. The key radionuclide is always included in the selection. This is done in an iterative process. The sums of *C*/*CL* for all radionuclides and for significant radionuclides are calculated. If the difference between the two sums, *F1*, is less than 10% of the sum of *C*/*CL* for all radionuclides, the selection of radionuclides for evaluation is completed. If *F1* is more than 10%,

one additional radionuclide (with highest *C*/*CL* among the remaining radionuclides) is added to the selection and new value *F2* is calculated. The process continues until the difference *F2* is less than 10%.

3.28. The following is an example for the selection method specified in Japanese standard of examination for approval of measurement and evaluation for solid materials clearance [22 NRA Japan]. The standard of examination for approval of measurement and evaluation specifies that *m* significant radionuclides should be selected from *n* listed radionuclides so as to satisfy the following formulae:

$$\frac{\sum_{j=1}^{m}\frac{C_j}{CL_j}}{\sum_{k=1}^{n}\frac{C_k}{CL_k}} \geq 0.9\,,\ \frac{C_1}{CL_1} \geq \frac{C_2}{CL_2} \geq \cdots \geq \frac{C_m}{CL_m} \geq \cdots \geq \frac{C_n}{CL_n} \qquad (2)$$

k is the assigned number for the radionuclide listed.

j is the assigned number for the selected radionuclide with high C_j/CL_j from the list for the evaluation.

C_k is the activity concentration (Bq/g) of the *k*th radionuclide in the material.

CL_k is the clearance level (Bq/g) of the *k*th radionuclide.

C_j is the activity concentration (Bq/g) of *i*th radionuclide for the evaluation.

CL_j is the clearance level (Bq/g) of *i*th radionuclide for the evaluation.

n is the total number of all listed radionuclides whose activity concentration limits are derived.

m is the total number of the selected radionuclides for the evaluation.

3.29. The response of the monitoring system can then be calculated in terms of the radionuclide composition. This approach can also allow a calculation of the likely variation in response of contamination monitoring equipment with the surface contamination. If the equipment, for example, has a good response over a wide range of beta energies, then the response will change quite quickly with the degree of self-absorption. Sometimes, a correction factor needs to be introduced, particularly if a significant proportion of the emissions are of low energy. Alternatively, the equipment can be modified to shield the low energy emissions, so that the variations are eliminated.

3.30. As mentioned above, the radionuclide composition (and the scaling factors) should be re-evaluated as monitoring of material proceeds, particularly on old, complicated facilities that cannot be characterized in detail before the clearance process begins. Quite simple means can sometimes be employed to check

on radionuclide composition stability, for example the ratio of the count rates from two different counting windows on a monitor or the influence of an absorber placed between the contaminated surface and the monitor. Gamma spectrometry is also a relatively cheap and easy process that can be employed to check on the photon emitting component. A combination of gamma spectrometry and gross beta measurement can also demonstrate stability where the main contaminants are ^{137}Cs + ^{137m}Ba, a gamma and medium energy beta emitter, and ^{90}Sr + ^{90}Y, a medium and a high energy beta emitter.

3.31. The following example demonstrates how to go from information on the radionuclide vector and the individual clearance levels for radionuclides present to identifying the clearance level for the key radionuclide that can be used for compliance measurements (CL_{eff}). In the example, the matrix has a mixture of two radionuclides ^{14}C (clearance level = 1 Bq/g) and ^{60}Co (clearance level = 0.1 Bq/g), contributing to the total activity with 75% and 25%, respectively. The derived clearance level for a mixture of radionuclides in this particular example is the following[7]:

$$\frac{1}{CL_{\text{eff}}} = \frac{0.75}{1\ \text{Bq/g}} + \frac{0.25}{0.1\ \text{Bq/g}} \quad (2)$$

$$CL_{\text{eff}} = 0.31\ \text{Bq/g} \quad (3)$$

In order to demonstrate compliance with this effective clearance level for a mixture of radionuclides, one or more easy to measure radionuclides should be selected for measurements. In the example above ^{60}Co is selected as the key radionuclide. The level to be used for compliance measurements, associated with this key nuclide in this given mixture, is then calculated by multiplying the CL_{eff} by the activity fraction of this key radionuclide. In the example given above, that level is 0.25×0.31 Bq/g. Hence, material with activity of ^{60}Co below this level can be cleared.

3.32. Following characterisation, the clearance levels that are to be applied during the clearance process are selected. Sampling and monitoring for compliance with these clearance levels might identify additional radionuclides or changes in the scaling factors between different radionuclides. This will then feedback into additional characterisation work, followed by a revised monitoring scheme for the clearance process.

MANAGEMENT OF THE CLEARANCE PROCESS

3.33. The clearance process requires careful planning and implementation in order to achieve optimum performance. This section describes good practice concerning the management of the clearance process

[7] CL_{eff} is used in this context to represent X_m from the equation I.2 of the GSR Part 3 [1].

in situations where this is a regular process as an integral part of the management system (according to paras.2.37-2.38), and where the material throughput is substantial, i.e. where the clearance process is not applied on a sporadic basis or for small quantities. Some aspects are still valid for small quantities of cleared material and should be applied in accordance with the graded approach.

Assignment of responsibility

3.34. Responsibility for the clearance process usually lies with the radiation protection or radioactive waste management department of a facility, in which radioactive material is handled. The staff implementing the clearance process should clearly be allocated and should be suitably qualified, properly trained and competent for their roles. The number of staff needs to be commensurate with the required measurement capacity and the quantities to be handled.

3.35. Additional staff are required to keep track of the material undergoing the clearance process by updating databases on the material and maintaining the documentation. Staff will also be needed to ensure continued movement of material and monitoring segregation of material that has been cleared.

Prerequisites for the clearance process

3.36. The implementation of the clearance process will require sufficient and adequate equipment to perform the radiation monitoring and equipment to handle the material. The area where clearance measurements are being performed should be cleaned previously and should have a low radiation background to the extent practically possible.

3.37. Prerequisites for the clearance process are a thorough radiological characterisation, where sampling has been performed in a representative way for the facility or facility section (including the material present), taking account of the operating history, and an adequate analysis of the radionuclide mixtures (including specification of the key nuclides for the facility or facility section) has been carried out.

3.38. The results of the radiological characterisation serve as the basis for defining appropriate batches of material in the clearance process. Using batches of materials with similar characteristics enables the clearance process to be more efficient than using batches of highly heterogeneous material, as the relevant settings of the measuring instruments are very similar for material with similar characteristics.

3.39. A further prerequisite for the clearance process is a database system in which the identification and location of the material and the results of the clearance measurements can be updated to reflect the current situation at any time.

DRAFT

3.40. The clearance process for materials is most effectively implemented if clearly assigned areas exist for material transfer, buffer storage, surface-related and mass-related measurements, and staging areas where the cleared material can be placed until it can be removed from the facility. Since the clearance of building structures, sites and floor slabs will be performed in situ, this is not practicable, hence appropriate processes should be developed taking similar aspects into consideration.

3.41. The following description refers to an idealized clearance process for solid materials. In practical cases, individual steps can be omitted or carried out in a different sequence.

(a) The material is transferred from its place of origin (e.g. an area in the facility where dismantling, segmentation and decontamination are taking place) to a buffer storage area. Material that has been segmented into pieces is usually moved in boxes. The individual parts usually have a size that enables them to be handled with a small electric hoist or by hand.

(b) On the buffer storage area, the material is assembled into batches depending on its origin and characteristics, in particular the technical system, the operation history, the radiological properties, and others. Batches entering the clearance process will therefore consist of material with similar characteristics.

(c) The next step in the clearance process is a measurement of surface specific contamination, including contamination of inner surfaces, if such measurements are required and possible. This is carried out in an area dedicated for this purpose. The individual parts are put on tables or racks where the total surface can be accessed with contamination monitors.

(d) The readout of the surface-related measurements is evaluated against the surface-related clearance levels to be complied with (if any), taking the averaging area, nuclide vectors and other specifications of the process into account. If the surface-related clearance levels are complied with, the material can be moved on to the next station; if not, additional decontamination may be necessary and the material is sent to a controlled area for further treatment or for management as radioactive waste. Note: If the measurement of surface-specific activity will also allow demonstration of compliance with mass-specific clearance levels through conversion (using density and thickness of the measured material) with appropriate significance and on an appropriate confidence level, then the next 2 steps can be omitted. Compliance with mass-specific clearance levels, however, needs to be demonstrated in any case.

(e) Following demonstration of compliance with the surface-related clearance levels (if this step is required), the material is then moved to the next buffer storage area, awaiting measurements for determination of the mass-related activity.

(f) The next step is usually the measurement of the bulk activity to be compared with the mass-related clearance levels. In cases where the percentage of gamma emitting radionuclides is sufficiently

high, bulk monitors based on gross-gamma counting or drum monitors based on gamma spectrometric measurements are used for this step (in such devices, the mass of material per measurement is usually in the range between a few 10 kg and a few 100 kg). In other cases, the bulk activity has to be determined from sampling, from surface-related measurements or from other measurement methods.

(g) The readout of these measurements is evaluated against the mass-related clearance levels, taking the averaging mass, nuclide vectors and other specifications of the process into account. If the mass-related clearance levels are complied with, the material has successfully passed all measurements; if not, a decision on alternative waste routes has to be taken.

(h) Before the material is released from the site, verification measurements by or on behalf of the regulatory body may be required to support the authority in its decision regarding approval according to 2.25. In this case, the material is brought to a further buffer storage site outside or at the border of the controlled or supervised area, where these checks can be performed. If compliance with clearance levels has been confirmed, the material may be released. Otherwise, the material stays under regulatory control or, in case of waste, it is managed as radioactive waste.

(i) Finally, the material is moved to a place where it can be handed over to a (conventional) waste management company (e.g. a scrap dealer or a recycling company for building rubble) that will take care of the material in accordance with any conditions that may be posed by the conditional clearance option, if used.

3.42. Once a certain batch of material has completed the clearance process, the database and the documentation are updated and archived accordingly.

Practical considerations regarding a smooth implementation of the clearance process

3.43. Practical experience from numerous decommissioning projects involving clearance of large amounts of materials have shown that the following considerations are beneficial for a smooth implementation of the clearance process:

(a) Moving the material in suitable containers like boxes (e.g. 1 m^3) or drums (e.g. 200 l) instead of as single items has the advantage that material of similar origin is always kept together, that the material can be traced easily via the identifier of the box and that bulk measurements can be performed directly for these containers.

(b) Planning for buffer storage areas of sufficient size between the various steps of the clearance process enables a smooth material flow even if there are delays (e.g. due to temporary unavailability of a measuring instrument) at one step.

DRAFT

(c) Having separated buffer storage areas between the individual steps avoids unintentional mixing of material or cross-contamination between steps and prevents material from skipping a step in the process and being unintentionally cleared. The buffer storage areas will also allow segregation of the material according to nuclide vectors, origin, material type or other criteria.

(d) Traceability of the material at any time and a thorough documentation of the results of each step reduces the likelihood of an erroneous clearance decision being taken, and ensures that the clearance decisions can be reviewed and understood even after many years.

(e) Undertaking the measurements in areas with a low background dose rate will enable high quality measurements and decision thresholds that are appropriately below the clearance levels to the extent practically possible.

3.44. If a facility is too small to allow for adequate space for the clearance process and if no space with sufficiently low background radiation is available, it may be advisable to construct a separate building (in lightweight construction) where the process can be implemented. As the material undergoing the clearance process will have residual activities in the range of clearance levels, it will pose a low radiological risk, even if it turns out that part of the material does not comply with clearance levels. The separate building may therefore be of simple design without extensive demands for shielding or ventilation. Larger decommissioning projects have erected separate buildings dedicated to clearance only. That could contribute towards reducing some non-radiological risks, as otherwise activities related to clearance are conducted in the same premises of the facility where other activities may be going on.

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4. CLEARANCE OF SOLID MATERIAL

OVERVIEW

4.1. The following diagram provides an overview of the available clearance options for solid materials coming from practices, which are addressed in this document.

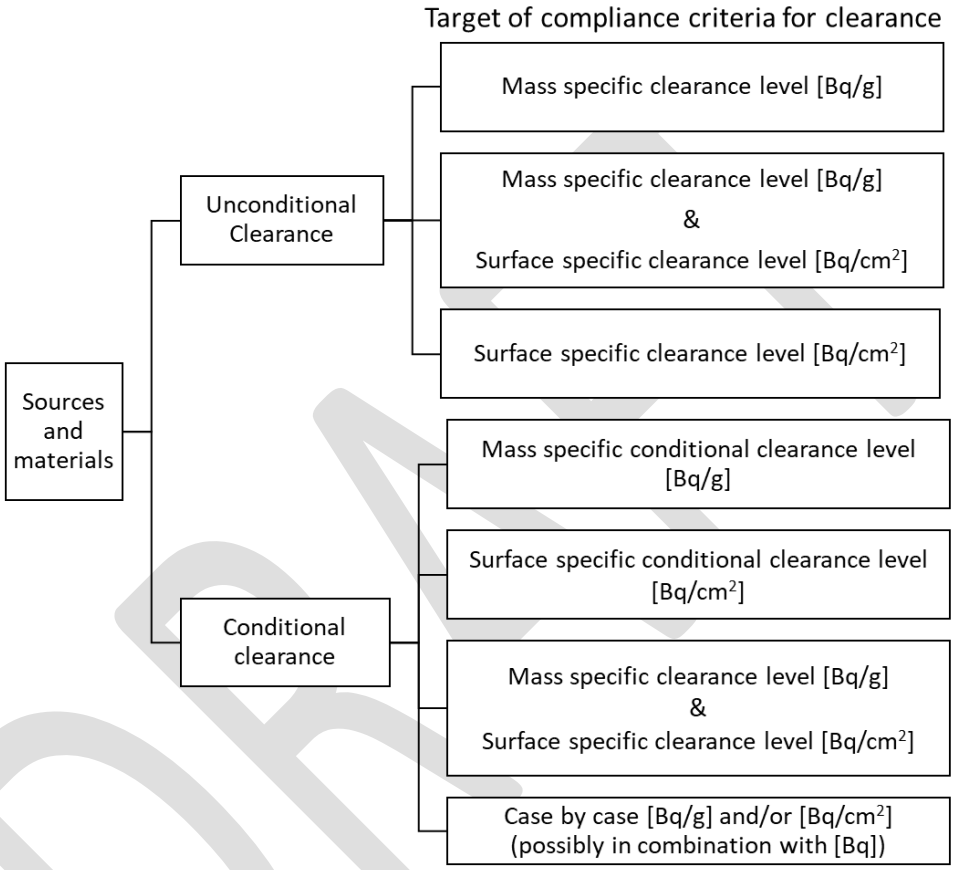

Fig. 4.1. Types of clearance options for solid materials from practices

4.2. The characterisation and management of the clearance process for solid materials should follow guidance provided in section 3. This section addresses the following aspects that are specific to solid materials:

(a) details on the mass specific and surface specific clearance criteria that can be applied;

(b) considerations pertaining to averaging criteria and to aspects related to situations where mixing is part of the material management process after clearance;

(c) description of the implementation of clearance measurements and considerations of related uncertainty.

THE TYPICAL CLEARANCE PROCESS FOR SOLID MATERIALS

4.3. The exact implementation of a clearance process for solid materials will depend on many details, like the type of the material (e.g. metal scrap), the origin of the material (e.g. a nuclear power plant), the way in which the radiological characterisation is carried out (e.g. immediately prior to dismantling the materials), on whether a melting process will be applied or not etc. A graphic representation of the clearance process in generic form will therefore necessarily have shortfalls when compared to a specific situation. The Figure 4.2 (from the German standard DIN 25457-4 on clearance of metal scrap [23]) provides an overview of the process using three strategies:

(a) Clearance strategy 1: Facility-wide radiological characterisation in advance, prior to dismantling;
(b) Clearance strategy 2: Characterisation by system in temporal proximity of dismantling;
(c) Clearance strategy 3: Characterisation on the basis of sampling during decontamination/melting.

DRAFT

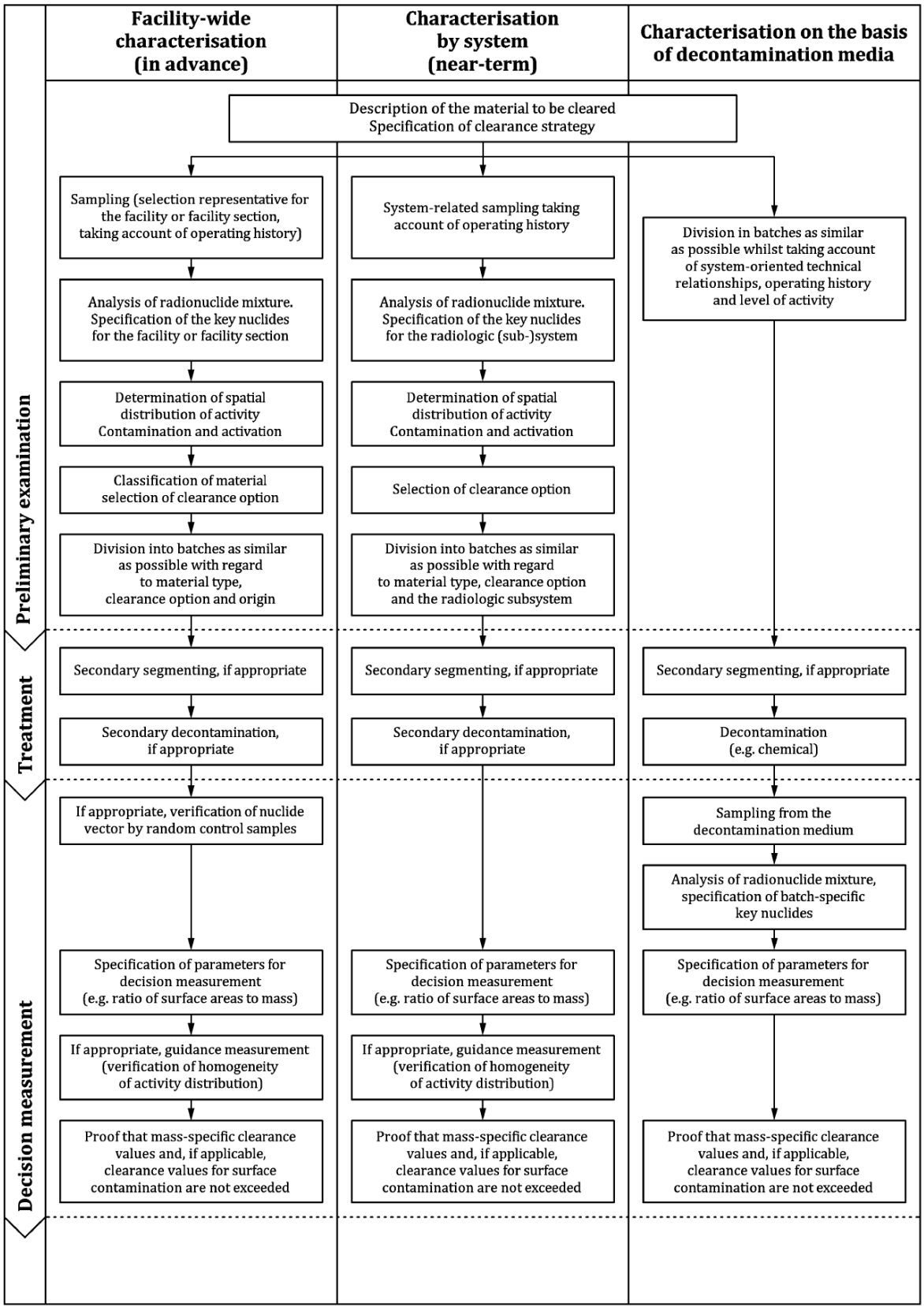

Figure 4.2. An example of a graphic representation of the process for clearance of metal scrap [23]

MASS SPECIFIC CRITERIA FOR CLEARANCE

4.4. The activity concentrations (mass specific clearance levels) specified in Tables I.2 and I.3 of GSR Part 3 [1] apply to bulk quantities of solid materials, e.g. waste material comprising contaminated or activated structural materials, and contaminated excavated soils. The same levels are applicable for materials considered for incineration, since the relevant scenarios were taken into account when deriving mass specific clearance levels. They are not applicable to foodstuffs, drinking water, animal feed or any material intended for use in food or animal feed. However, care should be taken that the quantities may not be unlimited as, e.g., in the case of excavated soil where the dilution factor applied in Ref. [4 SRS44] is not applicable to large quantities when dilution is not possible or permissible.

4.5. The methodology used to calculate these clearance values is described in Ref. [4 SRS44]. For each radionuclide of artificial origin, the mass specific clearance level was determined on the basis of a set of exposure scenarios encompassing external irradiation, dust inhalation and ingestion (direct and indirect). The clearance levels were derived as the lower of the values obtained from:

(a) The use of so-called realistic scenarios applying an effective dose criterion of the order of 10 μSv per year;

(b) The use of so-called low probability scenarios applying an effective dose criterion of 1 mSv per year and a skin equivalent dose limit of 50 mSv per year.

The parameter values applied in “realistic” and “low probability” scenarios were chosen on the conservative side, with parameter values in “realistic” scenarios generally lower or equal to those in “low probability” scenarios.

The derived results from the scenario calculations were then rounded to the nearest power of 10 using a near logarithmic rounding approach [4 SRS44]. This implies that the radiological models do not possess such a level of accuracy that a higher precision of the result would be justified. In turn, consideration of the uncertainty in demonstrating that the resulting dose will be of the order of 10 μSv per year or less requires compliance only to the extent of the accuracy of the logarithmically rounded values of the clearance level.

4.6. Mass specific clearance levels are specified in GSR Part 3 [1] for over 250 radionuclides of artificial origin. Values for other radionuclides of artificial origin should be derived using the models and approach for radionuclides of artificial origin described in Ref. [4 SRS44]. Examples of values for other radionuclides can be found in regulations of some Member States [24,25]. (regulations of Germany, Switzerland)

DRAFT

4.7. A scenario-based approach was not used in the case of material that contains radionuclides of natural origin not arising from practices. Instead, the mass specific clearance levels given in Table I.3 of the GSR Part 3 [1] were derived using a pragmatic approach that involved consideration of the worldwide distribution of the concentration of radionuclides of natural origin present in material that is found in the environment. Values are given for all radionuclides of natural origin in the ^{238}U decay chain and the ^{232}Th decay chain. The same pragmatic approach should be used to determine the mass specific clearance levels for other radionuclides of natural origin, e.g. primordial radionuclides. A mass specific clearance level of 1 Bq/g should be used for these primordial radionuclides pending establishment of specific values for these radionuclides on the basis of worldwide distribution.

4.8. Clearance of materials containing radionuclides of natural origin that arise from practices, where these radionuclides are processed for their radioactive, fertile or fissile properties, e.g. ^{238}U in waste arising from nuclear fuel fabrication facilities, uranium enrichment, uranium conversion, should be subject to the clearance criteria given in para I.11 in GSR Part 3 [1]. Therefore, the clearance levels that are applied to these radionuclides of natural origin arising from practices, where these radionuclides are processed for their radioactive, fertile or fissile properties, should be derived using the methodology for radionuclides of artificial origin described in Ref. [4 SRS44]. These values should then be included in the summation rule when considering a mixture of radionuclides.

4.9. GSR Part 3 [1] also specifies that the mass specific clearance levels given in Schedule I, Table I.3 in GSR Part 3 may also be applied for the clearance of materials arising from practices subject to the clearance criteria given in para. I.11, pending establishment of radionuclide specific values for the radionuclides of natural origin given in Table I.3. The member state should develop a programme for establishing these radionuclide specific values.

4.10. When establishing clearance levels for radionuclides of natural origin arising from practices, the following aspects should be considered:

(a) The methodology for radionuclides of artificial origin described in Ref. [4 SRS44] should be used;

(b) The dose contribution from progeny radionuclides should be included in the calculations in order not to underestimate doses. Following the approach taken in Ref. [4 SRS44], this is ensured by adding the dose coefficients of the progeny radionuclides to the dose coefficients of the parent radionuclides, using the appropriate weighting factors for the dose coefficients of the progeny radionuclides. For all pathways except the leaching and migration of radionuclides in groundwater (the water pathway), the weighting factors for the progeny nuclides are taken as the maximum activity ratio that the respective progeny radionuclides will reach during a time span of 100 years. The time span of 100 years ensures that material that does not exceed the activity concentration

values at a certain time (e.g. when a radiological characterisation of a facility has been carried out) will also not do so at any later point in time (e.g. when clearance measurements take place many years after the initial radiological characterisation), within a reasonable time frame (which may span several decades in cases where decommissioning of a nuclear facility involves a longer period of safe enclosure). For the water pathway, the calculations should consider the peak dose calculated over time i.e. there is no specified cut-off time.

(c) Mass specific clearance levels should clearly specify the radionuclides in the decay chain that have been included in the calculations. An example of an approach to radionuclide chains is given in Schedule I of GSR Part 3 [1] for the derivation of exemption levels for moderate amounts. If all the radionuclides in the decay chain present in the waste have been considered in secular equilibrium[8] in the calculations then only the clearance level of the parent radionuclide needs to be considered, as it already takes into account contributions from all progeny radionuclides. Otherwise, the sum of fractions rule needs to be applied to ensure that all the radionuclides in the decay chain are considered. For example, for wastes containing ^{226}Ra and progeny, if the calculations considered the decay chain in secular equilibrium (^{226}Ra and all progeny as listed in Schedule I of GSR Part 3), then only the clearance level of ^{226}Ra needs to be considered. However, if the waste contains the entire ^{238}U decay chain in secular equilibrium then the pre-cursers ^{238}U, ^{234}Th, ^{234m}Pa, ^{234}U, ^{230}Th also need to be considered, using the sum of fractions rule. Using the nomenclature given in Schedule I of GSR Part 3, the clearance level for the ^{238}U chain in secular equilibrium would be derived from applying the sum of fractions rule to the values for ^{238}U, ^{234}U, ^{230}Th, and ^{226}Ra only because the other radionuclides in the decay chain are already included in the calculations. Alternatively, calculations could be performed for ^{238}U-sec which explicitly includes all the progeny in secular equilibrium.

