

**SPESS F**  
**Document Preparation Profile (DPP)**  
**Version 1.0 dated 25-08-2016**

## 1. IDENTIFICATION

**Document Category or set of publications to be revised in a concomitant manner**

**Working ID:** DS499

**Proposed Title:** Specific Safety Guide: Application of the Concept of Exemption including Criteria for Trade in Contaminated Commodities

**Proposed Action:** Revision of RS-G-1.7 Application of the Concepts of Exclusion, Exemption and Clearance, 2004

**Review Committee(s) or Group:** RASSC (leading committee), WASSC and TRANSSC

**Technical Officer(s):** Igor Gusev, NSRW

## 2. BACKGROUND

Exclusion, exemption and clearance define the scope of regulatory control as it applies to planned exposure situations. 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 regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices.

Requirement 8 of *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* (GSR Part 3) makes provision for the exemption of practices and sources within practices and for the clearance of sources within notified or authorized practices, consistent with the use of a graded approach. Similar provisions for exemption were given in SS-115, the previous edition of GSR Part 3 that was published in 1996. SS-115 also provided values (in terms of both activity concentration and total activity) for exemption of moderate amounts of material from regulatory control.

The Safety Guide RS-G-1.7 explained the links between exclusion, exemption and clearance and also provided values that could be used for exemption or clearance, as appropriate, of bulk quantities of material. Values were provided for both natural and artificial radionuclides. The models used in the calculations of individual dose are described in SRS-44 — these are primarily clearance scenarios since these were found to be the most restrictive. These values for exemption and clearance of bulk amounts of material now appear in GSR Part 3, together with the values for exemption of moderate amounts of material from SS-115.

RS-G-1.7 also provided a partial response to General Conference Resolution GC(44)/RES/15 in 2000. In this resolution, the Secretariat was requested to develop radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood. In fact, the guidance in RS-G-1.7 can be applied to all commodities, other than foodstuffs and drinking water; foodstuffs are dealt with separately in documents developed by the Joint FAO/WHO Codex Alimentarius Commission and drinking water is covered in guidance documents of the WHO. In this context, it is noted that Resolution GC(59)/RES/9 included a request for the Secretariat to further develop a technical

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document on a harmonized framework for the current international standards relating to radioactivity in commodities<sup>1</sup>, a similar request to that given in 2000.

While volumetric concentrations are now well established, there are no internationally accepted values of surface activity for commodities that can be traded freely. However, levels for non-fixed contamination on the external surfaces of packages are given in the IAEA Transport Regulations (i.e. 4 Bq/cm<sup>2</sup> for beta and gamma emitters and low toxicity alpha emitters, and 0.4 Bq/cm<sup>2</sup> for all other alpha emitters); these have been developed only for scenarios related to transport and do not necessarily apply to other exposure pathways.

Surface activity on commodities is possible both when material is being cleared from a practice and following an accidental release of radioactive material. In the latter case, and once the emergency phase is over, the requirements for existing exposure situations apply. In particular, Requirement 51 of GSR Part 3 indicates that the regulatory body or other relevant authority needs to establish reference levels for radionuclides in commodities. The criterion for establishing reference levels for commodities is based on an annual effective dose to the representative person generally not to exceed a value of about 1 mSv/y. The values already established for exemption and clearance of volumetric concentrations of radionuclides of artificial origin in bulk quantities are based on a dose criterion of 10 µSv/y and therefore should easily meet this dose criterion, although with significant margins of conservatism. The values established for nuclides of natural origin are established more pragmatically but will also meet this criterion. However, further guidance is needed on the surface activity levels that would be appropriate. For consistency, it would be desirable if the transport levels could be used and the indications are that they would be appropriate, even though they were developed many decades ago and for a different purpose.

### 3. JUSTIFICATION FOR THE PRODUCTION OF THE DOCUMENT

**It is proposed to separate the material currently in RS-G-1.7 into two separate safety guides: one dealing with clearance and the other dealing with exemption. Guidance related to the control of contaminated non-food commodities that can be traded freely will be included in the safety guide dealing with exemption. Both documents will be developed in parallel to ensure consistency of approach and application.**

**It is recognized that the values for exemption and clearance currently defined for artificial radionuclides are unnecessarily restrictive in that the exposure scenarios used in their derivation are highly conservative. The direct application of the values for artificial radionuclides to commodities in national and international trade introduces an additional level of conservatism due to the different dose criteria of 10 µSv/y (for exemption and clearance) and 1 mSv/y (for trade). It is not intended that the revision of RS-G-1.7 will include the derivation of new values for exemption and clearance but, as part of the revision process, the groundwork will be laid for possible revision of these numbers in the future.**

The safety guide RS-G-1.7 was published in 2004, prior to the publication of the Safety Fundamentals SF-1 and the Basic Safety Standards (GSR Part 3). Other key related safety requirements are *Predisposal Management of Radioactive Waste (GSR Part 5)* and *Decommissioning of Facilities (GSR*

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<sup>1</sup> Resolution GC(59)/RES/9 includes the following: “*Strongly encourages the Secretariat to cooperate with relevant international organizations in developing a technical document on a harmonized framework for the current international standards relating to radioactivity in food and drinking water and urges the Secretariat to further develop a technical document on a harmonized framework for the current international standards relating to radioactivity in commodities;*”

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*Part 6*). There are some differences in terminology and approach between SS-115 and GSR Part 3 that necessitate revision of RS-G-1.7. Specifically, the requirements in SS-115 apply to practices and interventions while GSR Part 