4.11. The methodology in Ref. [4 SRS44] focusses on the handling (transport, trade, use or disposal) of the material outside the facilities in which they arise (reactors, accelerators or laboratories). The scenarios used to derive the mass specific clearance levels for radionuclides of artificial origin consider a decay time before the start of the exposure, which is assumed to be at least one day (or considerably longer for some scenarios). Therefore, the methodology used in the Ref. [4 SRS44] is not suitable for calculating activity concentration values for very short-lived radionuclides (fraction of a day or less), unless scenarios relevant to direct handling of the cleared material (without a significant decay time prior to start of the

[8] Secular equilibrium occurs when the quantity of a radionuclide remains constant because its production rate (e.g., due to decay of a parent radionuclide) is equal to its decay rate. It only occurs when the half-life of the daughter radionuclide is much shorter than the half-life of the parent radionuclide.

exposure) are added to it. An alternative approach is described in para 4.12. If direct handling without significant decay time could be avoided and a decay storage for several days or weeks arranged before clearance of materials with very short-lived radionuclides, that may eliminate the need for such considerations.

4.12. When direct handling after clearance of moderate quantities of material is considered, the exemption levels given in Table I.1 of GSR Part 3 [1] are applicable for clearance, since no decay or waiting time has been introduced when determining these exemption levels. It should be noted that the same dose criteria have been applied for derivation of both exemption and clearance levels [1]. For short-lived radionuclides where mass specific exemption levels are given in Table I.1 of GSR Part 3 but there is no clearance level for bulk material in Table I.2 of GSR Part 3, the following alternative approach could be taken:

(a) Use Ref. [4 SRS44] methodology radionuclides of artificial origin to obtain mass-specific activity concentration that meets the clearance criteria for direct handling;

(b) Identify the mass specific level for moderate quantities from Table I.1 of GSR Part 3 that meets the clearance criteria;

(c) Take the lesser of the two results as the clearance level.

CONSERVATISM IN THE DERIVATION OF CLEARANCE LEVELS FOR UNCONDITIONAL CLEARANCE

4.13. The derivation of clearance levels for unconditional clearance as performed in Ref. [4 SRS44] includes a number of conservative assumptions that were deliberately taken to encompass a large variety of exposure situations that could arise as a consequence of clearance from all types of materials. This general approach is explicitly stated in Ref. [4 SRS44]:

> "The approach to encompass the variety of situations that may be found in Member States around the world necessarily requires a degree of conservatism".

Nevertheless, several methods have been applied to keep the overall degree of conservatism at a reasonable level:

(a) Two sets of scenarios have been used in parallel, one applying so-called "realistic scenarios" for an individual effective dose limit of the order of 10 μSv per year, and one applying so-called "low probability scenarios" for an individual effective dose limit of 1 mSv per year. In this way, parameter values in general could be chosen on the less conservative side for the "realistic

scenarios". This approach fully satisfies the criterion for clearance as defined in para I.10 and I.11 of GSR Part 3 [1]:

> "Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance".

(b) The scenarios for workers and members of the public have been devised in such a way that those exposure pathways that could occur simultaneously (e.g. external irradiation and inhalation) have been analysed together and their dose contributions have been added. This allowed to distribute the necessary conservatism in the model over the sum of exposure pathways rather than applying it to each pathway individually, thus reducing the overall amount of conservatism in the model

4.14. The following points, on the other hand, show introduction of conservatism in the model:

(a) The application of the summation rule for cases where there is more than one radionuclide present is inherently a conservative approach since the pathways of exposure of the critical group of exposed individuals are not necessarily the same for each nuclide, because of partitioning or separation of nuclides by processes. A less conservative, but impractical approach would be to sum the contributions of the radionuclides in the radionuclide mixture for each scenario and each exposure pathway first and evaluate then the activity value leading to full utilisation of the dose criterion of the order of 10 µSv per year.

(b) The dose contribution from progeny radionuclides is always included together with the parent radionuclide with a percentage that corresponds to the highest ingrowth within a time span of 100 years after clearance. This leads to a slight overestimation of the dose coefficients for the mixture of parent and progeny nuclides in such situations.

4.15. Many individual parameter values have been chosen on the conservative side. Examples:

(a) In many so-called "low probability scenarios", absolutely bounding values have been assumed

i. For exposure times (8,760 h/a for the full year, 1,800 h/a for the full working year),

ii. For dilution (factor 1, i.e. no dilution),

iii. For decay time prior and during the scenario (1 d / 0 d corresponding to virtually no decay at all),

iv. For unfavourable exposure conditions.

(b) The groundwater model contains a number of highly conservative assumptions, such as:

DRAFT

i. The model assumes conservatively that the whole inventory of radionuclides in the material is available for migration.

ii. The K_d values have been selected conservatively from the values published in literature for different elements.

iii. The private well from which groundwater is abstracted for several uses has been assumed very close to the deposited material, thus reducing the effect of radioactive decay significantly.

(c) Skin contamination: Dose coefficients for the skin relate the skin equivalent dose to the concentration of radionuclides on the skin. The skin dose coefficients were taken conservatively for a skin surface weight of 4 mg/cm², while contamination would predominantly occur on the hands where the skin surface weight is significantly higher.

4.16. Less conservative parameter values have been applied in the so-called "realistic scenarios". It is recognized that the derived clearance levels have thus been derived on a sufficiently conservative basis, and their implementation in practice should avoid the imposition of further conservatisms.

4.17. The fact that the clearance levels have been derived on the basis of a certain degree of conservatism may, however, also be used with benefit in the implementation of the clearance process by reducing the conservatism in calibration of instruments (e.g. assuming homogeneous activity distribution rather than hotspot configuration), using larger averaging areas or averaging masses etc. Further aspects of conservatism in relation to the derivation of clearance levels and the implementation of the clearance process are provided in Annex V, which discusses quantitative estimates of typical levels of conservatism.

SURFACE SPECIFIC CRITERIA FOR CLEARANCE

4.18. For surface contaminated items where radioactivity may be concentrated on surfaces, compliance with the mass specific clearance level (activity concentration per unit mass) may not be sufficient in all cases because there are additional considerations relating to the handling of the material. In these cases, surface specific clearance levels should be derived by the authorized party and reviewed and authorized by the regulatory body. The authorized party should then comply with these surface-specific clearance levels, in addition to complying with the general (unconditional) clearance levels expressed as activity concentration per unit mass. Note: in many cases, compliance with mass specific clearance levels can be inferred from measurements of the surface specific activity through conversion, taking the measured are, the thickness of the density of the material into account (see example below).

4.19. The radioactivity inside and on the surface of the cleared material has to be appropriately limited to guarantee compliance with the criterion for the individual effective dose of the order of 10 μSv per year. An example of potential outcomes when applying both surface and mass specific clearance levels is given in Table 1. For items and bulk material, this is usually accomplished by limiting the mass-specific activity concentration, e.g. as provided in Table I.2 of GSR Part 3 [1]. However, when mass-specific clearance levels cannot be applied or are not sufficient as the sole criterion, the surface-specific activity concentration should be appropriately limited. Examples are:

(a) surface contaminated items with a large ratio of surface area to volume, such as paper, card, plastic sheeting and clothing, and glass and thin metal sheeting of low to moderate density, where meeting the mass specific limit is problematic, For this category of items, clearance should be granted solely on compliance with surface specific clearance levels;

(b) surface contaminated items with a large ratio of mass to surface area, where the mass of uncontaminated internal material would effectively dilute the Bq/g. If it can be demonstrated that no contamination has penetrated in the bulk of the material, clearance should be granted solely on compliance with surface specific clearance levels since compliance with mass specific levels will not be sufficient to restrict the surface contamination.

Another example of a situation where surface-specific activity concentration is limiting is the clearance of contaminated pipes and beams. Special attention should be given to thick layers of surface contamination (e.g. scale in pipes). A good practice is to decontaminate the pipes as much as possible, collect the contamination and clear it as bulk material (compliance with mass specific clearance levels). The pipes with a possible remaining thin layer of “fixed” contamination can then be cleared through surface specific clearance levels.

In general surface-specific clearance levels limit the contamination that is directly accessible and could be mobilized during handling. They also limit the contamination on larger areas from which direct exposure by external irradiation could result.

DRAFT

TABLE 1. EXAMPLE OF POTENTIAL OUTCOMES WHEN APPLYING BOTH SURFACE AND MASS SPECIFIC CLEARANCE LEVELS TO A SURFACE CONTAMINATED ITEM (adapted from Ref. [26 UK GOOD PRACTICE GUIDE])

Surface Specific Clearance Levels[9] [Bq/cm^2]	**Mass Specific Clearance Levels[10] [Bq/g]**	**Outcome**
Average < relevant limits	Average < relevant limits	No radiological requirement to undertake separation and segregation prior to clearing waste.
Average > relevant limits	Average < relevant limits	Separation and segregation should be undertaken unless a justification can be made that removal is not reasonably practicable, the expenditure (whether in time, trouble or money) is grossly disproportionate to the safety and environmental benefits gained, and the overall impact of disposal is less than of the order of 10 μSv per year.
Average < relevant limits	Average > relevant limits	Unless commercial considerations (e.g. recycling or re-use options) for the surface layer are sufficient to justify the safety and environmental impacts of separation and segregation, it would be expected that articles or substances in this configuration would be managed as radioactive waste in accordance with the national strategy for management of radioactive waste.
Average > relevant limits	Average > relevant limits	Manage as radioactive waste in accordance with national strategy for management of radioactive waste.

4.20. Surface-specific clearance levels have not yet been provided in guidance issued by the IAEA. However, a number of international studies and recommendations is available that use dosimetric modelling to establish a link between the surface specific contamination and the resulting annual dose to an individual. Examples of dosimetric models are given in Annex I.

[9] For example, paint, laminate or region of increased radionuclide concentration

[10] For example, brick, blockwork or metal structure

DRAFT

4.21. International studies and recommendations are available that provide surface-specific clearance levels applicable to clearance of items made of metal and other materials. Recommendations from Ref. [27 RP 101] in combination with Ref. [28 RP 89] issued by the European Commission contain surface-specific clearance levels for metallic items both for direct reuse and for recycling of metallic material by melting. The set of values recommended for direct reuse of items can be considered as surface specific-clearance levels for unconditional clearance of objects of all kinds, because the exposure scenarios considered are independent of the type of material. The examples of surface-specific clearance levels applicable for unconditional clearance are given in Annex II. In general, calculations of these surface specific clearance levels consider both the fixed and removable activity on the surface of materials.

4.22. The numerical values for some radionuclides differ among different international studies and recommendations. The differences are due to different conditions and parameters assumed in derivation of surface-specific clearance levels (material, size of the item, geometry, exposure scenarios, and other aspects). Hence, it is to be expected that various studies will determine different surface specific clearance levels that comply with the same dose criteria. Therefore, application of a set of existing values (derived for a particular situation) to a different situation should be done with care, taking into account adequacy of assumptions, characteristics of the material, exposure scenarios used, and other aspects. For example, applying surface contamination levels derived for clearance of large objects would be too strict and conservative for small objects.

4.23. This Safety Guide does not provide a single set of radionuclide specific values, but offers to the Member States a range of examples for selection in accordance with needs and prevailing circumstances.

4.24. Paragraph 106 of IAEA Safety Standards Series No. SSR-6 (Rev.1), Regulations for the Safe Transport of Radioactive Material 2018 Edition [29] states that the transport regulations apply to radioactive material, where radioactive material is defined in paragraphs 402 to 407, with additional exemptions defined in paragraphs 107. This definition includes material that exceeds the mass specific exemption values and total activity exemption values defined in Table 2 of SSR-6 [29], which are the same as those in Schedule I, Table I.1 of the GSR Part 3 [1]. Material that does not exceed these values is not subject to the transport regulations. The clearance process should consider the requirements of SSR-6 [29] if transport is required.

4.25. Any material that has been cleared on the basis of mass specific clearance levels established in Schedule I, Table I.2 and Table I.3 of the GSR Part 3 [1] will have mass-specific activity concentrations that meet (are equal or below) the transport exemption levels.

4.26. Surface specific clearance levels have not been established in all Member States yet. In such a case, compliance with mass specific clearance levels has to be demonstrated for materials with surface

contamination. This can be achieved by converting the total activity on the surface to a mass-specific activity concentration (Bq/g) taking account of the total mass of the material below the surface (i.e. the mass-specific activity concentration should not be calculated by just using the thickness of the thin surface contamination layer). In this process, considerations related to the radiological models used for deriving the clearance levels need also to be taken into account, particularly the averaging mass (see paras 4.35-4.44).

Example: A metal sheet with a thickness of 0.8 cm and a density of 7.8 g/cm³ has surface contamination on one of its sides and is subjected to measurements of the surface specific activity. The contamination consists only of ^{60}Co, for which the mass specific clearance levels according to Table I.2 of GSR Part 3 [1] is 0.1 Bq/g. The readout of the surface contamination monitor is 0.4 Bq/cm² (after appropriate conversion from the count rate into a surface activity value). The mass specific activity is calculated by dividing by density and thickness, resulting in 0.064 Bq/g. The material would thus comply with the mass specific clearance level.

4.27. If the contamination has penetrated through the surface and into the volume, a prudent approach is to estimate the total activity using the sum of the contamination present directly on the surface and the contamination inside the volume beneath the same surface area. For comparison with mass specific clearance levels, this activity should be divided by the total mass below the surface. This approach also applies to materials with activation inside the volume of the material.

CASE-BY-CASE APPROACH

4.28. International and also national guidance on clearance and clearance levels are based on the application of generic methods for evaluation of the radiological consequences of clearance. This is usually accomplished by using generic models that describe possible exposure scenarios caused by clearance in a generic and enveloping way. These generic models need to be biased to the conservative side so as not to underestimate the possible exposure in all relevant circumstances. An example for such a model can be found in Ref. [4 SRS44].

4.29. There are, however, situations where the generic approach is not suitable, either because a specific exposure scenario is not covered by the generic model or because key parameters describing a specific exposure scenario deviate significantly from the values used in the generic model. A case-by-case approach should then be used, in which a radiological model is developed specifically comprising the relevant exposure scenarios and parameter values for this case. Key parameters, where significant deviations from generic values are relevant, are likely to include exposure times, distances on which dose rates from external irradiation are based, shielding geometries, concentration of contaminated aerosols,

quantities of materials to be cleared, amount of material present at the destination (disposal site/landfill/incineration facility) and others.

4.30. Furthermore, the analysis of a specific situation may also show that certain scenarios having been included in the corresponding generic model are not relevant to this particular case. These scenarios should then be left out of further consideration in the analysis of this specific situation.

4.31. The radiological calculations should take account of the same exposure pathways as the generic models, e.g. the one described in Ref. [4 SRS44]. This means that all exposure pathways (external irradiation, inhalation of contaminated aerosols, direct ingestion of small quantities, secondary ingestion of radionuclides via the food chain and skin contamination) should be adequately included in the scenarios. Although being based on the specific features of the situation to be analysed, the parameters describing the exposure situations should still be chosen in such a way that their possible variation is sufficiently encompassed. Example: While in a certain clearance practice the assumption of an exposure time of a full working year (e.g. 1,800 h/a) may be too high and measured real exposure time varies between 240 and 480 h/a, it would be prudent to use a value of 500 h/a for the exposure time in this case-by-case analysis to account for contingency.

4.32. The use of case-by-case approaches for clearance is generally encouraged, because in this way certain situations that are not adequately covered in generic international guidance can be analysed in a specific country, taking account of industrial, environmental, climatic and other features and regulatory requirements valid for this country. In this way, inappropriate use of generic clearance levels can be avoided. Clearance levels derived using a case-by-case approach can be established on a national basis (in legislation) or in response to an application by an operator. If the derived clearance levels include conditions on the type of material, the amount of material or the destination of the material, then they are a type of conditional clearance level.

4.33. Following the graded approach described in section 2 and the general criterion for clearance specified in para. I.10 (b), Schedule I of GSR part 3 [1], for activity concentrations that exceed the relevant generic clearance levels given in Table I.2 of GSP Part 3 by several times (e.g. up to ten times), the regulatory body may decide (where the national regulatory framework so allows) that the optimum regulatory option is to remove the material from regulatory control. In making such a decision, the regulatory body will consider the doses from “realistic” and “low probability” scenarios and the degree of conservatism in the dose estimates, as well as other factors. The mechanism for giving effect to such a decision will depend on the nature of the national regulatory infrastructure. In many cases, a decision will be made by the regulatory body on a case-by-case basis, following notification by the authorized party to the regulatory body. If the decision contains conditions on the type of material, the amount of material or

the destination of the material, then this is an example of conditional clearance, see Section 7 for further details.

4.34. It can generally be expected that a case-by-case approach will lead to less restrictive clearance levels, as such an approach will only be endeavoured if the characteristics of a specific situation have been identified to be less conservative than in the generic model. It should, however, be kept in mind that it might cause problems in international trade if material that has been cleared according to clearance levels based on a case-by-case approach in one country is then exported to another country where e.g. the internationally agreed unconditional clearance levels as provided in Table I.2 of GSR Part 3 [1] are valid. When international trade will play a role, a case-by-case approach should be explicitly featured into the customized model and the target country should be informed in advance about that clearance practice.

AVERAGING MASSES AND AREAS

4.35. The general clearance levels specified in Schedule 1 of GSR Part 3 [1] for artificial radionuclides are calculated using a set of scenarios, and these scenarios consider exposure to a large quantity of homogenous material. For example, the transport scenario considers a truck containing 10 tons of material and the landfill scenario considers even larger quantities [4 SRS44]. When applying the clearance levels, the regulatory body should recognise that they were derived for bulk amounts and that the averaging should be done accordingly. Hence, very small averaging masses are not appropriate, and the exposure scenarios are consistent with some inhomogeneity within the averaging mass as long as the averaging mass is below 10 tons.

4.36. In this context the regulatory body should determine or approve appropriate averaging masses to be used as the decision units in the clearance compliance measurements, and averaging procedures used by the authorized party should take this into account. Examples of appropriate averaging masses are few hundred kilograms or order of tonne. The regulatory body should ensure that the averaging procedure is not used to intentionally release material above the clearance levels (see para. 4.39, 4.43 and 4.45-4.48 regarding ‘hotspots’). The authorized party should make averaging procedures an integral part of the verification scheme, selected according to the type of material. In case of small objects with a mass below the measurement unit, a minimum default averaging mass could be defined by the regulatory body (e.g. 1 kg) rendering a maximum allowed total activity for these objects for a specified radionuclide (e.g 100 Bq for ^{60}Co) or radionuclide vector. In case of several of these small objects, an alternative method would be to measure them together within one measurement unit.

4.37. In the case of surface specific clearance levels, these are intended as an average over moderate areas and regulatory authorities should authorise, depending on the type of material, contamination and

homogeneity of the contamination, averaging areas of several hundred cm^2 up to 1 m^2, in case of unconditional clearance[11]. For non-accessible surfaces for which some degree of surface contamination can be reasonably expected, the authorized party should make a conservative assessment of the surface activity for comparison with the clearance levels. Similarly to the mass-specific clearance of small and light objects, the regulatory body could define a default minimum averaging surface area for objects with surfaces below the measurement unit (e.g. 100 cm^2), giving a maximum total radionuclide specific activity based on surface specific clearance levels. In case of several of these small objects, an alternative method would be to measure surfaces together within one measurement unit.

4.38. Averaging masses and areas for decision making on compliance with clearance criteria (decision units) should be distinguished from masses and areas used for actual measurements (measurements units). For example, multiple samples of 100 g of soil could be used to determine whether a mass of a few tons complies with the clearance levels. In any case, the measurement unit (sentencing unit) should be smaller than or equal to the decision unit.

4.39. In deciding on a measurement strategy, the authorized party should batch the material so that it is as homogenous as possible in relation to both material and origin, and thus radionuclide vector and activity level. Variations of activity level within the averaging unit of mass or area for decision making should be allowed. For example, variations of up to a factor of 10 with respect to the average value for the decision unit are generally considered to be acceptable, whereas a greater variation would be acceptable if the overall average concentration was a very small fraction of the clearance level. Also, it is recommended that the maximum concentration in any measurement unit does not exceed ten times the clearance level, while the average value over the decision unit does not exceed the clearance level (Appendix A of Ref. [30 TECDOC-1000]).

4.40. The authorized party should make use of the maximum practicable and permitted averaging areas or masses when designing the monitoring regime as this improves the efficiency of the clearance process. The monitoring regime may be constrained by the form and nature of the contamination, for example, the choice of equipment available for monitoring for beta activity inside a small pipe is likely to be limited. Nevertheless, appropriate use of time integration in dynamic measurements (e.g. recording counts over a minute, rather than over a second) or numerically averaging over a number of single static measurements will enable a greater averaging area to be achieved.

[11] Averaging areas for conditional clearance could be higher, for example 10 m^2 for clearance of buildings for demolition.

4.41. When the authorized party makes a single measurement or multiple measurements to determine whether the material is in compliance with the clearance level, each measurement is based on a measurement unit that is defined by the chosen monitoring regime and instrumentation (e.g. contamination monitor, drum monitor, bulk monitor). The size of the measurement unit should be chosen based on practical considerations that reflect the size of an object and how the material will arise or be measured (e.g. a drum of waste, or an excavator bucket, or the actual geometry of the measurement system).

4.42. The authorized party should select measurement units and should propose decision units that are sufficiently representative of the material, with appropriate adjustments to satisfy homogeneity limitations and confidence level requirements for the clearance measurements. The measurement and decision units should therefore usually be related to the same origin of material for clearance, or one of several origins of a very similar nature. In general, larger measurement and decision units are acceptable where the contamination in the material is reasonably uniform and smaller measurement units should be used where inhomogeneity is significant. The decision units should be agreed with the regulatory body and formally recorded by the authorized party as part of the clearance measurement process. The regulatory body should also provide some guidance and quantitative criteria related to uniformity or inhomogeneity of the contamination.

4.43. The decision units will put an indirect limitation on the size of 'hotspots' (see next sub-section), since the total activity per decision unit will be the maximum activity level of the hotspot. The regulatory body should define a maximum value for a hotspot, that should be kept in mind when defining the size of a decision unit.

4.44. If the results of samples taken from the bulk waste or material are subject to considerable variability, as defined in Appendix A of Ref. [30 TECDOC-1000], then averaging over the whole waste or material mass (as a single decision unit) is unlikely to be acceptable without proper (documented) consideration of:

(a) The practicability of segregation and separation;

(b) Suitable revision of monitoring and numbers of samples;

(c) Suitable reduction in the size of each measurement unit (sentencing mass or volume);

(d) Whether it is practicable to make further measurements to identify each area or volume containing significant concentrations of radioactivity;

(e) Whether it is practicable to remove or segregate small areas or volumes containing significant concentrations of radioactivity (hotspots);

DRAFT

(f) The potential radiological significance of inhomogeneity.

Presences of hotspots and distribution of activity with depth and area

4.45. One of the most challenging tasks in the release of material from regulatory control is to ensure that the presence of hotspots is taken into account in an appropriate manner. It is important to distinguish between 'hot particles' and 'hotspots', where the latter are due to non-uniformity. Hot particles are generally small items which are not part of the material in which they are found, for example small metal flakes of high ^{60}Co content or small pieces of spent nuclear fuel which may be found in a cooling pond. These can be radiologically significant (giving doses that can lead to deterministic effects) and should be removed before the clearance process begins. It is important that during any decommissioning related characterisation survey the potential for hot particles is considered and, if found to be possible, that the monitoring and clearance process will identify their presence, rather than just considering them as contributors to the total activity of a large sentencing mass.

4.46. Hotspots, in terms of a local non-uniform distribution giving activity concentrations above the clearance levels, are to be expected. It is important that the range of activity concentrations in a measurement unit is reasonably restricted. Usually, variations of up to ten times are tolerated. The regulatory body should approve or specify additional monitoring criteria to the existing averaging criteria, in order to detect and manage any hotspots in the material considered for clearance.

4.47. In cases where the compliance with the surface specific clearance levels is demonstrated using instruments with much smaller surface area than the averaging area, information on the homogeneity and hence the presence of "hotspots" can be derived from the variation of the readouts of individual measurements. The final value of surface-specific activity concentration for comparison with clearance level is derived from an averaged result. It is generally possible to set a rate-based alarm related to the presence of "hotspots" for individual measurements, which will identify any particularly active areas.

4.48. For bulk material, many processes involving bulk measurement are based on scanning or multi-point measurements, both of which can be set up to identify particularly active volumes. Another approach to demonstrating compliance with the hotspot criteria [23 DIN 25457] is to use measurement techniques sensitive enough to detect 100% of the contamination in the 'worst case' 10% of the volume. For example, if measurements are taken on the outside of a drum, calculations to demonstrate compliance could assume that all of the contamination is located in the centre of the drum (surrounded by clean material), furthest from the detectors and shielded by the clean contents. This will result in higher efforts for measurement (e.g. longer counting times, more measurements or more sensitive detectors), but the additional cost may be small compared to using an additional sampling measurement to demonstrate compliance with the average and the hotspot criteria. This approach works well for a drum where the density is low and the

nuclide emits very high energy gamma radiation, e.g. ^{60}Co in concrete rubble, and where the general level of activity is well below the clearance level. It is not recommended if the material itself provides effective shielding, the gamma energy is lower (e.g. metal contaminated with ^{241}Am), and there is significant bulk activity concentration, as it will lead to significant over-estimation of the radionuclide content.

IMPLEMENTATION OF CLEARANCE MEASUREMENTS

Monitoring programme and strategy

4.49. The monitoring programme to support clearance process should be based on the results of the characterization, where isotopic vector or key nuclides have been identified and the level and the location of contamination have been quantified, as described in Section 3.

4.50. The monitoring programme should be managed as a material flow process that starts with well characterized material to be evaluated for clearance.

4.51. Material presented for clearance should be sorted into batches, consisting of the same type of material, same radionuclides, same history. This information from the characterization of the material should be used as a technical basis for the establishment of the monitoring programme.

4.52. Within the monitoring programme, distinction should be made between the monitoring strategy and the monitoring technique. The monitoring strategy relates to the batch process itself, whereas the monitoring technique is the tool within the monitoring strategy to facilitate decision making on clearance of a batch. The monitoring strategy should take into account the input material into the batch process and the output options, being cleared material or radioactive waste. The optimal strategy should be defined based on radiological criteria, occupational exposures, environmental requirements and cost-effectiveness.

4.53. In the definition or selection of batches, the spatial distribution of the contamination is an important selection criterion. Distinction should be made between bulk contaminated material and surface contaminated material.

4.54. The monitoring strategy should determine which of the three monitoring techniques (surface measurement, bulk measurement and sample analysis) is the most appropriate for a given batch and depending on the material being considered, a combination of techniques can be required.

4.55. The choice of the monitoring technique implies the selection of radiation measurement equipment. The response of the equipment will depend on radiation type, energy and geometry. A good knowledge of the radionuclides to be measured is therefore crucial and should be determined prior to the monitoring programme. Depending on the case, key radionuclides should be defined in the radionuclide mixture and

the contribution of other nuclides can be derived by the use of scaling factors to these key nuclides. Based on this information, the appropriate radiation measurement instrument should be selected for monitoring for compliance with the clearance levels, taking into account the level of activity concentration that has to be verified. Information on the selection of the instrument can be found in Ref. [16 SRS67]. The involvement of personnel with suitable qualifications, experience and knowledge in the selection of monitoring techniques is beneficial.

4.56. The response of the measurement equipment, expressed in operational units (e.g. counts integrated over a period of time), should be converted into activity values (Bq). The equipment might return a total number of counts over the whole energy range or provide a number of counts as a function of the energy. In the first case, identification of the measured radionuclide will not be possible, whereas in the latter, the spectral information will allow radionuclide identification. The choice will be part of the monitoring strategy and a sequential combination of both might be necessary.

Surface contamination measurements for compliance with mass specific clearance level

4.57. If the contamination in the materials for clearance is limited to the surface, i.e. for impermeable materials, surface contamination measurements (measurements of surface-specific activity concentration) could be applied for compliance with mass specific clearance level instead of performing measurements of mass-specific activity concentration. Conversely, if the material is permeable then the contamination will penetrate some distance into the material, and in this case both surface and mass specific measurements will be needed to demonstrate compliance with clearance levels. If the materials are relatively small objects, of the order of the averaging mass, for example, iron plates or stainless steel pipes, it is easy to convert from total radioactivity obtained by the surface-specific measurement to mass-specific activity concentration taking account of their thickness, their densities and the number of the contaminated surfaces (one surface or two surfaces) [23 DIN25457]. In such a case, it may be useful to derive a surface-specific criterion from the mass-specific clearance level. This derived criterion can be used to demonstrate compliance with the mass-specific clearance levels.

4.58. For the assessment of surface contamination, the principles and methods described in international standards (e.g. Ref. [31 ISO-7503-2016]) should be used for direct and indirect measurements and for the calibration of the associated instrumentation. If the use of surface contamination monitors in a ratemeter mode is not sufficiently reliable, reproducible and auditable for clearance measurement, then clearance measurements should use integrated counts over a defined time.

Measurement techniques

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4.59. Special attention should be given to the condition of the surface to be measured when using a direct measurement technique. The ideal surface should be clean, dry and flat. Cleanliness is required since dirt such as dust, grease, rust can mask the signal to be measured through absorption, especially for alpha contamination. It is therefore strongly recommended to clean the surface before measurement. This cleaning can be considered as a decontamination in case of the presence of non-fixed contamination. In addition, assessment of the removed fraction (e.g. by measurement of the cleaning tool) could give information on the nature of the contamination.

4.60. An uneven surface can occur e.g. after wall decontamination, which could affect the direct measurement due to unequal distance from surface to detector, affecting the detector response. On the flatness of the surface, the Ref. [31 ISO -7503] states: "*Generally, it is applicable to well defined flat surfaces where direct methods are applicable, however, it can also be used for surfaces which are not flat and where indirect wipe tests would be appropriate*."

4.61. For total gamma measurements, the calibration procedure is generally complex and is described by the manufacturer of the instruments. The procedure can be greatly simplified by performing the calibration for a single radionuclide and deriving the calibration factors for other nuclides through calculations or through scaling factors as defined in the radionuclide vector.

4.62. For in-situ gamma spectrometry, the situation is even more complex since the response to individual radionuclides, in addition to the energy of radiation, also depends on the distribution over the surface and/or in the volume underneath the surface. Computer codes are available that allow calculations of the calibration factors from a given radionuclide composition and spatial activity distribution [32]. Software for calibration calculations is also provided by different manufacturers of instruments for gamma spectrometry.

4.63. Samples may be taken through smear samples (wipe samples) in case of removable surface contamination (noting that the fixed proportion of any contamination will not be detected), or through collection of a small fraction of the material itself. In case of smear samples, they should be analysed through indirect surface contamination assessment or be subject to sample preparation and measurements in a laboratory environment (for example, dissolution for tritium measurements). It should be noted that only removable surface contamination can be quantified through smear samples and additional evaluation will be required to complete the clearance process. In case of material samples, they should be analysed in laboratories with specific equipment for spectral analysis. The laboratories should have a quality assurance system and it is recommended they are accredited according to national requirements or international standards, for example Ref. [33 ISO/IEC 17025:2017].

DRAFT

4.64. When sampling is used for compliance verification, additional issues should be addressed, such as sampling position, minimum sample size and number of samples. When the spatial distribution is unknown or assumed to be uniform, a sample grid should be used, where the distance between two grid points is determined by the total area sampled and the required number of samples. The position of the individual samples should be properly recorded. The sample measurements should provide information on the activity distribution in the material as a whole, to be compared with the clearance levels.

4.65. The minimum number of samples to be taken should be determined by the median value and the standard deviation of the activity concentration distribution on the basis of a statistical compliance test. The number of samples should be increased if the results of the statistical analysis are not satisfactory with respect to median value and standard deviation. The decision on clearance of material will be based on a statistical test on the measured activity concentrations. For the selection of the proper test, guidance can be found in Refs [19,20 MARSSIM, MARSAME].

4.66. Each instrument has a threshold for detecting radiation of a specific type. In order for an instrument to be suitable for compliance verification with the clearance level for a specific radionuclide, this threshold should be below the clearance level. The threshold is usually referred to as the detection limit or the MDA (minimum detectable activity). It should be determined according to international standards (e.g. Ref. [34 ISO-11929]). The MDA does not only depend on the measurement technique, but also on the measurement conditions, such as background and measurement time, and the accepted level of confidence in the measurement. The complementary concept to the MDA is the "maximum missable activity" [26 UK GPG], and this can be used in communication with the regulator and other interested parties.

4.67. In case of sampling, the minimum sample size should allow for providing a signal in the detector well above the detection limit when the activity concentration in the sample is a significant fraction of the clearance level. Possible loss of material in the sample preparation process should be taken into account when calculating the minimum sample size.

4.68. When using the concept of clearance of material, the background activity in the material prior to the planned (or existing) exposure situation should be subtracted from the measured activity in the material. The concept of clearance for practices should be applied to the mass specific (or surface specific) activity level that is above the natural background level in the material, not to the total activity level in the material. Activity from sources other than the licensed practice itself, for example naturally occurring radionuclides in building material (^{238}U- and ^{232}Th- decay chains, ^{40}K) or fallout from nuclear weapon tests and nuclear accidents (e.g. ^{137}Cs), should be disregarded when performing clearance measurements. Cosmic radiation and naturally occurring levels of primordial radionuclides should also be disregarded when performing clearance measurements. For NORM industries (if considered authorized practice

within the regulatory regime), the clearance levels for radionuclides of natural origin apply to the total activity level in the material.

4.69. When determining what background needs to be subtracted during clearance measurements, variations in the background activity level should be considered. Especially with total gamma measurements, the contribution from the activity that can be disregarded needs to be carefully established in order not to misinterpret the measurement signal from the activity undergoing clearance. The activity to be disregarded needs to be established using a suitable low percentile (e.g. 5 %) from the distribution of measured background values, thus preventing overestimating the signal to be subtracted. The distinction between these various contributions to the total activity can be significantly improved by using spectrometric information.

4.70. The requirement on the MDA for clearance verification has an impact on the acceptable background conditions during the measurement. They can be optimized by careful selection of the location, by adding shielding to the detector or by increasing the measurement time. The MDA also depends on the uncertainty level that is tolerable in comparing measured value with clearance level (see next section on uncertainty considerations).

UNCERTAINTY CONSIDERATIONS

4.71. The clearance process, in particular the measurements, involve a number of uncertainties that have to be properly taken into account, depending on the measurement techniques. These involve pure statistical uncertainties of the counting process (so-called "type A uncertainties"[12]) and uncertainties relating to situations in the measurements process that can be evaluated by means other than the statistical analysis of series of observations (i.e. based on experience or other information, so-called "type B uncertainties"[12]). The following list gives an overview of those type A and type B uncertainties that are most relevant for clearance measurement processes. These uncertainties are then addressed in the following sections in more detail.

(a) Statistical uncertainties of the counting process (type A);

(b) State of the surface of the measured material (type B);

[12]) Type A and Type B uncertainties are defined in the guidance document "Evaluation of measurement data — Guide to the expression of uncertainty in measurement" ("GUM"), JCGM 100:2008, of the Joint Committee for Guides in Metrology

(c) Fluctuation range of the geometry and the self-shielding of the measured material (type B);

(d) Fluctuation range of the activity distribution in the measured material (type B);

(e) Fluctuation range of the background effect (type B);

(f) Fluctuation range of the activity fractions of the radionuclides in the material in relation to the specified fractions in the nuclide vector (type B);

(g) Fluctuation range of the wiping efficiency during indirect surface activity measurement (type B);

(h) Fluctuation range of the content of natural radionuclides and other radionuclides to be disregarded in the measured material (type B);

(i) Measuring uncertainty during the calibration used (e.g. reference measured material for the total gamma activity measurement) (type B);

(j) Other uncertainties, including sampling uncertainty (type B).

4.72. Taking the influence of all Type A and Type B uncertainties into account, it can be determined whether a certain measurement technique including all relevant parameters, such as efficiency, calibration and measurement time, qualifies for demonstrating compliance with clearance levels. One prerequisite will be that the detection limit determined for this measurement technique will be below the clearance levels. Details on this process are provided in the document "Evaluation of measurement data — Guide to the expression of uncertainty in measurement"[12].

4.73. When performing actual clearance measurements, due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking all relevant uncertainties into account. Examples for this are provided in Refs [19] (MARSSIM), [23] (DIN25457), [34] (ISO-11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1-5.3 of the Ref. [16 SRS67]. However, noting the overall conservatisms built in the clearance levels, it is not appropriate to introduce significant additional conservatisms through this mechanism. For example, if one of the uncertainties is biased to a very high level, then fluctuations relating from the other uncertainties are less important.

4.74. If measurements results do not meet the criteria for generic clearance, as discussed in para. 4.74, the authorized party may still consider applying for conditional or case-by-case clearance, and the

regulator should assess such an application, taking into account radiological risks associated with the further management or disposition of the material.

Treatment of statistical uncertainties of the counting process

4.75. Radiation measurements used for clearance involve counting of events (detection of photons, beta particles, alpha particles and others) in monitors that either count the integral number of registered photons or particles over the whole energy range or that have spectrometric capabilities. Examples for such instruments are contamination monitors with proportional counters or scintillation detectors, bulk monitors used on packages with up to several 100 kg of material, in situ gamma spectrometers used on packages or on surfaces, laboratory gamma spectrometers used for samples, liquid scintillation counters used on specifically prepared samples, and others. When these instruments count events for a certain period of time repetitively, the count rates will scatter around a best estimate (which is associated with the "real" activity value), usually following a Poisson or normal distribution. This deviation between a single counting result and the (unknown) best estimate is a purely statistical effect and gives rise to a type A measurement uncertainty.

4.76. In addition, such measurement techniques to determine whether activity concentration values are in compliance with clearance levels rely on the performance of the instrument or the condition of measurement, for example, background level and measurement time.

Treatment of uncertainty related to the state of the surface of the measured material

4.77. The state of the surface influences the emission efficiency of the measured material for alpha and beta emitting radionuclides. Dirt or oxidized layers (in the case of metals) on the surface of the measured material typically influence the emission efficiency. The emission efficiency with respect to contamination monitors with proportional counters (sensitive for beta and alpha radiation) is strongly influenced by the layer thickness. A deeper penetration of the contamination is to be expected with porous materials, for example concrete and wood, which can be considered by separate tests. Up to a certain thickness of the layer, the effect can be taken into account by adjusting the value of the surface emission efficiency. If the layer becomes too thick, no meaningful measurement is possible anymore.

4.78. This uncertainty is relevant for all surface related measurements with beta and alpha sensitive instruments and needs to be included in the analysis of type B uncertainties. It is of minor relevance for gamma sensitive instruments (contamination monitors with scintillation counters), in situ gamma spectrometers or measurement of samples.

DRAFT

Treatment of uncertainty related to the geometry and the self-shielding of the measured material

4.79. When performing clearance measurements, the instrument is calibrated for certain geometries of the measured material, including assumptions on self-shielding. For example, plane surfaces with a certain distance between the surface and the window of the contamination monitor (e.g. a few mm) may be used for calibration purposes. In real measurement situations, the surface may be curved or uneven, or the distance to the instrument may need to be higher because of surface roughness. In such a case, there are differences between the calibration geometry and the real measurement geometry, reducing the efficiency of the measurement process. This can be taken into account by correction factors or by using multiple calibration geometries that cover all conceivable geometrical situations.

4.80. In a similar way, the self-shielding of a large quantity of material measured in bulk monitors needs to be taken into account in the calibration process. In real measurements, there may still be deviations from the calibration, e.g. because the material is more densely packed. This effect can be evaluated e.g. by numerical simulations.

4.81. In all such cases, the possible variation of differences between real measurement situations and the calibration need to be evaluated and included in the analysis of type B uncertainties.

Treatment of uncertainty related to the activity distribution in the measured material

4.82. During calibration of surface measurements or of bulk measurements, certain assumptions have to be made with respect to the spatial distribution of activity on the surface or in the bulk of the measured material, respectively. Often calibration of surface measurement instruments is performed with homogeneous thin-layer sources of known activity and surface emission rate while real surfaces may exhibit localised rather than homogeneous contamination. Likewise, calibration of bulk monitors may be performed with dummies with homogeneous contamination while real boxes with scrap of building rubble have localised contamination. In both cases, the measurement result needs to be corrected for the difference in spatial activity distribution between calibration and measurements. This correction therefore needs to be included in the analysis of type B uncertainties.

Treatment of uncertainty related to the background effect

4.83. Any measurement process is influenced by photons or particles that do not originate from the material to be measured but have their origin elsewhere, such as other material, terrestrial or cosmic radiation. This is summarised by the background effect which needs to be measured separately for subtraction from the gross measurement effect as well as for determination of the detection limit. Although the background effect is regularly measured (e.g. before and after a measurement campaign

during the working day), variations of the background during the measurement campaign will occur, thus leading to differences between the previously determined background effect that is subtracted from the "gross" measurement result to yield the "net" measurement result ("gross" minus background) and the current background during a particular measurement. The variation of the background effect therefore has to be determined and needs to be included in the analysis of type B uncertainties.

Treatment of uncertainty related to radionuclide vector

4.84. For situations where the activity of more than one radionuclide has to be taken into account in the decision for compliance with clearance levels, the summation rule described in para. 3.6 has to be applied. In treating uncertainties due to a mixture of radionuclides, the concept of the radionuclide vector is applied. This implies inclusion of uncertainties in determination of scaling factors (activity ratios) between the activities of difficult-to-measure (DTM) radionuclides and activities of key radionuclides that are easy-to-measure (ETM).

4.85. The uncertainty in the determination of a certain scaling factor is associated with variations of the activity ratios from which this scaling factor was derived (e.g. as a mean value together with a standard deviation). Usually, scaling factors for radiologically relevant radionuclides (e.g. of ^{90}Sr, using ^{137}Cs as a key nuclide) will be derived on a conservative basis so that the activity of the DTM nuclides will not be underestimated, taking into consideration large difference between the mass of samples used for determination of the scaling factors and the total mass of the material to be cleared.

4.86. The uncertainty in the determination of scaling factors or radionuclide vectors need to be taken into account in the analysis of type B uncertainties. However, the way in which uncertainties in the derivation of scaling factors and the (equivalent) radionuclide vector are treated can give rise to high conservatism in the whole clearance process. For example, if a scaling factor is to be derived from an ensemble of activity measurements of difficult-to-measure radionuclides and key nuclides, it may be a prudent approach not to use to highest activity ratio as the scaling factor, but appropriately selected upper confidence level.

Treatment of the wiping efficiency for indirect surface activity measurement

4.87. When surface activities are determined by wipe tests rather than by direct measurements, assumptions on the wiping efficiency have to be made. Usually, a conservatively small efficiency is assumed (often 10 % of the removable surface activity) [35 ISO/FDIS 7503-2:2015(E)] to account for the fact that the real wiping efficiency is hard to determine and will depend upon many factors. Even if the wiping efficiency is determined under certain well-defined conditions, the chemical and physical

boundary conditions during taking of wipe tests in real measurement environments may deviate from the idealised conditions. Assumptions on the variation of the deviation between idealised and real wiping efficiency have to be made and need to be included in the analysis of type B uncertainties for measurements with wipe tests only.

Treatment of uncertainty related to the content of natural radionuclides and other radionuclides to be disregarded in the measured material

4.88. Natural radionuclides can be present in the measured material, in particular in building rubble, where radionuclides of the ^{238}U- and ^{232}Th- decay chains as well as ^{40}K contribute to some extent to the measurement result, in particular for gross gamma measurements (performed using bulk monitors) and for measurements with surface contamination monitors, while this effect is less important for measurements with in situ or laboratory gamma spectrometry. When the radionuclides of natural origin were not part of the practice giving rise to the material to be cleared, they can be disregarded, and therefore their contribution to the measurement effect can be subtracted from the gross measurement effect. The activity of natural radionuclides will have to be determined in advance from a reasonable set of samples. However, the activity of natural radionuclides in real measurements may deviate from this previously determined value. Hence, this difference has to be determined and needs to be included in the analysis of type B uncertainties for gross gamma measurements and surface contamination monitor measurements on building rubble or on building surfaces.

4.89. The same consideration applies to other radionuclides in the material that are to be disregarded, e.g. ^{137}Cs from the fallout of nuclear weapon testing and/or the Chernobyl accident.

Treatment of uncertainty during measurements as part of the calibration

4.90. Finally, the measurements performed as part of the calibration itself will also be associated with uncertainties. Examples are uncertainties in the real activity content of calibration standards (even after adjustment for radioactive decay), readout of instruments or determination of distances. However, these uncertainties can mostly be neglected in comparison to those described in the previous sections.

Treatment of other uncertainties

4.91. While the list of uncertainties in the previous sections is comprehensive with regard to clearance measurements, there may be other uncertainties that need to be taken into account in specific situations. Ref. [16 SRS67] provides practical guidance and examples related to treatment of other uncertainties for decisions on clearance, such as those related to sampling (for example, uncertainties related to the selection of samples, their size and homogeneity). Uncertainties related to sampling can be greater than

those due to measurement uncertainty discussed above. Guidance on treatment of uncertainties related to sampling is given in the Data Quality Objectives (DQO) [36 US EPA DQO].

ASPECTS RELATED TO USE OF MIXING AND DILUTION AS PART OF THE MATERIAL MANAGEMENT PROCESS

4.92. Deliberate dilution of material to meet the clearance levels, as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration, should not be performed without the prior approval of the regulatory body.

4.93. The regulatory body should ensure that dilution is not used to clear materials with relatively high activity concentrations by deliberately diluting them in order to meet clearance levels. Clearance should be carried out while the history of the material is still well known. Decay storage prior to clearance is acceptable for materials containing short lived radionuclides.

4.94. Unavoidable mixing may occur, and is acceptable, where the extent of mixing is consequent on the operation or decommissioning technique employed. For example, the use of an excavator to dig out a volume of contaminated soil may result in some unavoidable mixing of soil with differing levels of contamination. In this case this is considered to be mixing as part of the material management process.

4.95. In cases where unavoidable mixing occurs, or where the distribution of radioactivity is inhomogeneous, care should be taken to ensure that any subsequent sampling or monitoring is suitably representative.

4.96. If it is necessary to reduce the uncertainty of the measurement result, it is acceptable to bulk two or more similar measurement units (e.g. drums) to produce a larger measurement unit. This has to be done after the initial measurement. This is not dilution as the purpose is solely to reduce the measurement uncertainty, not to alter the apparent characteristics of the waste or material. Similarly, two small samples of material could be put together.

4.97. In the case of conditional clearance, mixing with clean material can be part of the condition (e.g. melting of metals in a non-nuclear industrial melting facility). In this case, the destination of the contaminated materials should be restricted to non-nuclear facilities, providing for the average mixing ratio with clean materials, as considered in the radiological model. Destination of cleared materials should be documented by the authorized party and approved by the regulatory body prior to implementation in the clearance process, as part of the traceability of the clearance process for this material.

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5. CLEARANCE OF LIQUID MATERIAL

APPLICATION OF THE CONCEPTS OF DISCHARGE AND CLEARANCE OF LIQUIDS

5.1. Liquid effluents from nuclear facilities or from the use of radionuclides in medicine, industry and research are usually treated as discharges according to Requirement 31: Radioactive waste and discharges of GSR Part 3 [1]. Discharges require a licence or authorization. The dose criterion applying to liquid discharges is generally chosen in the range between 0.1 mSv per year to 0.3 mSv per year [37 GSG-9], which is a fraction of the dose limit to members of the general public. Using radiological models like those recommended in Ref. [29 SRS19], this dose criterion is converted into limits for annual discharge of single radionuclides or radionuclide groups, usually expressed in Bq/a. These limits are specific for a certain facility or a certain type of facility. More details are given in Ref. [37 GSG-9].

5.2. A dose criterion in the range between 0.1 mSv per year and 0.3 mSv/a for any member of the public is usually considered as a basis for the values calculated for discharges of (non-hazardous) aqueous liquids or effluents. Such liquids are subject to direct discharge to sewer systems or various water bodies and not to clearance.

5.3. There are situations where discharge of liquids contaminated with radionuclides is not a relevant concept and therefore these liquids have to be released from radiological regulatory control in a different way. Examples are situations where the facility in which the liquids arise does not possess a licence or authorisation for discharging liquids or where the liquids are not suitable for discharge into the environment. Clearance of liquids can also be used in cases where small amounts are produced, for which the management of a discharge regime (including its safety requirements) is not justified. There may also be cases where liquids constitute an asset and where there is commercial interest in reuse or recycling, e.g. in the case of lubrication oils used in pumps, cooling liquids in transformers in nuclear power plants or acids from the manufacturing process of nuclear fuel. Likewise, it may be beneficial to incinerate certain liquid chemicals used in industry, medicine or research in a conventional waste incineration plant because of hazardous chemical properties. In all such cases, it is not possible to treat the release of the materials as discharges, but instead the concept of clearance can be applied. For clearance of liquids, the basic principles given in Sections 2 and 3 of this Safety Guide apply as for solid materials. The clearance options presented on Figure 4.1 are also applicable to clearance of liquids, with exception of the ones related to surface-specific considerations (contamination always penetrate into the volume of liquids).

5.4. Clearance of liquids needs to be treated on the basis of the same dose criterion as clearance of solid material, i.e. individual effective doses of the order of 10 μSv per year. There is a fundamental difference between clearing and discharging liquids. In most cases, once released to the environment, discharges

DRAFT

remain dispersed, (i.e. the activity cannot be concentrated again by any process). Cleared liquids may remain together, so that after clearance the activity concentration may be increased (e.g. by filtration, evaporation, distillation or fractionation. The activity concentration present at the time of clearance may therefore be much smaller than at any later time. This needs to be taken into account appropriately in the derivation of clearance levels. Clearance of ^{3}H is a special case because the concentration of this radionuclide is highly unlikely to be significantly increased by natural processes in liquids, sediments, plants or animals (the ^{3}H behaves in the same way as water).

ASPECTS OF LIQUID MATERIALS DETERMINING THE CLEARANCE OPTION

5.5. Liquid materials, in particular aqueous liquids, have some properties that distinguish them significantly from solid materials with respect to application of the principle of clearance. These are:

(a) Aqueous liquids can be easily concentrated (by evaporation or distillation) so that the initial concentration of radionuclides in the liquid can change. Concentration processes will increase the radionuclide concentration in the liquid, if the radionuclides in question stay in the liquid phase during such a process.

(b) Radionuclides can evaporate from aqueous liquids and can thus become a source of contamination.

(c) Radionuclides can be accumulated on filters during filtration processes.

5.6. A range of liquids including some oils, lubricants, antifreeze agents or other organic substances often do not show such properties or only to a much lesser extent. This means that a given concentration in such liquids will remain constant or will decrease, but not increase, through subsequent steps of treatment. In this way, such liquids show properties that are similar to those of solid materials. In case of incineration of liquid material, there will be concentration of radionuclides in the dust, which should be properly covered in the radiological model used for derivation of clearance levels, similarly to the model used in Ref. [4 SRS44] for solid materials.

5.7. Furthermore, liquids containing contamination in the form of radionuclides bound to suspended particles can be purified by filtration processes, whereby, however, the activity in the filtrate accumulates. This may be the case for lubricants in which abraded particles that possibly bear some contamination accumulate.

5.8. Several Member States have therefore chosen to limit regulations for clearance of liquid materials to those types of liquids for which the likelihood of any processes leading to an increase of activity

concentration is very small or negligible, and which have been filtered prior to clearance. In this case the derivation of generic clearance levels should not include concentration processes.

NATURE AND SCOPE OF CLEARANCE REGULATIONS FOR LIQUIDS

5.9. If the application of the concept of clearance for liquids is limited to non-aqueous liquids, for which no inadvertent concentration processes have to be expected, this clearance is of the specific clearance type, as it is limited to certain types of materials, and cannot be termed "unconditional". In such a case, additional limitations, e.g. with regard to the destination of the liquid material, can apply. The following options can be distinguished:

(a) The liquids are cleared for any purpose, i.e. they can be directly reused, recycled or further treated (e.g. by incineration). This may be the case for oil or lubricants after filtration, which can be directly reused, recycled (by converting it into fuel or used for energy recovery) or treated (by incineration in a waste incineration plant).

(b) The liquids are cleared for a specific process only, e.g. for treatment by incineration in a conventional waste incineration plant.

5.10. Case-by-case decisions are of considerable importance for the release of liquids, in particular when aqueous liquids like dilute acids that have been used in certain processes in nuclear facilities (like hydrogen fluoride in uranium fuel manufacturing) are to be cleared for further use in the chemical industry. In this case, the first use and any possibilities for subsequent concentration processes (e.g. when instead of a dilute acid a strong acid will be required) have to be taken into account. Radiological models describing such types of specific (conditional) clearance need to include possible processes of concentration, filtration and in general all changes of the activity concentration in the liquid that are conceivable in the process, including those in water purification plants where many chemical elements are extracted from the water and concentrated in sewage sludge. The chemical toxicity of some liquid materials (like hydrogen fluoride in uranium fuel manufacturing) should be taken into account when deciding if some non-radiological regulatory controls need to remain in place after clearance.

5.11. Like for solid materials, specific (conditional) clearance of liquid materials requires that the conditions attached to the clearance process are being fulfilled, e.g. that the liquids are filtered before release, that they are brought to a specified use or a specified recipient or that limitations of total or annual quantities are respected.

5.12. Where the concept of clearance is applied to non-aqueous liquids, cleared aqueous liquids can also be discharged into a receiving water (lake, river, sea). As the liquid has been cleared, no authorization for

the discharge from the nuclear regulatory body would be needed (while the approval of the water authorities would still be necessary). In such a case, the model used for describing the radiological consequences of this type of clearance needs to take into account all relevant pathways in the environment, i.e. migration of radionuclides in the water body, sedimentation or use of water for radioecological pathways, as described in Ref. [38 SRS19]. Special consideration should be given to ^{3}H, as mentioned in para. 5.4.

PRACTICAL APPLICATION OF THE CLEARANCE CONCEPT TO LIQUID MATERIALS

5.13. Clearance of liquid materials may give rise to similar exposure pathways as clearance of solid materials, i.e. external irradiation, inhalation, direct ingestion and secondary ingestion. The details of a radiological model that is specifically designed for liquids from medicine, industry and research and that covers all relevant exposure pathways and exposure scenarios has been given in Ref. [30 TECDOC-1000], which includes guidance on the practical application of the concept of clearance to liquids for release into the environment. The values in Table IV of Ref. [30 TECDOC-1000] were derived with the intention of assuring that if complied with, annual doses to individual members of the public arising from any single cleared practice will not exceed 10 µSv. These values are expressed in Bq/a and can be converted into limits for volume-related concentrations (Bq/m^3 or Bq/l) if the annual amount of effluents is known. Compliance with these levels (or with similar levels derived on the basis of the clearance criteria in GSR Part 3 [1]) will not require further monitoring or institutional control of the release as would be the case with discharges.

5.14. In addition, the clearance levels provided in Table I.2 of GSR Part 3 [1] may also serve as the basis for clearance of some liquids, provided that concentration or filtration processes may not occur with the cleared liquids. The reason is that the scenarios of the radiological model underlying these clearance levels [4 SRS44] cover various exposure situations for solid materials that would also be bounding for reuse, recycling or disposal of liquid materials, e.g. storage in a large tank giving rise to external gamma irradiation, evaporation of the liquid leading to inhalation and ingestion of water sourced from contaminated groundwater. The only option that is not covered by the radiological model underlying these clearance levels [4 SRS44] is release of large quantities of liquids into the environment. This means that the clearance levels provided in Table I.2 of GSR Part 3 could be applied for clearance of non-aqueous liquids, such as oils and lubricants, for reuse, recycling or disposal by incineration. The clearance levels provided in Table I.2 of GSR Part 3 for bulk solids are given in Bq/g and should be converted into clearance levels that are suitable for liquids (in Bq/l) by multiplying the value in Bq/g by the density of the liquid to be cleared (in g/l).

5.15. A further example for practical regulations on clearance of liquids is the report [39 BEIS-2018], which introduces the notion of "relevant liquid" covering non-aqueous liquids, and certain types of aqueous liquid with specified hazardous properties to the water environment. The purpose of this definition is to allow clearance of such liquids on the basis of clearance levels for solid materials, as the exposure pathways considered in the derivation of clearance levels for solid materials encompass relevant exposure pathways for these liquids. An example of the practical application of the concept of clearance to liquids for disposal as waste (usually via disposal in a waste incineration plant) is provided in Annex III to this document.

5.16. Characterisation of liquids for clearance is based on the general principles and requirements described under the section on "Characterisation of the material to be cleared" (paras 3.13-3.32). Special attention should be given to the homogeneity of the liquid and the possibility of deposition of sediments. In case of measurement by sampling, the samples should be taken in compliance with measurement and sampling standards to assure their representativeness.

CLEARANCE LEVELS IN TERMS OF ACTIVITY CONCENTRATION OR TOTAL ACTIVITIY

5.17. Like for solid materials, clearance levels for liquids will usually be expressed in terms of activity concentration for each radionuclide. While for solids the activity is related to the mass (Bq/g), in the case of liquids the activity could be related to the volume (e.g. Bq/l). For example, the activity concentration defines the dose rates for gamma emitting radionuclides and the activity ingested with a given quantity of liquid material. A simple conversion of values expressed in Bq/g into Bq/m^3 or Bq/l using the known density of the liquid material should be done.

5.18. For certain clearance options, mainly for cases where liquids or their residues can accumulate in certain places, like in some case-by-case decisions, it may be necessary to limit the total activity for each radionuclide or of some radionuclide groups over time (e.g. in Bq/a), in addition to or instead of providing volume related clearance levels. Examples for such an approach are provided in Ref. [30 TECDOC-1000], where clearance levels in Bq/a were provided for liquid releases treated with the concept of clearance (not as discharges), as well as in Ref. [40 HPA CRCE005].

DILUTION

5.19. Concerning the aspect of dilution in the context of clearance of liquid materials, it needs to be carefully distinguished whether dilution would take place before or after clearance. As for solid materials, deliberate dilution of the liquid material with clean material (e.g. uncontaminated water) to reach the clearance levels prior to release of material from regulatory control is not an acceptable practice, unless a

permission is obtained from the regulatory body for such an action. Dilution of the cleared liquids after the act of release will occur at many subsequent stages and may be taken into account in the radiological models. However, there is a possibility of concentration in sediment downstream and in some industrial uses, and these situations need consideration. Dilution of radioactively contaminated liquids may be required to manage non-radiological properties, such as pH or salt content, prior to discharge.

5.20. A further aspect in which the question of dilution may play a role is clearance of liquid materials inside small containers, like residues of radiopharmaceuticals in vials with a volume of a few milliliters, for disposal by incineration in an incineration plant. Unlike liquids in large quantities, e.g. used oil in 200 l drums, the radiopharmaceuticals could not be emptied from the vials or could not be removed from gloves, syringes etc. to which they adhere. When determining compliance with clearance levels, the activities measured or calculated from the initial activity modified by radioactive decay should be related to the mass of the entire waste (i.e. the mass of the liquid – radiopharmaceuticals or other liquid material – plus the mass of the small containers or objects in which these liquids are contained or to which these liquids adhere).

NATURAL BACKGROUND

5.21. Like for clearance of solid materials, clearance of liquid materials will not be concerned with natural radionuclides in the liquid that do not originate from the practice in question. Examples for such background contamination may be radionuclides of the natural decay chains of Uranium and Thorium as well as potassium in water in appropriate chemical form (e.g. U or Th oxides and complexes, potassium iodide or iodate). The activity values of such radionuclides that can be attributed to the background level may be disregarded in the clearance process, i.e. their contribution to the measurement effect may be neglected during measurements in the clearance process.

6. CLEARANCE OF GASEOUS MATERIAL

APPLICATION OF THE CONCEPTS OF DISCHARGE AND CLEARANCE OF GASES

6.1. Gases originating from nuclear facilities are usually treated as discharges according to Requirement 31: “Radioactive waste and discharges” of GSR Part 3 [1]. Clearance levels for gases that are to be discharged can be calculated on the basis of individual effective doses of the order of 10 µSv per year. Gases that meet such clearance levels can be discharged without any regulatory authorization.

6.2. Unlike for liquids, it is highly unlikely that gases once used in a nuclear facility or a facility applying radionuclides in medicine, industry or research will constitute an asset for which reuse or recycling could

be envisaged. An example could be the need for clearance of nitrogen gas used in Pu-glove boxes to create an inert atmosphere in the glove box.

6.3. If, for some reason, it is nevertheless needed to apply the concept of clearance to reuse, recycling or disposal of gases, then the radiological analysis needs to take into account the possibility that the concentration of radionuclides in the gas is highly dependent on the volume in which the gas is present. The volume of the gas may change over orders of magnitude, depending on the pressure at which the gas is held in the container. Exposure scenarios relevant to a compressed gas in a container may be fundamentally different to those for a gas under standard conditions. Examples of clearance levels for gases disposed of by release from a vent at the side of a building are given in IAEA Tecdoc1000.

PRACTICAL APPLICATION OF CLEARANCE CONCEPT TO GASEOUS MATERIALS

6.4. The application of the clearance levels provided in Table I.2 of GSR Part 3 [1] or any other clearance levels derived for solid or liquid materials to the clearance of gases is not permissible for the reasons given above.

6.5. Guidance on the practical application of the concept of clearance to gases for release to the environment has been given in Ref. [30 TECDOC-1000]. The values in Table III of Ref. [30] were derived with the intention of assuring that if complied with, annual doses to individual members of the public arising from any single cleared practice will not exceed 10 μSv. These values are expressed in Bq/a and can be converted into limits for volume-related concentrations (Bq/m^3) if the annual amount of effluents is known. Compliance with these levels (or with similar levels derived on the basis of the clearance criteria in GSR Part 3) will not require further monitoring or institutional control of the release as would be the case with discharges.

6.6. Sampling, characterization and monitoring of gases for clearance purposes should be in compliance with measurement and sampling standards.

7. CONCEPT OF CONDITIONAL CLEARANCE

7.1. The concept of situation-specific clearance, which is called “conditional clearance” in this document, is introduced in para. I.13 of Schedule I, GSR Part 3 [1]. The radiological basis for conditional clearance is the same as for clearance, as described in §2.7 and §4.4, namely those specified in Schedule 1, sections I.10 and I.11. It should be noted that the term “conditional” refers to the conditions attached to the clearance act and the further use of the cleared material, and not to the radiological impact or the resulting dose.

CONDITIONAL CLEARANCE AS ADDITIONAL OPTION FOR MANAGEMENT OF MATERIAL

7.2. Conditional clearance is applied to a particular material, sometimes for a specified amount and to a particular fate and destination of that material: the type of material and the amount (when specified), fate and destination are therefore specified as the conditions attached to the conditional clearance authorisation. Examples of conditional clearance that have been considered in Member States are scrap metal for recycling (melting), buildings for demolition, and waste for disposal in landfill sites.

7.3. Conditional clearance is an additional option for management of material and waste, which provides for more flexibility in management of material/waste from authorized facilities and activities, remediation and post-emergency situations. It is essentially a form of application of the graded approach to regulatory control of materials and waste, and supports the application of "the waste hierarchy"[13], enabling reduction of amounts of waste to be managed as radioactive waste and increase of amounts to be reused/recycled or disposed of as non-radioactive waste. Conditional clearance can also be related to the criterion for clearance specified in para. I.10 (b) of Schedule I, GSR Part 3 [1], whereby the regulatory body may decide (in exceptional cases, where the national regulatory framework so allows) that the optimum regulatory option is to remove a particular material from regulatory control. When considering whether conditional clearance is appropriate the regulatory body should consider other factors, e.g. the need for measures at the recipient facility to ensure doses are acceptable and whether these can be relied upon without radiation protection regulatory oversight, and socio-economic factors. If radiation protection oversight is required, then conditional clearance is not appropriate and consignment to the facility would be an authorised practice and the facility would be an authorised facility.

CONDITIONAL CLEARANCE LEVELS

7.4. Following on from the concept of conditional clearance, introduced in Section 2, it is possible to derive conditional clearance levels in terms of activity concentration per unit mass, or activity concentration per unit surface area, using an appropriate set of scenarios. These conditional clearance levels ensure that the dose criteria for clearance are met for the specified material and the specified fate and destination. These conditional clearance levels would be expected to be higher or the same as the clearance levels specified in Table I.2 and Table I.3 of Schedule I, GSR Part 3 [1] because they consider a particular tailored set of scenarios rather than the general scenarios that were considered for the clearance

[13] The concept of "the waste hierarchy" is widely accepted to be fundamental to the sustainable management of all types of wastes, including radioactive wastes. The concept of the waste hierarchy has been widely adopted in national policies and has also been taken up internationally (e.g., EU, UNEP, OECD).

levels. Contamination with radionuclides of natural origin should be considered as well, when necessary. The conditional clearance levels calculated for a specific set of materials and/or destinations would not be applicable to other materials or destinations. The derivation of the conditional clearance levels should consider that the cleared material is handled as non-radioactive material would be handled, i.e., conditional clearance levels should not rely on special precautions to be taken by the receiving party to meet the dose criteria.

7.5. Problems could occur if the conditional clearance levels are such that the conditionally cleared material (e.g. metals for melting) would require notification or authorisation upon receipt at the specified destination (e.g. smelter). In order to avoid such legal and regulatory problems, one approach is to ensure that the mass specific conditional clearance level does not exceed the corresponding exemption level for moderate quantities specified in Table I.1 of Schedule I of [1]. In this way the conditionally cleared material will be below the mass specific exemption level for moderate quantities and therefore can be exempt from the requirement for notification. Alternatively, in accordance with Requirement 8 in GSR Part 3, when approving the material for conditional clearance, the regulatory body shall ensure that the conditionally cleared material does not again become subject to the requirements for notification, registration or licensing, unless it so specified. If the specified destination is an authorised practice, e.g. a licensed smelter, then these considerations are not relevant, conditional clearance may not be an appropriate concept to be applied.

7.6. It should be noted that during the metal melting process certain nuclides concentrate in the dusts and slags so that the activity concentration in these by-products may exceed the activity concentration in the metals, and hence exceed the exemption levels for moderate quantities [1]. The radiological assessment used to derive the conditional clearance levels should include scenarios that account for this phenomenon, and therefore this will ensure that the doses from exposure to such dusts and slags do not exceed a value of the order of 10 μSv per year. Examples of such assessment can be found in Ref. [4 SRS44] and Ref. [28 EC RP 89].In accordance with [1], practices using such material or the material in the practice should automatically be exempted, so notification, registration or licensing would not be necessary in such cases.

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SURFACE-SPECIFIC CONDITIONAL CLEARANCE LEVELS

7.7. Surface-specific clearance levels[14] for unconditional clearance need to be carefully distinguished from surface-specific clearance levels for conditional clearance options. Surface-specific levels for conditional clearance may be derived for the following options:

(a) Clearance of metals for melting;

(b) Clearance of buildings for reuse;

(c) Clearance of buildings for demolition.

7.8. In these options for conditional clearance, surface-specific clearance levels fulfil different purposes. For example, limitation of the surface activity on metallic items protects people handling the material prior to melting. Limitation of surface activity on building surfaces will protect people using the room as a new workplace from high concentrations of activity on the surfaces, leading to increased levels of direct irradiation. Likewise, this will protect people refurbishing the room from high concentrations of resuspended activity in the breathing air. Examples for surface-specific conditional clearance levels for metal scrap for melting can be found in Ref. [28 EC RP89] and for buildings for demolition in Ref. [41 EC RP113].

7.9. Clearance on the basis of surface-specific clearance levels generally only applies to surfaces where the contaminant can be detected by the surface measurement technique, and the depth of the contaminant is such that the measurement technique sees, to a reasonable degree, all the contamination. Surface-specific clearance levels are not relevant to excavated soil or building rubble[15].

7.10. When surface-specific clearance levels are given for surfaces where the activity can penetrate into the volume, like for building surfaces and unsealed ground, it needs to be specified whether the clearance levels apply only to the top layer (i.e. the actual surface) or to the surface and a part of the volume beneath this surface. Usually it is a prudent approach to relate the surface-specific clearance levels to the sum of contamination present directly on the surface and inside the volume beneath the same surface area.

[14] Surface-specific clearance levels are clearance levels expressed in Bq/m2 that apply to activity on the surface of a material.

[15] Building rubble that has to be cleared as such is usually measured in bulk monitors that can measure several 100 kg of material at a time, applying mass specific clearance levels like those in Table I.2 of GSR Part 3. Buildings that are to be cleared in the form of the standing structure are most often cleared, e.g. for subsequent demolition, using surface-related clearance levels like those given in Ref. [41 EC RP 113]. The building rubble originating from demolition of these buildings does not have to be subjected to additional clearance measurements and no mass specific clearance levels need to be complied with in this case.

Surface-specific clearance levels can then be understood as a limitation for the activity beneath the surface projected onto the surface area. Details are given in Ref. [41 EC RP 113].

In addition, careful distinction needs to be made between surface-specific clearance levels for unconditional clearance on the one hand and other uses of surface-specific activity levels, such as in the IAEA Safety Standards Series No. SSR-6 (Rev.1), Regulations for the Safe Transport of Radioactive Material 2018 Edition [29 SSR-6].

7.11. It should be noted that the values defined in SSR-6 (Rev.1) [29] are derived from a radiological model for transport of radioactive material [42 SS6], which is not relevant for clearance. A more recent endeavour to update those values [43 TECDOC-1449 CRP] provides up-to-date radiological modelling for exposure during transport activities from surface contamination on various types of packages for radioactive waste and spent fuel. However, this model is also unsuited for application to clearance of surface contaminated material.

7.12. Radiological models for the derivation of surface-specific clearance levels need to take account of all exposure pathways that can be caused by presence of surface contamination. In particular, these include:

(a) External irradiation from the contaminated surface,

(b) Ingestion as a consequence of hand-to-mouth pathways when handling such objects and transferring part of the contamination to the hands,

(c) Inhalation as a consequence of resuspension of the contamination into the breathing air when handling or machining such objects,

(d) Skin contamination as a consequence of transfer of part of the contamination onto uncovered parts of the skin.

7.13. The dose criteria for clearance, specified in Schedule I, paragraphs I.10-I.12 of [1], should be applied when using these radiological models for derivation of surface specific clearance levels. In addition, an equivalent dose limit to the skin of 50 mSv in a year should not be exceeded for low probability scenarios, as described in para. 4.5.

7.14. If material has been activated by particles (e.g. concrete structure of the reactor's biological shield), and there is no surface contamination present, surface specific clearance levels are not applicable.

DRAFT

MEETING THE CONDITIONS

7.15. It is clear that under conditional clearance, the condition(s) attached to the fate or destination of the material need to be achieved in order to consider the clearance process to be complete. Metal scrap that was cleared on the condition that it was melted needs to actually reach a furnace and be melted there, and not be reused before that point. In case mixing is required with non-radiological metal as part of the condition, the mixing ratio used in the derivation of the conditional clearance levels should be respected. Likewise, a building that was cleared on the condition that it would be demolished must not be used in the meantime for new workplaces (e.g. as an office building or a workshop) but must be demolished without prior reuse.

7.16. Hence, it is necessary to establish a form of contract or arrangement between the site operator (consignor) and the operator of the final destination to ensure that the conditions are met. The arrangement should provide a high level of assurance that the material cannot be diverted prior to completion of clearance, and that radiation risks are minimised. The practicalities of this will need to be agreed with the regulatory body. This could include overseeing the transport to the specified destination or requiring receipts to be sent to the consignor that can be reviewed by the regulatory body. If the destination is in a foreign country and a transboundary movement of the conditionally cleared material is planned, the clearance process should take that into account, so the material can be accepted for transport and further management (for example recycling) in the destination country.

7.17. Conditional clearance can therefore be considered as a two-stage process. Stage 1 is the act of clearance when it is confirmed that (a) the material meets the conditional clearance levels, (b) the fate or destination is agreed, and (c) a specific contract is in place for that material. Stage 2, confirmation, occurs when evidence is provided that the conditions attached to the conditional clearance have been met.

7.18. In the case of conditional clearance of scrap metal for melting, the process of dealing with scrap metal in the Member State will need to be understood so that the appropriate conditions can be identified. Scrap metal often goes to scrap dealers who store metals until they have a sufficient quantity of a particular type of metal to sell on to a metal melting company, and there is significant international trade in scrap metal. This is not appropriate for conditionally cleared scrap metal. Therefore, conditions should ensure that conditionally cleared metal for melting is sent directly to the specified melting facility.

7.19. Similarly, in the case of conditional clearance of material sent to a landfill, the specificities of the landfill have to be understood and included in the scenarios taken into considerations for derivation of the corresponding clearance levels. The conditions that are specified should take account of the capacity of the receiving landfill, the mass-specific activity concentration levels and leachability of radionuclide from

DRAFT

the cleared material. Also the post closure period should be considered in the scenarios. Possible intrusion scenarios after the end of the institutional control period should be treated as low probability scenarios, whereby exposure does not exceed the 1 mSv per year criterion.

7.20. In the concept of conditional clearance it is important to specify when the process of clearance may be considered to be finished, so that the residual activity of the material can be disregarded in a legal sense(compare with para. 2.13). While in the case of unconditional clearance the process of clearance may be considered complete once compliance with clearance levels for unconditional clearance has been established, conditional clearance requires the material to reach a certain destination or end state (e.g. metal cleared for melting must reach the smelter, waste cleared for disposal must reach the landfill, buildings cleared for demolition without prior reuse must be demolished). In such cases the question often arises whether transport of the material to its destination, which is necessary to complete the clearance process, will require a license in accordance with SSR-6 (Rev. 1) [29], and whether handling the material during this time will require an authorisation, permit or license (if so, it would be necessary that the transport is performed by a licensed shipping company)..

7.21. Any facility that receives conditionally cleared material does not require a license during operation nor after closure since the material it receives is not radioactive in a legal sense (compare with para. 2.13).The radiological models used for derivation of clearance levels for conditional clearance options should explicitly take into account transport processes, including the time prior to transport activities and amount of material to be moved in each consignment. There may be situations where conditionally cleared material would exceed the transport exemption levels (including surface contamination) defined in SSR-6 (Rev. 1) [29] at the time of transportation.

7.22. In these cases it should be concluded that conditional clearance may not be suitable for that particular material and should not be used. This is to ensure that statement from the para 3.12 of Ref. [1] is met, so *"that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing…"*.

7.23. Hence, conditional clearance should be considered to be finished when the material has reached the final destination specified in the conditions. However, the regulator may decide that the conditional clearance is already finished when the material leaves the facility if they are confident that all the conditions will be met.

DRAFT

8. INVOLVEMENT OF INTERESTED PARTIES AND ENHANCING PUBLIC UNDERSTANDING

8.1. Clearance is a regulated process that is safe and in accordance with GSR Part 3 [1]. It is defined as the release from radiological regulatory control of material that poses a trivial level of risk to people and the environment, irrespective of its future use. Hence, clearance involves the release of material arising within a radiation regulated activity, e.g. nuclear industry, medical or educational facility, to a destination that is not part of a radiation regulated industry. Cleared material will most likely be processed or used by people who are not familiar with radiation protection and who do not necessarily understand the concept of radiation risk, nor equate the dose criterion of the order of 10 μSv per year with a trivial level of risk to people and the environment. Also, people who use the cleared material without taking any particular radiation protection measures may not understand that they are implicitly protected by the application of the clearance levels (because the scenarios used to derive the clearance levels assume that the material is used by people who are unaware of the origin of the cleared material and therefore do not apply any particular radiation protection measures).

8.2. Therefore, authorized parties and regulatory bodies should engage with interested parties to explain the concept of clearance, the rationale(s) for it and how it is regulated and performed in practice. The feasible scope and volume of interested parties may vary from country to country and from case to case. To build up confidence in the clearance process, this engagement should be carried out using clear terminology to avoid ambiguities, it should be carried out in a transparent manner, and it should take different forms depending on the interested parties. Examples of different forms of communication are a formal consultation or communication on the national framework; discussions between regulators, authorized parties and waste management organisations; seminars and workshops with interested parties; printed material including leaflets; and the use of electronic media such as web pages and social media.

8.3. The aim of the engagement is not only to understand the concerns of the interested parties and to address them with respect and in a proportionate manner, but also to share the social, economic and environmental benefit obtained from the cleared materials through recycling and a more sustainable use of resources. Communication should be maintained in order to develop a common understanding, based on trust, of the concept of clearance with interested parties. Both the regulators and the authorized parties should be involved in pursuing the social, economic and environmental benefits of clearance.

8.4. Demonstration of the clearance procedures undertaken and the measurements that are made as part of the clearance process can be effective in enhancing understanding by interested parties, and, in some cases, may be sufficient to build confidence in the application of clearance.

DRAFT

8.5. One approach that is useful in enhancing public understanding of the trivial radiation risk from cleared materials is to compare the radiation risk from the cleared material with the average lifetime background cancer risks in the member state, and with the variation in these average lifetime background cancer risks in the different regions in the member state. This comparison of risks should use the LNT (Linear Non-Threshold) model and the radiation risk coefficient of 5% per Sv, as defined by Ref. [45 ICRP103/2007]. Comparisons of the trivial risk from cleared material with commonly accepted radiation risks, e.g., intercontinental flights, natural radionuclides in foodstuffs, are also useful communication tools. Relevant information for these comparisons can be found in IAEA posters and leaflets about radiation protection [46].

8.6. Communication of radiation risks from exposures to cleared materials could benefit from experiences, tools and examples used to enhance public awareness of radiation risk in other situations, for example dialogue forums held in affected areas just after Fukushima Daiichi accident [47,48] (Ogino and Hattori; Murakami, Nagatani, Oki).

8.7. In the case of conditional clearance, where the fate and destination of the material is specified in the conditions, the authorized party proposing the conditional clearance should engage with the operator of the final destination so that the conditional clearance option is founded on an agreement and understanding between the authorized party clearing the material and the final destination. Other interested parties should also be consulted, e.g. transport operators, and the regulatory bodies. Since conditional clearance levels are normally higher than generic clearance levels (unconditional clearance levels), the regulators and authorized parties should carefully explain the difference between them to the interested parties in an easy-to-understand manner.

8.8. An important point to communicate to interested parties is that the process of clearance is overseen by the regulatory body. Cleared material is no longer required to be regulated from a radiation or radioactivity point of view. Waste management organisations that send cleared material to other destinations with no radiation marking and/or no reference to the radiation regulatory regime are complying with the law.

8.9. The last decade has seen an increased focus on the importance of involvement of interested parties, including the public, in a number of policy areas, particularly those concerned with environmental issues or technology evaluation. There are a number of arguments for involving interested parties in setting up the clearance process, as described in Ref. [49 NW-T-2.5].

DRAFT

APPENDIX 1

SCREENING LEVELS FOR RECYCLING OR DISPOSAL ON LANDFILLS OF MATERIAL AND WASTE AFTER AN EMERGENCY

GENERAL

A1.1. Nuclear or radiological emergency and subsequent recovery operations may continue for a long time (weeks to potentially decades). After the early and intermediate phases of the emergency, a next phase will be to manage recovery of the affected people and area under a regulatory system in association with radiological protection in the existing exposure situation.

A1.2. In the post-emergency period, under an existing exposure situation, the reference level for the optimisation of protection of people living in the affected areas is selected from the 1–20 mSv per year band.

A1.3. Using the reference level, the regulatory body may need to set up a new regulatory system for the material and waste management in the affected area, e.g. for disaster waste, rubbish after cleaning homes up, paddy straw, and soil and waste generated from decontamination work. According to the regulatory system, some highly contaminated material and waste may be put under the regulatory control.

A1.4. Due to radioactive decay, there is a possibility that the activity concentration of the material or waste that has been designated for need of regulatory control may become lower than the regulatory value. In this case, if necessary, recycle or disposal on landfills of the material and waste could be allowed, without further regulatory control in some cases, in the post-accident existing exposure situation, which is similar to a concept of conditional clearance in a planned exposure situation.

RELATIONSHIP TO CLEARANCE IN THE PLANNED EXPOSURE SITUATION

A1.5. In the planned exposure situation, the term of “clearance” is usually used for the release of material and waste from regulatory control. The primary radiological basis for establishing values of activity concentration for clearance is that the effective doses to individuals should be of the order of 10 μSv or less in a year. To take account of the occurrence of low probability events leading to higher radiation exposures, an additional criterion is used, namely, the effective doses due to such low probability events should not exceed 1 mSv in a year. In this case, consideration was also given to doses to the skin; an equivalent dose criterion of 50 mSv in a year to the skin was used for this purpose.

DRAFT

A1.6. In existing exposure situations, the concept of reference levels 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.

A1.7. Recycling of material or disposal of waste on landfills in post-emergency existing exposure situation often cannot be done using the same dose criteria as for clearance in planned exposure situation, due to the increased background radiation. In such cases different dose criteria may be selected, which is more appropriate, and which takes into account specificities of the existing exposure situation. This criterion is not the same as the reference level for the remediation actions. Considering such a difference in the radiological basis used for clearance in planned exposure situation and for recycling or disposal on landfills under an existing exposure situation, the term "clearance level" for limiting concentrations of radionuclides in materials should not be used for the latter, as it may create confusion in the public. This Appendix instead uses the term "screening level" for the operational values used in measurements.

A1.8. If a clearance-like process in such situations is necessary, any derived screening level should be based on an underlying, individual effective dose criterion whose numerical value is smaller than or equal to the selected reference level for the existing exposure situation under consideration. That effective dose criterion is related to exposures to people coming from material to be managed, and don't include the exposures from the existing exposure situation. In such cases the value of the dose criterion should be specified by the regulatory authority, considering the band of reference levels for existing exposure situations and adhering to the general criteria for clearance as specified in para I.10 (a) and (b), and in paras I.11-I.13 of Schedule I, GSR Part 3 [1], below which no further optimisation or protective actions may be necessary. An example of such a dose criterion, for the later stage of recovery after an emergency, could be of the order of 1 mSv per year or less for reasonably expected scenarios (e.g. the dose to operators and the public under normal operations, doses during normal transportation, doses associated with recycling, and doses from groundwater migration following disposal in a landfill). Dose criteria for low probability scenarios such as intrusion into a landfill site post-closure should also be specified and these would be expected to be greater than, or equal to, the dose criteria for reasonably expected scenarios. Hence, for practical application to support decision making in a clearance-like process, an approach of using "screening levels" of measurable quantities (in Bq/g), derived from suitable dose criteria, is recommended. Note that an annual dose of 1 mSv per year corresponds to the dose criterion that was applied when deriving the clearance levels for residues with radionuclides of natural origin specified in GSR Part 3, where no further protective actions may be necessary as they would yield no net benefit, and it is also the dose criterion applied to low probability scenarios when deriving the general clearance levels for artificial radionuclides specified in GSR Part 3.

CATEGORIZATION FOR RECYCLING OR DISPOSAL TO LANDFILL

A1.9. When a nuclear or radiological emergency happens, in the affected area there is usually a facility containing nuclear or radioactive materials. It may even be the cause of the emergency. That facility has been already regulated by the relevant radiological regulatory system before the emergency. Hereinafter, the facility in the affected area is referred to as on-site. On the other hand, there may also be contamination in the broad area outside the facility due to the emergency. Hereinafter, the affected area except for the facility is referred to as off-site. In the off-site, it may be necessary for the regulatory body to set up a new regulatory system for the material contaminated as a result of an emergency.

A1.10. When we consider recycling or disposal of the material and waste in the post-accident existing exposure situation, a distinction should be made between on-site and off-site in locations of the origin of material or waste and the target location of recycle or disposal on landfills, because the -applicable regulatory systems are different. In this sense, according to the locations of the origin and the target of the material and waste, the possible ways to recycle or dispose of to landfill would be categorized into three types; category 1: from off-site to off-site; category 2: from on-site to on-site and category 3: from on-site to off-site.

A1.11. After the Fukushima Dai-ichi Nuclear Power Station (1F plant) accident, as for the category 1, the Ministry of the Environment (MOE) of Japan, which is responsible for regulating off-site contamination, developed activity concentration for recycling of the removed soil in 2016. This is a good example for recycling of the material and the waste generated from off-site, but is not the case of a clearance, because this is a recycle under the Act on Special Measures concerning the Handling of Environment Pollution by Radioactive Materials Discharged by the NPS Accident Associated with the Tohoku District - Off the Pacific Ocean Earthquake That Occurred on March 11, 2011 (Act on Special Measures, issued by MOE).

A1.12. The Minister of the Environment (MOE) defines waste contaminated by radioactive material over 8,000 Bq/kg of ^{134}Cs and ^{137}Cs as designated waste, for which the national government is responsible for the treatment under the Act on Special Measures. The MOE established the procedure of cancelling the designation of the designated waste, which is applicable when the radioactivity concentration of the designated waste is reduced to 8,000 Bq/kg or less due to the radioactive decay. This is also an example for disposal on landfills of the material and waste, but the cancellation is not the case of a free release, since after the cancellation the waste is disposed on landfills under the standard in the Waste Management and Public Cleansing Act.

DRAFT

A1.13. As for the category 2, in 2017 the Japan Atomic Energy Agency (JAEA) examined activity concentration of the waste generated in the 1F plant for recycling on-site, which is under regulatory oversight by the Nuclear Regulatory Authority (NRA) of Japan. This is also not an example of clearance of the waste because the recycled material is still under the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors (the Nuclear Reactor Regulation Law).

A1.14. As for the category 3, it has not been applied yet in Japan.

A1.15. The above-mentioned two examples of the categories 1 and 2 after the 1F plant accident are given below.

Category 1: From off-site to off-site

- **Example of recycle of removed soil off-site generated from decontamination work in off-site**

A1.16. The MOE established the Technology Development Strategy for Volume Reduction & Recycling of Removed Soil in April 2016 towards the final disposal of removed soil outside Fukushima Prefecture. In this strategy, it was clarified that the MOE would make a basic concept on safe use of recycled removed soil keeping the safety of radiation for the recovery workers who handle the soil and for the public. According to the strategy, the MOE subsequently established the basic concept on safe use of recycled removed soil in June 2016.

A1.17. In the basic concept, it is clarified that the use of the recycled removed soil is limited such as for basic structure material of banking for coastal levee, disaster prevention forest on the beach, or roads, which is assumed not to change the form artificially for a long time period and is constructed in the public projects managed by the public authority. The recycled removed soil has to be used by the appropriate management according to the criteria based on the Act on Special Measures under the condition that activity mass concentration level of recycled removed soil is restricted by shielding of radiation with soil-covering in order to confine additional exposure dose below 1 mSv per year for workers and the public. The safety assessment was carried out by setting some exposure scenarios by the MOE in order to ensure that the dose exposed to the removed soil for workers and public was 1 mSv per year or less. Later, the concept was extended to management of other materials, when facilities were constructed using the recycled materials. In such cases the appropriate thickness of the shielding for radiation was ensured in order to make the exposure dose for workers and public below the level that needs no measures for prevention of radiation hazards.

A1.18. The activity mass concentration level is below 8,000 Bq/kg in principle and is set to7,000, 6,000, 5,000 and 4,000 Bq/kg according to the purpose of the recycle, the shielding condition and annual working time for the use of the recycled removed soil. The value of 8,000 Bq/kg is the same as the concentration

level that is given in the Act on Special Measures as a kind of a screening level for exemption from radiological regulatory requirements in the existing exposure situation.

- **Example of disposal on landfills off-site of the material and waste from off-site -**

A1.19. The MOE designates waste contaminated by radioactive material over 8,000 Bq/kg (designated waste). If the activity mass concentration is over 8,000 Bq/kg, the exposure dose for workers and public would be above 1 mSv per year, according to the safety assessment provided by the MOE setting some exposure scenarios. The national government is responsible for treating the designated waste since special control is necessary. On the other hand, when the radioactivity of the waste is 8,000 Bq/kg or less, it can be treated technically and safely using normal treatment method as additional exposure dose by the treatment is 1 mSv per year or less for both workers and the public.

A1.20. Taking into consideration such a situation, the MOE established the procedure to cancel the "designated waste" as follows:

(a) When the radioactivity of the designated waste reaches 8,000 Bq/kg or less due to radioactive decay, the Minister of the Environment can cancel the designation after consultation with person or entity who stores the designated waste temporarily and person or entity who has obligation for the material management, including transport and disposal in landfills after cancelling the designation (local municipalities or business operators). The cancellation of the designation is not carried out without their acceptance.

(b) After cancelling the designation of the designated waste, the waste is treated by local municipalities or business operators according to the treatment standards in the Waste Management and Public Cleaning Act. The MOE provides technical and financial support for the treatment as necessary such as explanation for safety of the treatment of the waste whose radioactivity is 8,000 Bq/kg or less, in order to facilitate the disposal of the waste after cancelling the designation.

Category 2: From on-site to on-site

- **Example of recycle on-site of waste generated on-site -**

A1.21. Tokyo Electric Power Company (TEPCO) has planned that contaminated rubbles with less than 5μSv/h of surface dose rate, which are stored outdoor in the Fukushima Daiichi Nuclear Power Station (1F) on-site, will be recycled and applied in a restricted use only within 1F on-site. On that basis, the Japan Atomic Energy Agency has started a study for recycling of rubbles within 1F on-site. If the rubbles can be appropriately recycled to construction materials with suppressing additional effective doses for

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workers in 1F on-site and for the public outside 1F on-site, it will contribute to reduce the amount of radioactive wastes in the future because clean materials are not brought from outside of the site.

A1.22. Activity concentration for recycling to restricted use within 1F on-site is estimated using a case-by-case approach in consideration of decommissioning activities of 1F on-site under existing exposure situation. This approach is based on the following basic concepts:

(a) The recycle within 1F on-site should not lead to increasing the effective dose unduly in the work environment and restrain a series of future decommissioning activities.

(b) The policy of radiation protection to regulate the implementation for 1F Nuclear Power Station should apply to the radiation risk to the hypothetical member of the public immediately outside the 1F site boundary due to additional sources and activities associated with the recycling on-site.

A1.23. Figure A1.1 shows the procedure for estimation of activity concentration for the recycle within 1F on-site. At the first step, activity concentration in material to be recycled is determined to meet the criteria of 1μSv/h of additional exposure due to the recycling. The 1 μSv/h corresponds to the minimal value of the dose rates in the air at the 1m height from ground surface observed in 1F site. To justify estimated activity concentration, additional effective doses for workers closest to recycling material do not exceed 10% of dose limit for worker, 20 mSv per year, in consideration of small margin to it at the 1F decommissioning activities. Additionally, two kinds of criteria are set up to assure the justification of radiation protection for the public outside the 1F site boundary. One of the criteria is effective dose rate along the boundary of less than 1 mSv per year brought from all radiation sources of 1F after the recycle. Secondly, activity concentrations in groundwater for radionuclides migrated from recycling material do not exceed the concentration for operational target at 1F boundary to the ocean.

A1.24. According to the above procedure, Japan Atomic Energy Agency (JAEA) calculated activity concentrations for recycling to restricted use; road materials and base of concrete building, within 1F on-site [50,51]. As shown in Table A1.1, for example of radioactive cesium (^{134}Cs and ^{137}Cs), the results of estimated concentrations were 1.3×10^{4} Bq/kg for the roadbed of asphalt road, 7.4×10^{3} Bq/kg for the pavement of asphalt road, 1.0×10^{5} Bq/kg for the roadbed of concrete road, 8.1×10^{3} Bq/kg for the pavement of concrete road, and 1.6×10^{4} Bq/kg for the base of the concrete building, under the ratio of ^{134}Cs to ^{137}Cs of 0.209 as of March 2016.

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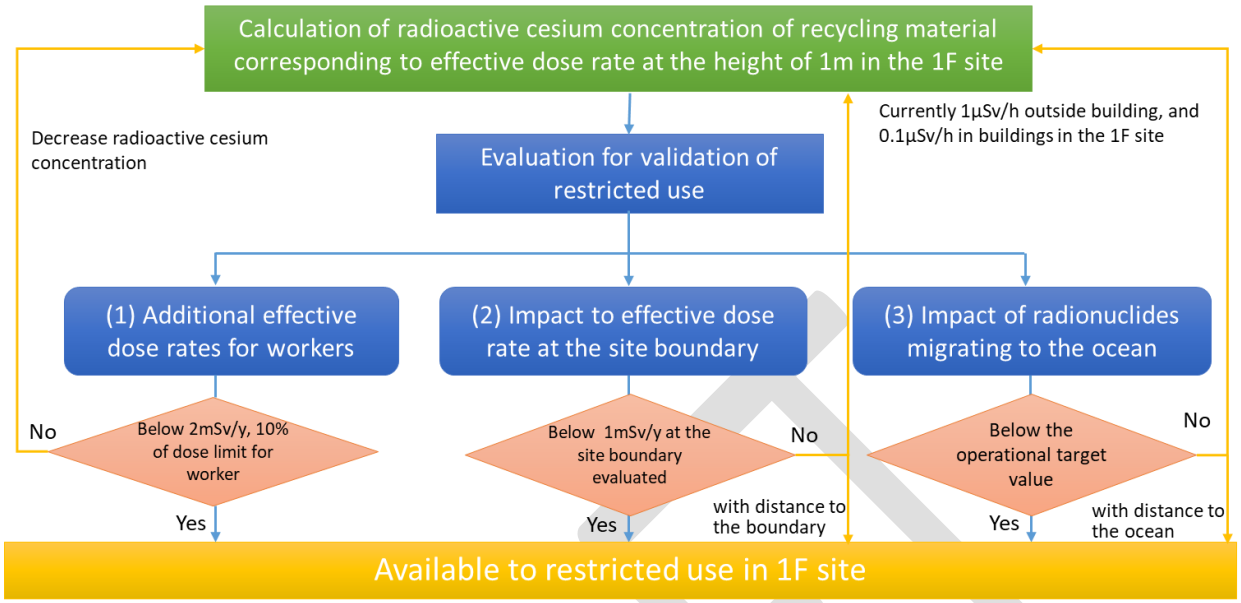

Figure A1.1. Procedure for estimation of activity concentration for the recycle within 1F on-site

TABLE A1.1. ESTIMATED ACTIVITY CONCENTRATIONS FOR RECYCLING TO RESTRICTED USE; ROAD MATERIALS AND BASE OF CONCRETE BUILDING, WITHIN 1F ON-SITE

Material	Application		Activity concentration (Bq/kg)	Shielding condition
Concrete	Asphalt road	Roadbed	13,000	Pavement thickness 5cm
		Pavement	7,400	No shielding
	Concrete road	Roadbed	100,000	Pavement thickness 15cm
		Pavement	8,100	No shielding
	Building concrete	Base	16,000*	Floor slab thickness 20cm

*Restricted use in the building based on an effective dose rate of 0.1μSv/h in the building (scaled from a value of 160,000 Bq/kg corresponding to 1μSv/h that was calculated by JAEA).

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ANNEX I

DOSIMETRIC MODELLING FOR DERIVATION OF RADIONUCLIDE SPECIFIC VALUES FOR CLEARANCE BASED ON SURFACE CONTAMINATION MEASUREMENTS

I-1. Calculation of clearance levels for surface contamination has been endeavoured in various national and international studies in Europe, in the USA and by the IAEA. The following list is a non-exhaustive overview of available studies:

- European Commission: RP 89 [I-1] and RP 101 [I-2]
- USA: NUREG 1640 [I-3] and ANSI/HPS N 13.12 [I-4]
- USA: Argonne National Laboratory "Surface Clearance Criteria for Workers" [I-5]
- JAPAN: JHPS Standardization Committee [I-6,I-7,I-8]
- UK Code of Practice [I-9]
- SUDOQU [I-10,I-11]

I-2. The radiological models underlying these studies are presented briefly in the following sub-sections.

RECOMMENDATIONS ON CLEARANCE BY THE EUROPEAN COMMISSION: RP 89 / RP 101

Overview of the approach

I-3. The recommendations RP 89 [I-1] and RP 101 [I-2] on clearance issued by the European Commission contain radiological models for the derivation of surface specific clearance levels. RP 101 as the technical document contains the detailed description of this model, which is briefly summarised in this section. While the surface specific clearance levels were derived for metal scrap (steel, copper and aluminium), they can be regarded as fulfilling the requirements to be posed to clearance levels for unconditional clearance, as they cover scenarios for reuse and recycling. Because of the nature of the underlying scenarios, especially those for reuse, these clearance levels are applicable not only to metals but also to other items that are handled, treated and used, e.g. items made from plastics, wood, or glass.

I-4. The surface specific clearance levels recommended in RP 89 apply to the total surface activity concentration, fixed plus non-fixed, and are intended as an average over moderate areas, which is understood as "several hundred square centimetres up to 1 square meter", "depending on the type of material, contamination and homogeneity of the contamination". It is further argued in RP 89 that "surface contamination limits for metal scrap are largely independent of the metal type (steel, copper, aluminium), since the transport and handling are similar regardless of the metal."

I-5. The scenarios used for the derivation of surface specific clearance levels for metal scrap for recycling or reuse are based on a number of scenarios outlined in the following subsections. An overview of these scenarios is provided in Figure I-1. It can be seen that both sets of scenarios are very similar in structure. However, the significance of surface-specific clearance levels is deemed different in RP 89 and RP 101 in the two areas recycling and reuse of metal scrap: recycling is mainly governed by mass-specific clearance levels, while "the clearance criteria for direct reuse are primarily surface contamination limits since measurement of the bulk activity would in many cases mean destroying the equipment's integrity."

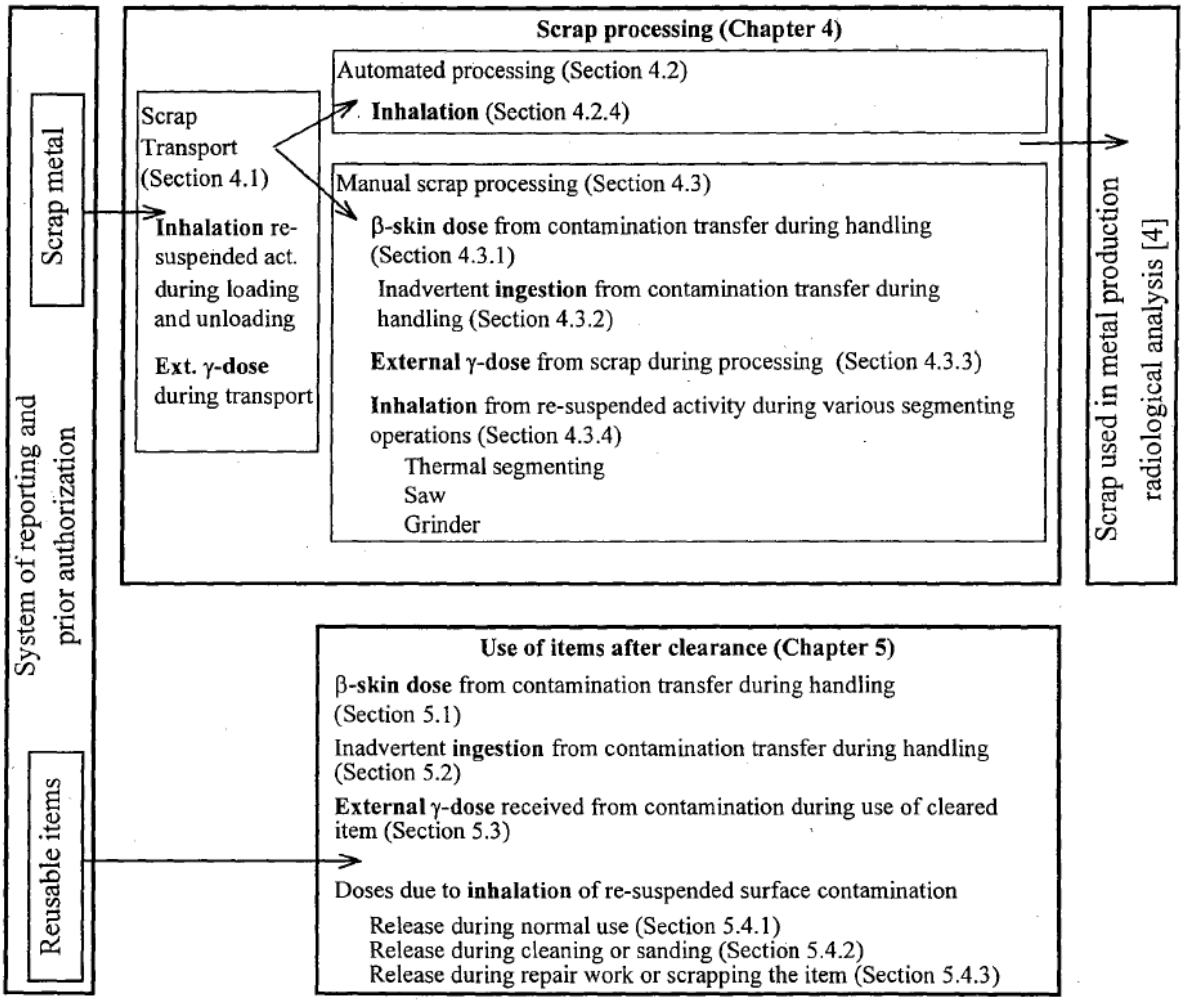

Figure I-1: *Overview of the scenarios for the derivation of clearance levels for metals for recycling and reuse from RP 101 [I-2]*[16]

[16] The section references in the Figure I-1refer to sections of the publication RP 101

I-6. The scenarios developed in RP 101 are primarily of deterministic nature and represent normal situations during which contact and exposure to the cleared metal can occur. It should be noted that the radiological model for surface-specific clearance levels developed in RP 101 is totally independent from that developed for mass-specific clearance levels in Ref. [I-12] (EC RP 117) for metal scrap. This means that the surface-specific clearance levels are not derived using a conversion factor accounting for a mass to surface ratio.

I-7. In addition, the clearance levels for all radionuclides possessing radioactive decay products include the dose contributions from these decay products, which are accounted for by assuming they are in secular equilibrium with the parent nuclide and adding their doses to the dose calculated for the parent nuclide. Lists of these parent and daughter nuclides are provided in RP 89 and RP 101.

I-8. The following sub-sections describe those scenarios that have been used in RP 101 for the derivation of surface-specific clearance levels for unconditional clearance. Scenarios that explicitly pertain only to recycling are not discussed here.

General considerations in RP 101 to modelling reuse scenarios

I-9. RP 101 defines that "the continued use of items after clearance from an authorized facility is termed reuse. The reuse of equipment and tools is a common practice in the nuclear industry and is economically preferable to disposal or scrapping the equipment." It is pointed out that "modelling reuse requires different scenarios than in the case of melting. Unlike reuse, recycling scrap involves melting and reforming the scrap into new products. During this process the scrap is mixed with scrap from non-nuclear sources leading to a reduction in the mass-specific activity concentration of the product compared to the cleared scrap." As this is not the case for reuse, no dilution or any modification of the material is assumed.

I-10. The surface-specific clearance levels for reuse rely primarily on surface contamination limits since the measurement of the mass-specific activity concentration would in many cases mean destroying the equipment's integrity.

I-11. All relevant exposure pathways are taken into account in the radiological model:

- external irradiation,
- direct ingestion of contamination via a hand-to-mouth pathway,
- inhalation of contamination from resuspension of activity,
- skin dose from transfer of contamination to parts of the human body.

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External y-dose incurred during the reuse of cleared equipment

I-12. In RP 101 it is acknowledged that there may be a large variety of exposure conditions by which a person using for instance a cleared piece of equipment may be exposed. Therefore, an enveloping approach has been taken where a worker is exposed by a large item, in this case a tool cabinet that has a comparatively large overall surface (2 panels (doors and back), 6 shelves, 2 sides; overall dimensions 2 m height, 1 m width, 0.4 m depth, leading to a total surface of 8 m^2). It is assumed that the person using the cabinet is effectively exposed to 4 m^2 which represents the front and back of the cabinet. The exposure time is set to 1800 h/a, representing a full working year.

Dose from inadvertent ingestion incurred during the reuse of cleared equipment

I-13. An inadvertent ingestion dose during the reuse of a cleared item can occur when the contamination is transferred from the item to the mouth via the hands, for example while eating a sandwich or smoking a cigarette. This part of the model has been chosen similar to the one used for derivation of surface-specific clearance levels for recycling. It is conservatively assumed that ingestion takes place during 200 h/a with an ingestion rate of 1.2 cm^2/h and a transfer of 1 % of the surface activity to the hand.

Inhalation dose incurred during the reuse of cleared equipment

I-14. RP 101 points out that basically four types of inhalation scenarios can occur:

- during normal use the surface activity can be shaken lose and re-suspended leading to inhalation of the activity;
- the item can be cleaned or sanded, for example in preparation for a new paint job, leading to re-suspension of the surface activity;
- repair work like welding or thermal cutting can be carried out; and
- at the end of the item's useful life it will almost certainly be scrapped, which means it could be thermally segmented,

of which the last two scenarios are very similar and are therefore treated together.

I-15. The normal-use scenario uses the following assumptions: exposure time 1,800 h/a, fraction of dust in the breathing air originating from the reused item 1 %, ambient dust concentration 0.2 mg/m^3, normal breathing rate 1.2 m^3/h.

Skin dose from the reuse of cleared equipment

I-16. During the reuse of a cleared item the contamination can be transferred to the skin and cause a β-skin dose. This scenario uses the following parameter values: contaminated area of the skin 0.1 m^2,

exposure time 1,800 h/a, factor describing transfer of contamination from the item to the skin: 1%. This scenario converts the skin dose to effective dose by using the weighting factor for the skin as 0.01.

Other scenarios for the derivation of surface-specific clearance levels

I-17. As seen in Figure I-1, RP 101 contains a number of other scenarios that are also used for the derivation of surface-specific clearance levels. These include scenarios for automated scrap processing (mainly for use of automated shear presses, shredders, hammer mills and scrap presses), for which external irradiation and ingestion pathways are analysed, and for manual scrap processing (mainly for manual cutting with thermal techniques), for which scenarios covering all exposure pathways as listed above are included, yet with different parameter values. Manual scrap processing leads to the highest doses per unit activity, since the workers are in direct contact with the contaminated scrap.

I-18. A further analysis of the two most important exposure situations, inhalation from manual processing of scrap and external gamma irradiation from using cleared items, has been performed in RP 101 using dedicated stochastic models. These two exposure situations are deemed critical since they involve prolonged close contact with large quantities of scrap or large items and since the leading radionuclides in typical contamination vectors contain either high energy γ-emitters like ^{60}Co and ^{137}Cs or radionuclides with large inhalation dose coefficients like uranium and plutonium. It is shown in RP 101 that the choice of parameters in the deterministic scenarios has been chosen on the conservative side.

USA: REPORTS NUREG 1640 AND ANSI/HPS N 13.12

I-19. The radiological model chosen in the very comprehensive report NUREG 1640 [I-3] for the derivation of surface-specific clearance levels is different from the one described for RP 101, as NUREG 1640 primarily develops a complex radiological model aiming at deriving mass-specific clearance levels for the reuse, recycling and disposal of iron and steel scrap, scrap aluminium, scrap copper, and concrete rubble. These categories comprise the bulk of components that would be potentially cleared from nuclear or other licensed facilities.

I-20. Surface-specific clearance levels are derived from the mass-specific values by a conversion factor describing the mass-to-surface ratio of the material in question. The most probable values for these conversion factors have been set to 5.1 g/cm² for steel and to 280 g/cm² for concrete. This approximately 50-fold difference is why the clearance of steel or copper scrap yields the highest mean surficial effective dose equivalent or, correspondingly, the lowest surface-specific clearance levels.

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I-21. A similar approach has been used in ANSI/HPS N 13.12 [I-4], where a similar conversion has been performed on the basis of the clearance levels provided in RS-G-1.7. The conversion factor in this case has simply been set to 1 g/cm², so that the values in Bq/cm² are numerically equal to those in Bq/g.

I-22. It should thus be noted that neither NUREG 1640 nor ANSI/HPS N 13.12 contain a genuine model for the derivation of surface-specific clearance levels. Nevertheless, the conversion of mass-specific to surface-specific clearance levels may be a viable approach for cases where a dedicated radiological model for derivation of surface-specific clearance levels would be too challenging.

USA: ARGONNE NATIONAL LABORATORY "SURFACE CLEARANCE CRITERIA FOR WORKERS"

I-23. The document "Potential Dose Distributions at Proposed Surface Radioactivity Clearance Levels Resulting from Occupational Scenarios" [I-5] contains an evaluation of the potential dose distribution resulting from surface radioactivity, using occupational radiation exposure scenarios. The aim was to test a set of surface-specific clearance levels for their compliance with dose limits or constraints for workers.

I-24. Two scenarios were considered in calculating dose distributions for thirteen selected radionuclides, most common in nuclear facilities:

I-25. The first scenario assumes the use of a contaminated building by workers. Two buildings, a large warehouse and a small office, with different building dimensions were analysed. Contamination was assumed to exist on the surfaces of interior floor and inside of the four surrounding walls, with equal levels on all surfaces. A worker inside such a building was assumed to incur radiation doses through (1) external radiation from the floor and interior walls; (2) inhalation of contaminated particles suspended from the contamination on the floor and interior walls; (3) ingestion of deposited dust particles; (4) external radiation from submersion in contaminated air; and (5) external radiation from deposited dust particles.

I-26. The second scenario assumes use of a contaminated desk in an office setting. It was assumed that the top of a writing desk of ordinary size was uniformly contaminated and that the receptor (worker) was sitting at a normal distance from the centre of the desk. A worker was assumed to incur radiation doses through (1) external radiation from the top of the desk; (2) inhalation of contaminated particles suspended from the contamination on the desk; (3) ingestion of deposited dust particles; (4) external radiation from submersion in contaminated air; and (5) external radiation from deposited dust particles.

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I-27. The analysis was carried out assuming statistical distributions for each key parameter value, with a distribution type appropriate for the parameter and limited by reasonable boundaries. The analysis establishes a link between a given contamination on the surfaces and the distribution of resulting dose values, using the mean for the final assessment. As in this case scenarios for workers were analysed, the dose values against which the results were assessed were in the range between 50 and 100 μSv per year. On this basis, the surface-specific clearance levels from which the analysis started were judged to be applicable.

JAPAN: JHPS STANDARDIZATION COMMITTEE - GUIDELINE FOR MOVING OUT COMMODITIES CONTAMINATED WITH RADIOACTIVE MATERIALS IN PLANNED EXPOSURE SITUATION[17]

I-28. With respect to the surface contamination control of commodities, guidelines have been developed by the Standardization Committee on Radiation Protection of Japan Health Physics Society for planned, emergency and existing exposure situations [I-6]. Table I-1 summarizes the main points of the guideline for planned exposure situation. In the Guidelines document the “commodities” are defined as solid-state valuable goods justified for the reuse or recycle when moving out from controlled area (e.g., vehicles, equipment and the other items). In this Annex, the word is replaced by the more pertinent term “object”.

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[17] The term “commodities” is used in the official translation of the document. However, in the context of this Annex the meaning “object” is more appropriate.

TABLE I-1: SUMMARY OF A GUIDELINE FOR MOVING OUT OBJECTS CONTAMINATED WITH RADIOACTIVE MATERIALS IN PLANNED EXPOSURE SITUATION BY STANDARDIZATION COMMITTEE ON RADIATION PROTECTION OF JAPAN HEALTH PHYSICS SOCIETY (extracted from Ref [I-6] with permission).

	Planned Exposure Situation
Dose criteria (effective dose)	Order of 10 μSv/y or less
Referred concept	Clearance
Basic point of view	• Moving out from controlled area to general • Application of the concept of clearance of many relatively small objects moved out
Exposure Scenarios	Handling of small packages [I-7] Handling of general objects [I-8]
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)

I-29. This guideline is assumed to be applied for moving out objects from radiation controlled area. In this case, applicability of the concept of clearance to moving out was examined. In general, there is no control of usage after moving out, and therefore it is similar to the concept of clearance. Clearance concept is based on an assumption of handling large amount of materials such as dismantling waste from a nuclear facility, while moving out objects in planned exposure situation assumes handling of many relatively small objects.

I-30. The surface contamination level of small objects moved out from radiation controlled area were calculated that correspond to the clearance criteria of the order of 10 μSv or less of annual effective dose, on the basis of realistic exposure scenarios. It was also concluded that continuous control of objects moved out is not justified in terms of radiation protection. The applicability of clearance concept for objects moved out in planned exposure situation is demonstrated and included in the guideline.

I-31. Two exposure scenarios are used for derivation of surface contamination levels equivalent to the dose criterion for moving out objects in planned exposure situation. These are handling of small packages [I-7] and handling of general objects [I-8] (includes manually handled objects with 0.1 m^2 area, closely handled objects with 1 m^2 area and remotely handled objects with 10 m^2 area). Considering both scenarios, ^{60}Co and ^{137}Cs surface contamination levels corresponding to the dose criterion of 10 μSv of annual effective dose are calculated to be 10 Bq/cm^2 for both nuclides. These surface contamination levels for ^{60}Co and ^{137}Cs correspond to readings of 1,000 cpm and 2,300 cpm respectively, using a typical GM surface contamination survey meter with 20 cm^2 window based on JIS Z4504 (2008).

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I-32. It should be noted that in the case of especially high energy gamma emitters, such as ^{60}Co and ^{137}Cs, surface contamination levels equivalent to the dose criterion of 10 μSv of annual effective dose significantly depends on the assumption of the size of the contaminated surface. Such high energy gamma emitters sometimes become key nuclides for surface contamination measurements of beta radiation. The contribution of such radionuclides is sufficiently high for surface measurements to be carried out for demonstrating compliance with clearance levels.

I-33. When the daily radiation control at nuclear or radiological facilities involves mostly objects of small size (much smaller than vehicles), applying surface contamination levels derived for clearance of large objects would be too strict and conservative. Separate numerical radiological criteria for surface contamination, used for daily radiation control and clearance, are recommended to be applied according to the dimensions of the surface likely to be contaminated.

UK: NUCLEAR INDUSTRY GUIDE TO CLEARANCE AND RADIOLOGICAL SENTENCING

I-34. The UK Nuclear Industry Guide to Clearance and Radiological Sentencing [I-9] contains a derivation of surface clearance levels for contaminated items in its Appendix F. This Appendix illustrates the calculation of maximum alpha, beta and total activity levels for reuse of metallic equipment from dismantling of nuclear installations. The model given there is a direct reproduction from RP 101 [I-2], leading to the same derived surface-specific clearance levels.

SURFACE DOSE QUANTIFICATION – THE SUDOQU MODEL

I-35. A model for “SUrface DOse QUantification” or SUDOQU [I-9] is currently under development. This model is intended to evaluate the annual effective dose for members of the public resulting from exposure to surface-contaminated objects. Its initial objective thus was to calculate exposure from objects contaminated e.g. from nuclear accidents, taking into account all relevant exposure pathways (external-gamma radiation exposure, inhalation, indirect ingestion and skin contamination through wipe-off).

I-36. Recently, the applicability of this model to calculation of surface-specific clearance levels was evaluated [I-11]. The model calculations were applied to a number of deterministic scenarios for calculating the annual effective dose resulting from exposure to a typical office item, i.e. a bookcase, considering different scenarios of use and different nuclides. The scenarios were then used to calculate surface-specific activity concentrations that would correspond to an annual effective dose of 10 μSv per year.

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I-37. The results of these calculations were then compared with the results of RP 101 [I-2]. Differences were traced to different assumptions in parameters and exposure situations. One of the main differences of both models is the fact that the SUDOQU approach considers reduction of the surface activity with time not only by the radioactive decay, but also by resuspension and wipe-off (transfer of activity to the hands). Likewise, the resuspended activity contributes to the increase in airborne activity concentration and can, in turn, partly re-deposit onto the object surface.

I-38. It was concluded in [I-11] that the suitability of the SUDOQU model for dose assessments related to clearance of objects from nuclear facilities could be demonstrated, but that further development will be needed to develop this model to such a level suitable for calculating surface-specific clearance levels.

REFERENCES TO ANNEX I

[I-1] EUROPEAN COMMISSION, Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations; Series Radiation Protection No. RP 89, Luxemburg, 1998

[I-2] European Commission: Basis for the definition of surface contamination clearance levels for recycling or reuse of metals arising from the dismantling of nuclear installations; Series Radiation Protection No. RP 101, Luxemburg, 1999

[I-3] U.S. Nuclear Regulatory Commission: Radiological Assessments for Clearance of Materials from Nuclear Facilities; Report NUREG 1640; Office of Nuclear Regulatory Research, Washington, 2004

[I-4] American National Standards Institute, Inc.: American National Standard ANSI N 13.12 “Surface and Volume Radioactivity Standards for Clearance”; May 2013; published by the Health Physics Society

[I-5] ARGONNE NATIONAL LABORATORY, Environmental Science Division: Potential Dose Distributions at Proposed Surface Radioactivity Clearance Levels Resulting from Occupational Scenarios; report ANL/EVS/TM/11-3, July 2011

[I-6] JAPANESE STANDARDIZATION COMMITTEE ON RADIATION PROTECTION, Summary of the Three Guidelines for Moving Out of Commodities with Radioactive Contamination in Planned, Emergency and Existing Exposure Situations. Jpn. J. Health Phys., 52, 311-314 (2017). Available at https://www.jstage.jst.go.jp/article/jhps/52/4/52_311/_pdf/-char/ja

[I-7] MUNAKATA, M. Applicable limits on non-fixed surface contamination for safe transport of radioactive materials, Packag. Transp. Storage Secur. Radioact. Mater., 24, 191–206 (2013).

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[I-9] UK Nuclear Industry Safety Directors' Forum: Clearance and Radiological Sentencing: Principles, Process and Practices. V 2.01. UK Nuclear Industry Good Practice Guide. May 2017 http://www.nuclearinst.com/write/MediaUploads/SDF%20documents/CEWG/Clearance_and_Exemption_GPG_2.01.pdf

[I-10] T. VAN DILLEN: SUDOQU: a new dose model to derive criteria for surface contamination of non-food (consumer) goods, containers and conveyances, Radiation Protection Dosimetry, 164 (1 -2) (2015), pp. 160-164

[I-11] F. RUSSO, C. MOMMAERT, T. VAN DILLEN: Clearance of Surface-contaminated Objects from the Controlled Area of a Nuclear Facility: Application of the SUDOQU Methodology, Vol. 53 (2018), Issue 1, January 2018

[I-12] EUROPEAN COMMISSION, Methodology and models used to calculate individual and collective doses from the recycling of metals from the dismantling of nuclear installation; Series Radiation Protection No. RP 117, Luxemburg, 2000

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ANNEX II

EXAMPLES OF SURFACE SPECIFIC VALUES FOR UNCONDITIONAL CLEARANCE

GENERAL

II-1. While no surface-specific clearance levels are provided in GSR Part 3 [II-1], there are a number of international and national recommendations and guidelines containing surface-specific clearance levels. This Annex is limited to examples on surface-specific clearance levels for unconditional clearance, as a comparison of values is only meaningful for radiological models for unconditional clearance. In all cases where the models aim at providing clearance levels for a specific clearance option, too many differences in model assumptions, exposure scenarios and parameter values will exist that preclude a direct comparison of the models.

OVERVIEW OF EXISTING RECOMMENDATIONS AND STUDIES

II-2. This Annex provides a short overview of the following recommendations and studies in which surface-specific clearance levels have been derived. In addition, the IAEA Transport Regulations are addressed, which do not contain clearance levels, but from which surface-related activity values have been frequently misused as clearance levels, in order to point the fundamental differences in the radiological models underlying calculation of exposure from surface contaminations in the case of clearance and in the case of transport.

II-3. A synopsis of the derived surface-specific clearance levels for unconditional clearance is given below.

European Commission: RP 101 and RP 89

II-4. The most comprehensive and pertinent study on surface-specific clearance levels for unconditional clearance is RP 101 [II-2]. This document is a technical support document for the European Commission's recommendation Radiation Protection 89: "Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations" [II-3] and contains a compilation of the methods and parameters used to derive the clearance levels for surface contamination published in RP 89 (while a second technical document deals with the methodology and models used to derive the clearance levels for mass-specific activity concentrations). The surface-specific clearance levels have been derived for metallic material originating from nuclear installations and intended for recycling and

reuse outside the nuclear regime. All calculations are based on an individual effective dose of 10 µSv per year.

II-5. The scenarios have been divided into two major categories: scrap processing and the reuse of cleared items. The scrap processing scenarios have been divided up further into the categories: transport, automated processing and manual processing. The results of the deterministic radionuclide specific dose calculations are presented in tables as µSv per year for a unit surface activity of 1 Bq/cm². To derive the surface contamination clearance levels, the set of deterministic scenarios is used to calculate the nuclide specific contamination level for each scenario which would lead to a dose of 10 µSv per year. The smallest derived value has then been used as the clearance level for the radionuclide in question. In most cases, this value is based on the reuse scenario.

Germany

II-6. The study [II-4] was conducted in the course of the preparation of a new version of the German Radiation Protection Ordinance in 1998 and 1999. Much of this work was carried out in parallel to the study RP 101 [II-2] presented in section 0 above, so that many of the scenarios are similar. The main aim of the study [II-4] was to derive surface-specific clearance levels for unconditional clearance, so that only one set of clearance levels has been provided, so that reuse and recycling are both fully covered. This makes the surface-specific clearance levels applicable also for unconditional clearance.

United Kingdom

II-7. A Guide on good practice concerning clearance and radiological sentencing [II-5] provides guidance on the principles, processes and practices that should be used when determining whether an article or material may be released from any further controls on the basis of radiological protection considerations. It identifies approaches to segregate radioactive or potentially radioactive substances and articles from substances and articles that are ‘out of scope’ of radiation protection considerations. This document does not derive surface-specific clearance levels itself, but makes reference to document RP 101 [II-2]. The surface-specific clearance levels provided in [II-2] are discussed in the Guide [II-5] for application in clearance of objects with surface contamination.

USA

II-8. A very comprehensive study on clearance of metal scrap carried out in the USA has been published as report NUREG-1640 [II-6]. In this report mass-specific and surface-specific clearance levels have been derived for metal scrap. This report provides a description of calculations and their results

estimating potential annual doses, normalized to a unit concentration, to an individual following the clearance of specific materials. These materials are scrap iron and steel, copper, aluminium, and concrete rubble from licensed nuclear facilities. The estimated potential doses are calculated probabilistically to account for a large number of possible variations in each of the 86 scenarios. These scenarios encompass the full range of realistic situations likely to yield the greatest normalized doses. Each scenario was analysed with the 115 radionuclides considered most likely to be associated with materials from licensed nuclear facilities. The design basis of the analyses is to realistically model current processes, to identify critical groups on a nuclide-by-nuclide basis, and to enable the conversion of a dose criterion to a concentration.

II-9. Normalized surficial effective doses to critical groups are provided for the various recycling and reuse scenario for each material stream, given in µSv per year per Bq/cm². Surface-specific clearance levels can be calculated by dividing the dose criterion 10 µSv per year by these values.

Sweden

II-10. The safety guide of the Swedish Radiation Safety Authority [II-7] covers guidance on clearance of materials, building structures and land areas for practices with ionising radiation. It contains surface-specific clearance levels for unconditional clearance of materials. It also contains surface-specific clearance levels for clearance of buildings for reuse or demolition, taken directly from the Guide RP 113 [II-8].

IAEA Transport Regulations: SSR-6 (Rev. 1)

II-11. The IAEA Safety Standards Series No SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material 2018 Edition [II-9] contain surface-related values of 0.4 Bq/cm² for beta and gamma emitters and low toxicity alpha emitters and 0.04 Bq/cm² for all other alpha emitters in the definition of contamination (for fixed and non-fixed contamination) as well as values of 4 Bq/cm² and 0.4 Bq/cm², respectively, for the limit of surface contaminated objects (SCO-I) and surface contamination on packages and conveyances, relating to the non-fixed contamination only. These limits are applicable when averaged over any area of 300 cm² of any part of the surface.

II-12. These values have been derived in 1961 [II-10] using a very simple model [II-11], i.e. more than half a century ago, with adjustments in the transition from Ci to Bq and appropriate rounding applied. A review of this model together with proposal of new modelling approaches for limiting the surface contamination on packages and conveyances in transport has been given in [II-11] and [II-13]. The following assessment of the Fairbairn model was provided in [II-12]:

"The Fairbairn model limits its consideration to inhalation of airborne contamination and transfer of contamination to the hands under a specified set of exposure scenarios. The permissible levels of contamination are constrained so as not to result in an airborne concentration greater than the maximum permissible concentration in air (MPCa) specified in the 1959 recommendations of the International Commission on Radiological Protection (ICRP). These levels should also constrain the dose to contaminated hands to what was considered to be good-practice in the 1960s. These constraints were applied to the alpha- and beta-emitting radionuclides then considered the most hazardous, ^{239}Pu and ^{90}Sr respectively, giving the limits noted above.

Since these limits were derived there have been a number of changes in radiation protection philosophy and dosimetry, mainly as a result of the recommendations of the International Commission on Radiological Protection. These include changes in the dose coefficients for inhalation of radionuclides and a change in the specification of the annual dose limit for workers. Also, during the period since the contamination limits were derived much experience has been gained in their use, and in contemporary transport operations. These developments have created the conditions in which a review of these limits is required.

Some inherent limitations of the Fairbairn model have also been recognised. For example, the limited range of radionuclides and exposure pathways considered, the high occupancy times assumed, uncertainties in the resuspension mechanism, out-dated dose coefficients and dose criteria, and the fact that the possible exposure of members of the public were not considered."

II-13. The limit values derived in 1961 [II-10] are therefore not applicable to clearance.

SYNOPSIS OF SURFACE-SPECIFIC CLEARANCE LEVELS

II-14. The studies and recommendations discussed above contain the surface-specific clearance levels given in TABLE II-1. This table contains only those clearance levels that refer to a clearance option which can be reasonably identified with unconditional clearance, i.e. these values are not clearance levels for buildings or land. All surface-specific clearance levels given in this table have been derived on the basis of an individual effective dose of 10 µSv per year.

II-15. The comparison shows that for strong gamma emitters like ^{60}Co, ^{137}Cs or ^{154}Eu as well as for alpha emitters like ^{242}Pu and ^{241}Am, there is generally good agreement, indicating that the model assumptions for external irradiation (gamma emitters) as well as those for inhalation of resuspended surface contamination (alpha emitters) are based on similar assumptions.

II-16. Agreement of the values for strong beta emitters like ^{90}Sr can also be considered to be fairly good, indicating that ingestion pathways (direct and secondary ingestion) are generally based on similar assumptions.

II-17. The values for weak beta emitters and electron capture emitters like ^{3}H, ^{14}C, ^{36}Cl and ^{55}Fe, differ more significantly, indicating that the scenarios in the assessment underlying the derivation of these surface-specific clearance levels are significantly different with respect to assumptions on secondary ingestion pathways, skin contamination and other scenarios.

TABLE II-1: OVERVIEW OF SURFACE-SPECIFIC CLEARANCE LEVELS FOR UNCONDITIONAL CLEARANCE FROM THE STUDIES DISCUSSED IN THE ANNEX II

Radionuclide	RP 101 MIN [Bq/cm²]		German StrlSchV [Bq/cm²]	NUREG 1640 – [Bq/cm²] based on the:	
	unrounded	rounded	rounded	Mean	95th percentile
H-3	25,000	10,000	100	1,500	700
C-14	770	1,000	100	1,600	1,100
Cl-36	130	100	100	29	7
Fe-55	1,500	1,000	100	110,000	30,000
Co-60	1	1	1	1	0.3
Sr-90	8.5	10	1	83	34
Cs-137	3.7	10	1	3.1	1.0
Eu-154	1.8	1	1	2.3	0.6
U-234	0.49	1	1	3.7	1.2
Pu-242	0.11	0.1	0.1	1.6	0.5
Am-241	0.12	0.1	0.1	1.1	0.3

REFERENCES TO ANNEX II

[II-1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

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[II-5] UK Nuclear Industry Safety Directors Forum: The UK's Nuclear Industry Guide to Clearance and Radiological Sentencing: Principles, Process and Practices; May 2017

[II-6] U.S. Nuclear Regulatory Commission: Radiological Assessments for Clearance of Equipment and Materials from Nuclear Facilities. - NUREG-1640, Washington D.C., June 2003

[II-7] Swedish Radiation Safety Authority: The Swedish Radiation Safety Authority's regulations concerning clearance of materials, building structures and land areas for practices with ionising radiation; Stockholm, 2018

[II-8] EUROPEAN COMMISSION, Recommended radiological protection criteria for the clearance of buildings and building rubble from the dismantling of nuclear installations, Radiation Protection No. 113, Luxemburg, 2000, ISBN 92-828-9172-0

[II-9] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

[II-10] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Materials, Safety Series No. 6, IAEA, Vienna (1961).

[II-11] A. Fairbairn: The Derivation of Maximum Permissible Levels of Radioactive Surface Contamination of Transport Containers and Vehicles, p.79 ff., part of "Notes on Certain Aspects of the Regulations", Safety Series No 7, IAEA, Vienna, 1961

[II-12] Hughes, J.S. et al.: A Model to Determine the Radiological Implications of Non-fixed Radioactive Contamination on the Surfaces of Packages and Conveyances; 14th International Symposium on the Packaging and Transportation of Radioactive Materials (PATRAM 2004), Berlin, Germany, September 20-24, 2004

[II-13] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological aspects of non-fixed contamination of packages and conveyances, IAEA-TECDOC-1449, IAEA, Vienna (2005).

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ANNEX III

EXAMPLES OF MASS SPECIFIC VALUES FOR CONDITIONAL CLEARANCE

III-1. Examples of conditional clearance levels that have been derived in Member States are: scrap metal for melting (EC RP 89 [III-1] for activity concentration per unit mass and EC RP 101 [III-2] for activity concentration per unit surface area), and conditional clearance levels for buildings for demolition or reuse (EC RP 113 [III-3] and EC RP 114 [III-4]). Conditional clearance levels for disposal of wastes in landfill sites have been adopted in Germany [III-5] and in the UK (for small volumes of very low level waste VLLW).

Example from United Kingdom

III-2. In the UK, this conditional clearance is called conditional exemption (for reasons of continuity with old UK terminology) and the conditions relating to conditional clearance of VLLW for disposal are given Table III.1.

TABLE III-1. UK CONDITIONAL CLEARANCE OF VLLW FOR DISPOSAL IN LANDFILL SITES [III-6]

Radioactive waste	**Maximum concentration of radionuclides**	**Maximum quantity of waste to be disposed of per calendar year**
Solid radioactive waste, with no single item >$4x10^4$ Bq	$4x10^5$ Bq for the sum of all radionuclides per 0.1 m^3	2 x 10^8 Bq/a
Solid radioactive waste containing tritium and C-14 only, with no single item >$4x10^5$ Bq	$4x10^6$ Bq of tritium and C-14 per 0.1 m^3	2 x 10^9 Bq/a

Example from Belgium

Introduction

III-3. FBFC International is a nuclear facility situated in Dessel, Belgium. From 1960 until 2012, it produced fuel assemblies of uranium for NPPs. In October 2011, it was decided to shut down the installation for economic reasons.

III-4. During operation, water was used in contaminated zones as part of the production process and for personnel utilities (washrooms). This contaminated water circulated through underground pipes to be collected in the water treatment building, where it was treated before discharge in the environment. During operation a reduction of the discharge limit happened due to regulatory change (the discharge limits were never exceeded).

III-5. An initial decommissioning survey identified several leaks in the underground network (mostly at the level of joints between pipes) resulting in deposition of small amounts of uranium in the soil (mainly sand). In addition, slightly contaminated sand was found in canals outside the facility site due to sedimentation. This sand was brought on-site and was part of the contaminated soil to be evacuated. The total volume was estimated at 8300 m^3 and about 12000 ton.

III-6. For unconditional clearance of soil, a level of 1Bq/g for U_{tot} is accepted by the Belgian nuclear regulator (Federal Agency for Nuclear Control - FANC). The soil samples showed levels slightly above this concentration.

III-7. According to the Belgian regulation, conditional clearance is possible based on a licence from the regulator. In his license application, the authorized party has to propose a conditional clearance level below the exemption level and include a radiological impact study demonstrating that the individual dose criterion of the order of 10 µSv per year is not exceeded and that the collective dose stays below 1man.Sv per year.

III-8. The authorized party decided to apply for a conditional clearance license and to radiologically sort the sand in 3 categories, with final destination based on the activity concentration:

- < 1Bq/g : unconditional clearance
- 1Bq/g to 10 Bq/g : disposal in conventional landfill
- > 10 Bq/g : radioactive waste to NIRAS/ONDRAF[18]

<u>Impact study for disposal in conventional landfill</u>

III-9. The selected landfill site for disposal of the uranium contaminated soil is situated in the province of Antwerp and is destined for hazardous waste. It also accepts NORM-waste. Specific zones of the disposal will be used for the low-level contaminated soil of FBFC.

[18] Belgian Waste Management Agency

III-10. The impact study [III-7] considered the exposure scenarios for handling 8300 m^3 of soil as a worst case, assuming a contamination level of 10 Bq/g U_{tot}. The expected volume is lower.

III-11. The results are summarized in the table below for non-radiological workers who might be affected by the conditional clearance process.

TABLE III-2. RESULTS OF THE IMPACT STUDY FOR DISPOSAL IN CONVENTIONAL LANDFILL [III-7]

Non-radiological workers	**Type of exposure**	**Annual dose (µSv)**
Transporter (driver) of soil	External	1.5
	Inhalation	Negligible
	Ingestion	Negligible
	Total	**1.5**
Worker on landfill during unloading	External	7.3
	Inhalation	7.4
	Ingestion	0.2
	Total	**14.9**
Worker on landfill during disposal	External	3.3
	Inhalation	1.6
	Ingestion	0.1
	Total	**5.0**
Other worker on landfill	External	2.8
	Inhalation	Negligible
	Ingestion	Negligible
	Total	**2.8**

III-12. The Table III-2 shows that the most exposed worker will be the worker involved in the unloading of the sand on the landfill site. It is assumed that the considered workers perform only one of the listed tasks and that the job of unloading would be shared by 2 workers. Therefore, it was concluded that an activity concentration level of 10 Bq U_{tot}/g of soil will not give an individual annual effective dose in excess of 10 µSv to any non-radiological worker.

III-13. A similar analysis was performed for members of the public for all age categories, living in the vicinity of the landfill, cultivating a garden and walking on the landfill, leading to a similar conclusion.

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III-14. In addition, a dose calculation was performed to estimate the impact of on-site sorting of sand on involved workers. The result was also found to be below 10 µSv per year, if workers use protective equipment typical for such works. Nevertheless, these workers are considered as occupationally exposed workers by the authorized party.

III-15. On the basis of this study, a licence for conditional clearance up to activity concentration levels of 10 Bq U_{tot}/g of sand was granted to FBFC by the FANC for removal of a maximum of 12450 ton of waste to a conventional landfill for hazardous waste.

III-16. Since the activity concentration stays below 10 Bq U_{tot}/g, no transport license for evacuation to the landfill site is required.

Traceability of the conditionally cleared soil

III-17. The information about the amount and the location of the cleared soil will be preserved by means of 2 sets of documents per transported container:

- Departure document by the nuclear operator containing: Container ID, Type and amount of packages, Radionuclide and Activity content, Total mass, Date of pick-up.
- Reception document by the landfill operator containing: Container ID, time of delivery, total mass, location on site.

The documents have to be kept by the operator during 30 years. At license termination, the documents are transferred to the FANC.

Example from Germany

III-18. Clearance levels for clearance of material to be disposed of as waste on landfills or for incineration in waste incinerator plants have been derived in Germany by the German Commission on Radiation Protection on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in 2006. The values are provided in Ref. [III-5] and have been taken over into the German Radiation Protection Ordinance in 2011. The clearance is meant for normal landfill disposal sites and for normal waste incineration plants that are also used for ordinary refuse, i.e. no landfills or incineration plants with a radiation protection licence of any kind.

III-19. These clearance levels have been derived on the basis of a complex radiological model that takes into account all relevant exposure situations and exposure pathways from the point of clearance until the material reaches its final destination, i.e. emplacement in the landfill site or burning in the waste incineration plant. The structure of this model is shown in Figure III-1.

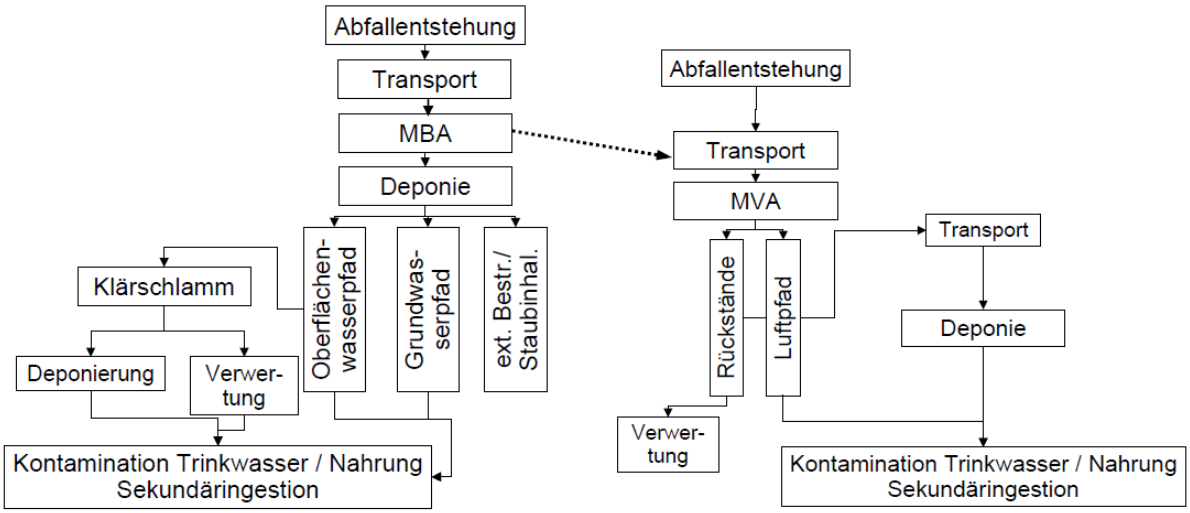

Figure III-1. Radiological model used in Germany for calculation of clearance levels for disposed on landfills and for incineration [III-5] (will be replaced by English version)

III-20. The model took into account scenarios both for the personnel transporting the material to the landfill site or the waste incineration plant, the material in both types of facilities and the general public. Scenarios describing gradual release of radionuclides via environmental pathways and subsequent entering into the human food chain include airborne dusts and their deposition on ground, leaching of radionuclides from the waste by precipitation to surface waters and after a few 100 years to groundwater and use of the water for drinking, irrigation and preparation of food stuff.

III-21. The model distinguishes between “small” quantities, i.e. up to 100 Mg per year and landfill or incineration facility and “large” quantities, i.e. up to 1,000 Mg per year. In this way, smaller waste producers like medical, research or industrial facilities could be treated differently from large producers like nuclear power plants in decommissioning.

III-22. Clearance levels were derived for a large number of radionuclides. Examples are given for Co-60, Sr-90 and Cs-137 in the Table III-3.

TABLE III-3. EXAMPLE OF CLEARANCE LEVELS FOR CONDITIONAL CLEARANCE IN GERMANY

	Clearance for landfill disposal		Clearance of incineration	
Radionuclide	up to 100 Mg/a	up to 1,000 Mg/a	up to 100 Mg/a	up to 1,000 Mg/a
Co-60	6 Bq/g	2 Bq/g	7 Bq/g	2 Bq/g
Sr-90	6 Bq/g	0.6 Bq/g	40 Bq/g	4 Bq/g
Cs-137	9 Bq/g	3 Bq/g	9 Bq/g	1 Bq/g

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These values are applied at several landfills and incineration plants. Their use requires the execution of the normal administrative procedure for waste disposal under the jurisdiction of the waste authorities in addition to the clearance process under the jurisdiction of the radiation protection authorities.

Example from new IAEA publication on disposal of waste in landfill sites

III-23. IAEA is preparing a publication on disposal of wastes in landfill sites [III-8]. The information provided in this document will enable Member States to derive conditional clearance levels for disposal in a landfill site that are relevant to their situation (e.g. climate and rainfall).

III-24. The study was triggered by the Fukushima Daiichi accident, where large amounts of solid materials with a low level of radioactivity had to be disposed of in the remediation phase. Large amounts of solid materials with a low level of radioactivity are also encountered in decommissioning projects. The study started therefore with a focus on specific clearance of waste into landfills.

III-25. For the purpose of the study, a new tool, called "Clearance Tool" was developed for derivation of specific Clearance Levels (CLs) for different types of landfills and ultimately also for reuse and recycling of materials from decommissioning projects. The dose criteria and scenarios for derivation of these clearance levels are based on IAEA SR44 [III-9] and GSR Part 3 [III-10], namely 10 µSv per year for realistic scenarios and 1mSv per year for low probability scenarios.

III-26. The derivation of the conditional clearance levels focuses on radionuclides that are potentially relevant for accidental releases from nuclear power plants and takes into account the following 10 radionuclides: ^{90}Sr, ^{99}Tc, ^{106}Ru, ^{131}I, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{239}Pu, ^{241}Pu, ^{241}Am.

III-27. A basic set of exposure scenarios covers the situation where the materials are disposed on an ordinary landfill without any special radiation protection arrangements. They take into consideration exposure of workers that may arise from transportation of the material to the site, the handling of the material at the landfill and releases of radionuclides to the atmosphere in case of a landfill fire. Also, exposures of residents living close to the landfill are considered.

III-28. For the post-operational phase, a scenario with recreational use of the previous landfill, including the possibility of small excavations being performed in the landfill. In addition, an intrusion scenario is considered for estimating doses arising in case residential houses were to be built on the landfill. For this scenario, only the exposure of people living in this house are considered because these will be because of longer exposure duration and additional exposure pathways (ingestion of contaminated garden products) substantially higher than exposures of construction workers building the house.

III-29. Furthermore, the consequences of the controlled and uncontrolled release of leachates to groundwater and surface water are considered.

III-30. The model considers three generic landfill types:

- Landfill for inert waste (IWL)
- Landfill for municipal non-hazardous waste (MWL)
- Landfill for hazardous waste (HWL)

III-31. The different landfills types are assumed to have different properties concerning bottom liner, leachate collection system and top cover.

III-32. The life time of the landfill is divided into two phases, namely the operational phase and the post-operational phase, where a distinction is made between the period during and after institutional control.

III-33. In addition, the developed calculation tool [III-11] may be used to calculate conditional clearance levels that take account of specific site features.

III-34. Applying the clearance dose criteria described in section 2, conditional clearance levels for disposal of solid radioactive waste to landfill were derived.

III-35. The scenario in which a resident is living on the closed landfill after closure and after end of institutional control was treated as an unlikely scenario. Therefore, for this scenario the 1 mSv per year criterion is used.

III-36. Both deterministic and probabilistic calculations have been performed. The deterministic results are shown in the Table III-4 for the 10 radionuclides and for the 3 types of landfill. The results are not yet finalized.

TABLE III-4. RESULTS OF DETERMINISTIC CALCULATIONS OF ACTIVITY LEVELS ALLOWING DISPOSAL OF WASTE IN CONVENTIONAL LANDFILLS [III-8]

Radionuclide	Clearance level (GSR part 3) [Bq/g]	Activity level allowing disposal on landfills [Bq/g] (Deterministic calculation)		
		IWL	MWL	HWL
Sr-90	1	1.1	2	8
Tc-99	1	0.5	0.5	0.9
Ru-106	0.1	6	6	6
I-131	10	20	20	20
Cs-134	0.1	0.4	0.4	0.4
Cs-137	0.1	1	1	0.8

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Ce-144	10	20	20	20
Pu-239	0.1	1.2	1.2	1.2
Pu-241	10	30	30	30
Am-241	0.1	1.4	1.4	12

III-37. The parameter values used in this calculation for food ingestion have been updated according to the latest IAEA publication on this subject [III-12].

III-38. These results have not applied the order-of-magnitude rounding used in SR-44 whereby, for example, a clearance level of 0.5 Bq/g was rounded to a clearance level of 1 Bq/g.

Example on clearance of liquids

III-39. In the framework of a regulatory initiative, the Health Protection Agency of the UK conducted two studies on clearance levels for liquids. Distinction was made between aqueous and non-aqueous liquids.

III-40. The study on non-aqueous liquids [III-13] (HPA-CRCE-006, 2010) demonstrates that the clearance levels for solids as recommended in RP122 part 1 are suitable for use for unconditional clearance of non-aqueous liquids for a majority of radionuclides. Some exceptions are ^{32}P, ^{33}P, ^{35}S, ^{65}Zn and ^{99}Tc. For these radionuclides it may be necessary to proceed to conditional clearance by e.g. restricting the activity concentration or applying disposal constraints. Guidance is given in the referenced study.

III-41. A similar study performed for aqueous liquids [III-14] (HPA-CRCE-005, 2010) and based on a dose criterion of 10µSv per year gives clearance values ranging from 10^{-4} Bq/l to 10^{3}Bq/l, 80% of them laying between 0.01 Bq/l and 1Bq/l. HPA recommends that the volume of these liquids at these levels that can be disposed of to a sewer is restricted to 3000 m^3/a. At the same time, HPA illustrates in this report the difficulty of measurement of these clearance levels for some radionuclides under laboratory conditions.

REFERENCES TO ANNEX III

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[III-13] HPA-CRCE-006: Investigation of Possible Exemption or Exclusion Levels for Non-Aqueous Liquids to Support the RSA93 Exemption Order Review, Public Health England, 2010.

[III-14] HPA-CRCE-005: Derivation of Liquid Exclusion or Exemption Levels to Support the RSA93 Exemption Order Review, Public Health England, 2010.

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ANNEX IV

EXAMPLE OF THE APPLICATION OF THE CLEARANCE CONCEPT IN SMALL MEDICAL FACILITIES[19]

INTRODUCTION

IV-1. Certain facilities conducting practices with unsealed or sealed radiation sources use different amounts of radionuclides with short and very short half-lives (less than 100 days). Examples of such facilities are small research laboratories, medical departments and facilities for industrial applications where radiation sources with those characteristics are used, processed or stored. These facilities may be identified with the term 'small medical, industrial and research facilities'[20]. The amount of activity of the radionuclides used in such small facilities varies according to the practice under development. For example, for medical purposes, the activity used can vary from less than 1 MBq up to 100 GBq depending if it is for medical research, clinical therapy or diagnostic. Information on unsealed sources and sealed sources and their range of activity per practice can be found in several IAEA's documents [IV–1, IV–2].

IV-2. In such small facilities and activities, moderate amounts of radioactive waste[21] are generated, requiring an adequate management in order to guarantee the radiological protection of people[22] and the environment. With the proper methodology, the best option for management of a significant volume of these radioactive wastes could be clearance.

SCOPE

IV-3. The small facilities considered in this Annex are those which, due to the simplicity of the practices from the radiological perspective, have standardized procedures for the safe use of the radioactive sources. A standardized methodology for the clearance of radioactive material within those practices would be a useful recommendation to facilitate the safe management of the radioactive waste

[19] This Annex is based on the Practical Guide of the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO), developed through a FORO project on Implementation of the Clearance Concept and Criteria for Small Nuclear Installations Handling Radioactive Waste. The project was implemented under the IAEA's extrabudgetary programme on nuclear and radiation safety and security in Ibero-America. The Practical Guide entitled "Guía práctica para la implementación de la dispensa en instalaciones radiactivas" is available at www.foroiberam.org.

[20] See, for example, Decommissioning of Small Medical, Industrial and Research Facilities, Technical Reports Series No. 414 and Decommissioning of Research Reactors and Other Small Facilities by Making Optimal Use of Available Resources Technical Reports Series No. 463

[21] By moderate amounts of wastes, moderate quantity means less than 3 tons per year and per facility [IV–3].

[22] The term 'people' may refer to occupationally exposed workers, workers in general and members of the public.

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by the authorized parties and, at the same time, to smooth the regulatory control process, including the records, regulatory inspections and verification of compliance with the relevant standards and regulations.

IV-4. The present Annex describe, as an example, a methodology applicable for the solid radioactive waste in a nuclear medicine department. This example of a methodology could assist authorized parties and regulatory bodies to protect people and the environment effectively and efficiently by using the concept of clearance in a practical way. Solid radioactive waste in a medical department is generated in the form of paper and plastic, contaminated materials, discarded radiopharmaceutical containers, bandages, protective clothing, plastic sheets and bags, gloves, masks, filters, overshoes, paper wipes, towels, metal and glass, hand tools and discarded or contaminated equipment [IV–1].

IV-5. Liquid radioactive waste generated in a nuclear medicine department, that includes contaminated water and effluent, waste arising from chemical processing and decontamination solutions, blood or body fluids, discarded liquid radiopharmaceuticals, wound or oral discharges, and urine [IV–1], needs a special consideration by the treatment systems in the facility, making difficult to provide a general example. For this reason, it is not discussed in detail in this Annex, but some considerations are presented at the end.

CASE STUDY

IV-6. Considering a nuclear medicine department that has authorization of practices using the following 2 techniques:

- Gammagraphy studies for diagnostic and follow-up with Technetium-99m;
- Thyroid function tests and treating thyroid cancer with Iodine-131.

IV-7. The maximum activity of each radionuclide as well as the number of patients per week authorized in the facility for these practices is shown in Table IV–1[23].

IV-8. In a nuclear medicine department that provides the above-mentioned treatment and diagnosis techniques, radioactive solid waste is generated, needing adequate management to guarantee radiological protection of the workers, public and environment.

IV-9. The following is a non-exhaustive list of the types of solid radioactive waste that may occur as a result from the use of radionuclides, such as Technetium-99, and Iodine-131 [IV–2]:

- Solid compactable waste (papers, cottons, chiffon gloves);

[23] This example is taken from a real nuclear medicine department. All information presented in the tables are based on real case.

- Metals (syringe needles);
- Glass (vials).

TABLE IV–1. MAXIMUM ACTIVITIES AND NUMBER OF PATIENTS FOR THE PRACTICES WITHIN THE EXAMPLE

Practice	Radionuclide	Half-life	Type of emitter	Patient per week	Maximum activity per week
Diagnostic	Mo–Tc-99m Generator	6.03 hours	gamma	70	40 GBq
Diagnostic and Therapy	I-131	8.04 days	gamma	45	74 GBq

Methodology for the clearance of waste in small facilities and activities

IV-10. The practical methodology presented in this Annex for the clearance of waste arising in small facilities and activities consists on the following main steps:

1. Segregation and collection;
2. Measurement/estimation of the activity in the waste;
3. Management options (storage, decay, clearance, disposal);
4. Reports.

STEP 1: Collection and Segregation

IV-11. Appropriate collection and segregation of the remnant radioactive material is a very important step of the methodology, and it is required in order to minimize waste hazards and to facilitate subsequent management of waste. A recommended procedure is that the waste collection and segregation is performed at the time and place where it is generated. This process would be done according to the type of radionuclide, its half-life, physical and chemical form, and other properties of the wastes such as pathogenic or physical hazards (stabbing).

IV-12. In contrast to other nuclear applications, the use of radionuclides in small facilities and activities usually involves only one radionuclide being used per medical procedure. This makes segregation of waste by individual radionuclides feasible [IV–1].

IV-13. In some cases, it may be convenient to segregate wastes according to their half-life, e.g. wastes with a half-life of about 10 hours or less, wastes with a half-life of less than 10 days, and wastes with a half-life of less than 100 days.

IV-14. In other cases, the solid wastes can be segregated depending on their physical characteristic such as compactible, non-compactible, incinerable, non-incinerable. It is important to remark that the bags and the containers used to collect wastes would not be over-filled such that their integrity is compromised.

IV-15. To assure an adequate collection and segregation, the nuclear medicine department needs to be provided with containers and bags with the corresponding labelling. For further information on segregation and labelling of wastes in nuclear medicine department it is recommended to refer to Ref. IV-1.

STEP 2: Measurement or estimation of activity concentration of the wastes

IV-16. The proposed methodology in this Annex to measure or estimate the activity concentration of the solid wastes in a nuclear medicine department is practical and simple. However, it is considered appropriate for the purposes of clearance in this type of small facilities, due to the low activities and the short lives involved[24]. By using this methodology, it is valid to assume that the risks of exposure to workers, public and environment is very low, particularly if the simple practice is conducted systematically and with adequate precaution.

IV-17. Once the waste is adequately segregated and collected as explained in Step 1, it is important to carry out its radiological characterization to determine the initial activity concentration or total activity for each waste stream generated in the practice under consideration.

IV-18. A standardized process for the measurement of initial activity concentration or initial total activity in the wastes is difficult to define, due to existence of a wide variety of containers with different geometries and materials properties in different medical departments. Consequently, each facility or activity needs to establish a measurement procedure according to their recipients or containers used for the practice and considering the technical properties of the devices employed to perform the measurement.

IV-19. It is important to emphasize that, due to the characteristics of medical applications, the activity and radionuclides involved in each medical practice, as well as the total activity authorized, is known with precision. Hence, the remnant activity in the waste could be estimated by mean of a simple balance of activity and the corrections for decay, in correspondence with the characteristics of the practice and the time frame involved.

IV-20. It is a responsibility of each nuclear medicine department to establish a simple and practical method to estimate the activity of the wastes, and to consider the existence of shielding factors that could affect the result of the measurements and make the appropriate corrections.

[24] Measurements or estimations of the activity within this type of facilities and activities is more a matter of confirmation of the inexistence of risk and a reassurance.

IV-21. The methods for initial activity measurement or estimation in the wastes differ depending if the wastes were originated from liquid or solid radioactive material. For example, for solid wastes which will result from the remaining liquids, after they dry, the measurement of activity is done directly on a radionuclide calibrator. For solids wastes generated as a consequence of patients' treatment (papers, cottons, chiffon gloves), the method to estimate the activity on the waste bags could be done by simple measuring the dose rate or counts rate at a certain distance.

IV-22. The methodology proposed to perform a simple and gross estimation of the activity concentration is described for solid wastes in the next paragraphs. In addition, the activity concentration of the wastes originated in the nuclear medicine department, are also calculated to show how to apply the proposed methodology.

IV-23. In case of solid waste disposed in containers, it is recommended to perform the measurements related to each container at the time in which the container/recipient/bag is shut, usually when the remnant activity is the highest. This would allow an adequate labeling of each container indicating activity, date and its transfer to the storage room. In order to ensure representativeness, it is recommended to take several measurements in connection with each container/bag and use the most conservative (i.e. the maximum measured value) for the subsequent calculations, described below.

IV-24. Depending on the involved radionuclides, the measurement of the activity in the wastes can be done by counting on a detector for beta emitters or by measuring the gamma dose rate at a certain distance.

IV-25. For practical reasons, it can be assumed that the container/recipient behaves like a point source, and the measurement is done as if there was no shielding, as shown in Figure IV–1:

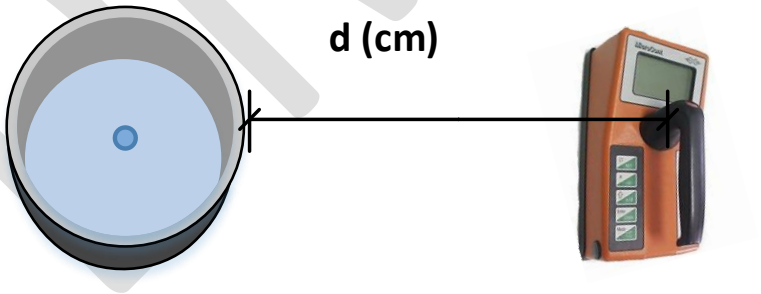

Figure IV–1. Geometry of the measurement. Reproduced courtesy of FORO [IV–4].

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Estimation of the activity concentration from the measurement of the counts rate in the waste bag/containers[25]

IV-26. Taking into account the distance between the source and the detector, the activity concentration of the wastes could be estimated using the expression (V–1) [IV–5]:

$$C_A = \frac{N \cdot 4 \cdot \pi \cdot d^2 \cdot Fc}{A_D \cdot \varepsilon \cdot M_B} \quad \text{(IV–1)}$$

where C_A is activity concentration on the waste (Bq/g), N is measurement of the counts on the detector minus the background (cps), ε is efficiency of the detector (0 – 1), A_D is area of the detector (m^2), d is distance between the surface of the waste bag and the detector (m), M_B is waste bag weight (g) and Fc is correction factor[26] (equal to 2).

IV-27. For beta emitters radionuclides, the bag used for the wastes would be of a lower thickness of the one used for collecting gamma emitters so as to decrease the absorption of the beta particles at the time of the measurement. It is recommended to take several measurements near the surface of the bag, at a distance of ~5cm, and use the most conservative one (i.e. the highest measured value).

Estimation of the activity concentration from the measurement of the dose rate in the waste bag or container[27]

IV-28. The activity concentration could be estimated by measuring the dose rate of the waste bag or container, using the expression (IV–2).

$$C_A = \frac{\dot{D} \cdot d^2 \cdot Fc}{\Gamma \cdot M_B} \quad \text{(IV–2)}$$

where C_A is Activity Concentration of the waste (Bq/g), $\dot{D}$ is Dose rate at the distance d, minus the background dose rate (mSv/h), d is distance between the surface of the bag and the detector (m), Γ is specific gamma constant for the radionuclide (mSv m^2/h Bq), M_B is waste bag weight (g) and Fc is correction factor (equal to 2).

[25] This expression applies for beta and gamma emitters.

[26] The empirical correction factor is to considers geometry and autoabsorption effects

[27] This expression only applies for gamma emitters.

IV-29. The distance between the bag or the container and the detector recommended for gamma emitters is ~30 cm.

IV-30. In both cases, Fc would be applied in order to compensate the fact that, for practical reasons, the source is assumed to be a punctual source. Empirical studies [IV-4] show that if the measured activity is multiplied by a factor of 2, the correction factor can be assumed as adequate.

IV-31. For illustration purposes, examples of the measured dose rate in each radioactive solid waste stream in a nuclear medicine department is presented in Table IV–2.

TABLE IV–2. EXAMPLE OF RESULTS OF MEASUREMENT OF DOSE RATES OF THE SOLID WASTES IN A NUCLEAR MEDICINE DEPARTMENT

Radionuclide	Waste bag	Waste type	T ½ (days)	Weight (g)	Dose rate to 30 cm (mSv/h)
Tc-99m	1223	Gloves, paper, cotton	0.25	3000	0.05
	1224	Vials, syringes (without needles)	0.25	2500	0.09
I-131	3220	Gloves, paper, cotton	8.04	2500	0.045
	3221	Vials, syringes (without needles)	8.04	3250	0.062

IV-32. Using the expression (IV–2), the activity concentration for each waste stream is estimated and shown in Table IV–3.

TABLE IV–3. CALCULATION OF ACTIVITY CONCENTRATION OF SOLID WASTE

Waste bag	Radionuclide	$\mathbb{\Gamma}$ (mSv m^2/h Bq)	Activity concentration (KBq/g)
1223	Tc-99m	3.317E-11	90.4
1224	Tc-99m	3.317E-11	195.3
3220	I-131	7.64E-11	42.4
3221	I-131	7.64E-11	44.9

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IV-33. Taking into consideration the activity concentration values obtained by using the expression (IV–2), and the clearance levels for the radionuclides involved, the most adequate waste management option for these wastes can be defined according to the Fig. IV–2: Management Options.

STEP 3: Management options and storage decay time

IV-34. As mentioned before, once the measurement or estimation of the activity concentration of the waste has been done, the management options needs to be chosen taking into consideration the Figure IV-2.

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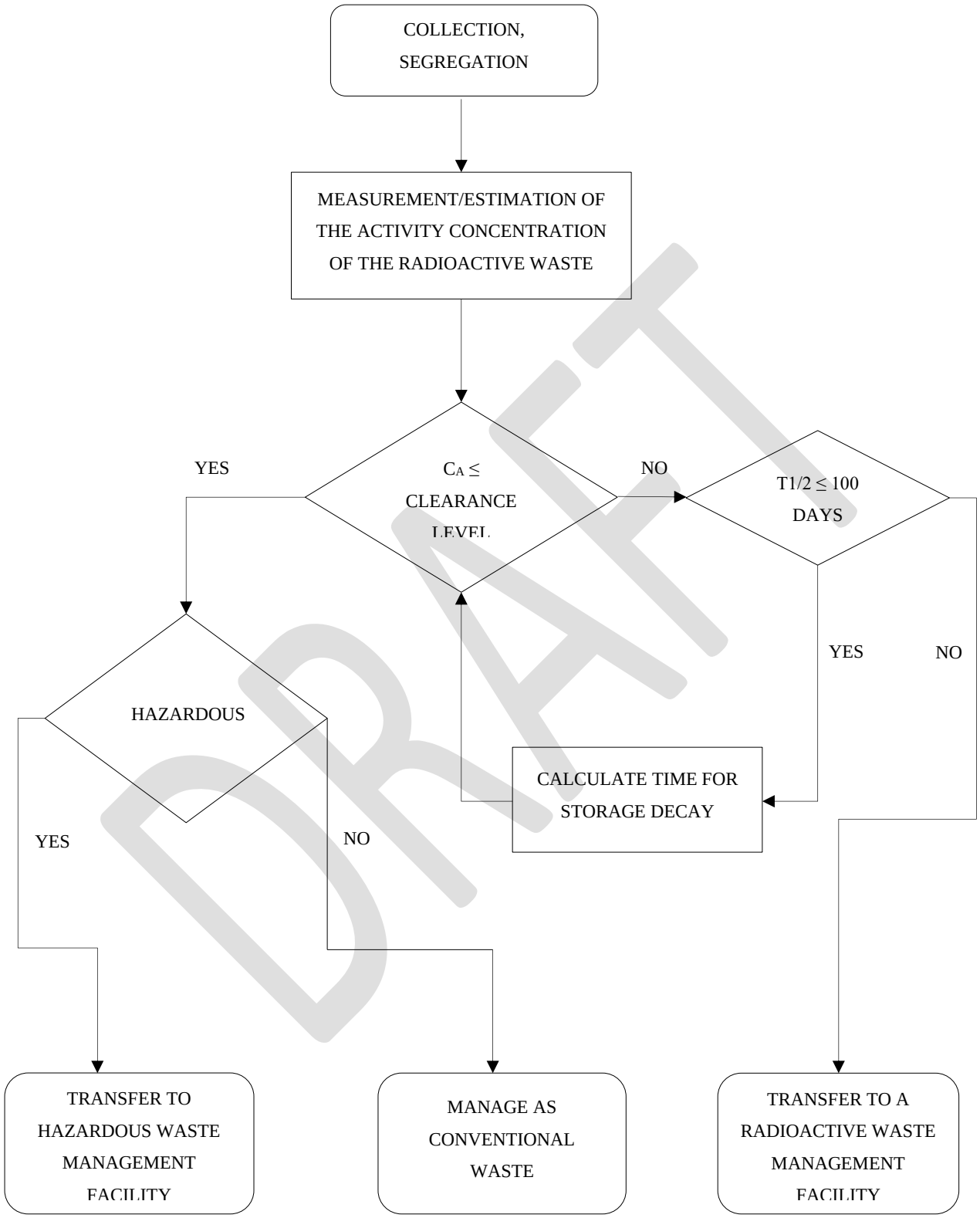

Fig. IV–2. Management Options

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IV-35. As mentioned above, once the wastes resulting from the practices have been properly collected and segregated, the measurement or estimation of the activity concentration of the waste would be performed to determine the management option. The result of this estimation of the activity concentration from the measurement should be compared to the relevant clearance level for the radionuclide involved as established in GRS Part 3.

IV-36. Wastes from a nuclear medicine department with an activity concentration below the clearance level could be managed as conventional waste because, from the radiological perspective, if they do not contain other hazardous material. If the wastes do not comply with the clearance level, they should be transferred to a conventional or hazardous waste treatment facility as appropriate for their management.

IV-37. If the activity concentration is above the clearance level and the half-life of the radionuclide of the radioactive waste is below 100 days, the wastes could be stored in the small facility for a period of time (t) in order to allow radioactive decay until the clearance levels authorized are met. For radioactive material which is not in conditions to be cleared with the described methodology because the activity concentration is so high that they would require long term storage in the small facility, it is recommended to transfer them to a radioactive waste management facility for adequate treatment or disposal, according to the applicable regulations in the country.

IV-38. In order to calculate the period of time (t) for radioactive decay the following IV–3 expression could be used [IV–6]:

$$t = \frac{T_{1/2} \cdot \ln\left|\frac{C_A}{N_D}\right|}{\ln 2} \qquad \text{(IV–3)}$$

where $T_{l/2}$ is half-life of the radionuclide, N_D is clearance level of the radionuclide (Bq/g o Bq/l) and C_A is activity concentration of the radionuclide (Bq/g or Bq/l).

IV-39. In the example of the nuclear medicine department the storage decay time for each solid waste stream is shown in Table IV–4.

IV-40. Once the calculation of the storage decay time until the clearance level is met has been performed, the wastes should to be transferred to the radioactive waste storage room for temporary storage. In addition, the labelling of the wastes should be carried out including radionuclide, activity concentration, date and probable clearance date.

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TABLE IV–4. STORAGE DECAY TIME FOR SOLID WASTES

Waste bag	Radionuclide	T ½ [days]	Initial activity concentration [kBq/g]	Clearance level* [Bq/g]	Storage decay time [days]
1223	Tc-99m	0.25	90.4	100	2.46
1224	Tc-99m	0.25	195.3	100	2.73
3220	I-131	8.04	42.4	100	70.17
3221	I-131	8.04	44.9	100	70.85

* For the purposes of the example of the methodology for the application of the clearance concept, the clearance levels where taken from GSR Part 3 Table I.1.

IV-41. For the example under development, it can be observed that the wastes should be stored in the facility only for a few days before performing the actual release to the environment. The waste stream that requires more storage decay time is the one corresponding to the wastes arising from clinical therapy, where usually higher doses are used.

IV-42. It is recommended that after the storage decay time is reached and before proceeding to clearance measurements of the wastes, a quick and simple check is performed to indicate whether the applied methodology provided the expected outcomes or not. Such quick check could be performed by gamma dose rate measurements. Normally, the result is expected to be close to the background radiation level. If the result of such measurement is double the background or above, that is a clear indication of a failure in the procedure. Therefore, the pertinent investigation should be conducted, and if necessary, the procedure repeated. If the result is below, one could proceed with the final activity concentration measurements to confirm compliance with clearance levels.

IV-43. Wastes that are in condition to be cleared from regulatory control could be treated as conventional or hazardous waste, as relevant. If conventional, they can be disposed in common landfills with domiciliary wastes without any further consideration on radiation protection. If hazardous, they are sent to a hazardous material landfill. This management option is the most convenient for the small facilities and activities given that minimizes the costs of waste treatment or disposal in special landfills that requires continuous surveillance.

IV-44. Table IV–5 shows the management option for each waste stream of example of the nuclear medicine department after the storage decay time has been reached.

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TABLE IV–5: SOLID WASTE MANAGEMENT OPTION

Waste bag	Initial activity concentration [kBq/g]	Estimated activity concentration after decay time [Bq/g]	Control-measurement	Management option
1223	90.4	100	Background	Conventional waste
1224	195.3	100	Background	Conventional waste
3220	42.4	100	Background	Conventional waste
3221	44.9	100	Background	Conventional waste

IV-45. It can be observed that after the decay storage time in the nuclear medicine facility, each of the waste streams fulfill with the clearance level [IV-7]. Therefore, they are in conditions of being treated as conventional wastes. It is important to remark that in some countries vials and containers are often recycled instead of being disposed in landfills.

STEP 4: Record keeping

IV-46. Once the compliance with the clearance levels is verified, it is important to remove any label with the radioactive material logo of the waste packages before proceeding the release dispose as conventional or hazardous wastes.

IV-47. It is necessary that small facilities like nuclear medicine departments implement an adequate record keeping system that ensure that the clearance procedure has been performed in the framework of a management quality system, and that wastes are traceable from the cradle to the grave. These records are important to guarantee authorized parties and regulatory bodies control, and to allow tracing of every step in the waste management procedure. In addition, the records should be kept at least during the whole life of the nuclear medicine facility.

IV-48. For the purpose of record keeping, the following information could be registered for solid wastes:

- Identification of container;
- Radionuclide;
- Waste weight;
- Result of measurement and date;
- Activity or activity concentration;
- Decay time;

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- Clearance probable date;
- Result of control measurement;
- Release date.

IV-49. The record of each solid waste stream considered in the example of the nuclear medicine department is presented in Table IV–6.

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TABLE IV–6. RECORDS OF EACH WASTE STREAM FOR THE NUCLEAR MEDICINE DEPARTMENT

[ID] Waste bag	[RN] Radio-nuclide	[$T_{1/2}$] Half-Life [days]	Net container weight (g)	Dose rate (mSv/h)	Measurement date [DD-MM-YYYY]	[CA] Activity concentration [kBq/g]	[CL] Clearance level [Bq/g]	[t] Decay time [d]	Clearance probable date [DD-MM-YYYY]	Check measurement	Release date [DD-MM-YYYY]
1223	Tc-99m	0.25	3000	0.05	12-03-2018	90.4	100	2.46	15-03.-2018	background	16-03-2018
1224	Tc-99m	0.25	2500	0.09	12-03-2018	195.3	100	2.73	15-03.-2018	background	16-03-2018
3220	I-131	8.04	2500	0.045	12-03-2018	42.4	100	70.17	22-05-2018	background	23-05-2018
3221	I-131	8.04	3250	0.062	12-03-2018	44.9	100	70.85	22-05-2018	background	23-05-2018

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Considerations on liquid wastes

IV-50. Accumulation of liquids could arise in a nuclear medicine facility or in any other small facility or activity, if remnants of the vials are placed in a recipient for storage, pending proper management. Even though this Annex does not provide an example for clearing liquids some general recommendations are provided[7].

IV-51. For segregation of liquids wastes containing radioactive material, the following two categories could be used: aqueous or organic.

IV-52. The existence of a wide variety of shapes and volumes of containers used for liquid radioactive materials makes it impossible to develop a unique simple method for activity estimation of the liquid's waste. As consequence, every small facility or activity should have its own procedures for the activity estimation according to their ways of storage. For example, the measurement of liquid samples could be done in an ionization chamber, calibrated to a specific radionuclide, where the vial is introduced.

IV-53. For the management of radioactive waste, it is usually recommended to make available standardized containers, using certificate reference materials (CRM) from a laboratory to proceed to measure the activity in the waste. It is necessary to select a representative sample of the waste. In the case of aqueous solutions, this is usually achieved by mechanically homogenizing the liquid before taking the sample. In the case of two or more liquid phases, it is necessary to take a sample of each phase and use the most conservative value of the activity concentration, this means the highest activity concentration measured.

IV-54. The activity concentration of a liquid sample could be estimated using the expression (IV–4):

$$C_A = \left(\frac{N - N_0}{\varepsilon \cdot V_M}\right) . Fc \qquad \text{(IV–4)}$$

where C_A is activity concentration of the Radionuclide Bq/l, N is counts rate s^{-1}, N_0 is background (s^{-1}), ε is efficiency of detector, V_M is volume of sample (l) and Fc is a correction factor.

IV-55. Fc is usually applied after the activity concentration is estimated (for example, 1.2 or more) in case of gamma or beta emission [IV–3].

IV-56. For liquid wastes the following information would be registered:

- Identification of liquid;
- Radionuclide;

[7] Usually, in a nuclear medicine department a significant part of the radioactive wastes results from the urine of the patients that are treated with radioactive material for diagnosis or therapy, especially with Iodine-131. The management of these liquid wastes are not treated in the present example.

- Volume;
- Estimated Activity or activity concentration;
- Date of estimated activity;
- Decay time;
- Clearance probable date;
- Result of control measurement;
- Released activity and annual released limit;
- Release date.

REFERENCES TO ANNEX IV

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ANNEX V

ILLUSTRATION OF TYPICAL CONSERVATISM IN THE CLEARANCE PROCESS

V.1. It is helpful to assess the level of exposures that will result in practice from clearance processes. In order to do that it is necessary to look holistically at the complete clearance system and not focus solely on any one step in the process. This involves looking at the degree of conservatism that exists in each step, and then comparing the outcome with the basic required standard.

V.2. The principal criterion for exemption and clearance was derived by IAEA in 1988 [V-1 SS89] on the basis of 'trivial dose' considerations. In practical terms this is:

> "Under normal operating conditions, there should be a very low probability that any person will exceed a dose of a few tens of microsieverts per year as a result of clearance activities."

V.3. There were additional criteria addressing collective dose and low probability situations, but the above principal criterion provides the essential basis for practical clearance considerations.

V.4. Taking the basis from the principal criterion as above, there are five components to the practical application of clearance:

1. Define the dose rate requirement for any individual practice
2. Conversion from the dose rate criterion to activity concentration (Bq/g)
3. Margins incurred in practical clearance measurements
4. Taking account of multiple nuclides: Radionuclide vector and 'sum of fractions'
5. The composition of the cleared waste stream

V.5. The levels of conservatism embedded in these components are discussed below, with numerical assessments of conservatism based on judgement regarding typical practice.

V.6. Important considerations for these components are as follows:

1) Application to an individual practice

V.7. Because an individual could possibly be exposed to several clearance practices, a margin has been applied to the principal criterion such that any specific practice should not lead to individual exposure exceeding of the order of 10 µSv per year, i.e. reducing from 'a few tens' to 'of the order of ten' µSv per year . Given the wide range of clearance practices and scenarios, with many different reference groups, and the very low expectation of overlapping exposure at any significant level, this is a very conservative assumption.

Implied conservatism: 3

2) Conversion from the dose rate criterion to activity concentration (Bq/g)

V.8. This step uses scenario assessment modelling to derive activity concentration values for each nuclide. Many different models are used, with different reference persons. Each model utilises a number of parameters, usually combined via multiplication, falling into two principal groups – parameters representative of the specific model (such as time at exposure, geometrical assumptions, resuspension factors etc), together with standard radiological parameters such as environmental transfer factors and dose per unit intake. The number of parameters specific to a model can vary between a minimum of typically four or five up to a maximum of around 12 (especially when environmental transfers are involved).

V.9. It is normal practice in such assessment modelling to apply inherent conservatism in almost all model parameters. For example, for public dose assessments there is guidance from ICRP [V-2/ICRP101a, V-3/ICRP101b] and IAEA [V-4/IAEA GSG-9, V-5/IAEA GSG-10], which leads to an expectation to use habit data at the 95 percentile level, and clear guidance that 'the assessment methodology needs to be conservative in order to avoid underestimating the impact'. Whilst this guidance primarily may be aimed at assessments relating to compliance with higher level exposures such as dose limits, the same approach tends to be embedded in virtually all modelling assessments.

V.10. Whilst it is accepted that the extent of conservatism will vary between the different scenarios, this review takes a broad overview. As an example, in a six parameter model if the factors of conservatism for each parameter compared to realistic values were in the range 1.2 to 2, then this implies an overall conservatism in the range from 3 to well over an order of magnitude. This judgement is not considered to be an unrealistic outcome of such modelling.

Implied conservatism: 3–15

3) Margins required in practical clearance measurements

V.11. The activity concentration values derived as in (2) above are usually established as legally binding values in national legislation – in effect they become limits. It is then an offence in law to release material exceeding these values, and it is seen as an extremely sensitive offence in terms of public perception. Operators working with clearance must therefore allow margins of confidence within their clearance measurement regime. Different approaches to both material sampling arrangements and instrumentation measurement outcomes are discussed in this safety guide, including such issues as the confidence level of compliance. The inherent degree of conservatism in the measurement process is very dependent on the confidence requirement, the uniformity of activity distribution in the material and on the particular instrumentation/measurement regime used.

Implied conservatism: 1.5–2.5

4) Radionuclide vector and 'sum of fractions'

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V.12. In most practical situations there are several radionuclides within material for clearance, and the standard assessment regime makes due allowance through consideration of the radionuclide vector and application of the 'sum of fractions' approach. In the modelling approach deriving the concentration values as in (2) above, different nuclides will typically have differing exposed reference groups, so the exposures are not strictly additive.

Implied conservatism: 1.2–2

5) Activity distribution in cleared material

V.13. The assessment models typically assume that all released material contains activity at the derived concentration value. In practice there is a range of activity concentrations in cleared material, ranging from virtually zero up to the cut-off value defined in the sentencing measurements. Experience shows that it is virtually impossible to have a consistently uniform waste stream at the maximum allowed activity concentration, and the average activity concentration is usually significantly below the maximum allowed. Operator experience indicates that the average activity concentration in cleared material lies within the range of a factor of 2-5 (or more) below the cut-off value.

Implied conservatism: 2–5.

CUMULATIVE IMPACT OF CONSERVATISMS

V.14. It is intrinsic in the clearance logic that individual conservatisms in the five process steps accumulate in a multiplicative manner. The outcome of this regime can therefore be summarised in Table V-1.

TABLE V-1. CUMULATIVE CONSERVATISMS IN THE CLEARANCE PROCESS

Reference	**Description**	**Factor of Conservatism**
1)	Application to a specific practice	3
2)	Conversion to Activity Concentration	3 - 15
3)	Practical measurement margin	1.5 – 2.5
4)	Sum of fractions	1.2 - 2
5)	Activity distribution	2 - 5
Cumulative Impact (Range)		33 -1125
Typical Cumulative Impact		100 - 1000

V.15. It is highly unlikely that in any one clearance process the conservatisms within each process step will be consistently at the high or low end of the range. Hence it is possible to broadly conclude that typical conservatism for a clearance process will lie perhaps between two and three orders of

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magnitude. This implies that actual individual doses to the most exposed persons are unlikely to exceed around a few tenths of a microsievert per year, and are in all probability much lower.

CONCLUSIONS

V.16. Given the level of overall conservatism in the clearance system demonstrated in this appendix, and noting the very significant societal burden implied when rejecting material for clearance release resulting from these conservatisms, it is important that all reasonable steps are taken to reduce the degree of conservatism. The opportunity to implement this to significant effect in the standard free release system based on the requirements of GSR Part 3 may be limited because steps (1), (2) and (5) above are essentially fixed. This places particular importance on addressing such issues in steps (3) and (4). However, when addressing conditional clearance options there is more flexibility across all the steps to ensure that conservatism is kept to an appropriate level.

REFERENCES TO ANNEX V

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Comments on IAEA Draft Safety Guide
***Application of the Concept of Exemption* (DS499)**

COMMENTS BY REVIEWER Reviewer: Country/Organization: Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.							
2.							
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Comments on IAEA Draft Safety Guide
***Application of the Concept of Clearance* (DS500)**

COMMENTS BY REVIEWER Reviewer: Country/Organization: Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.							
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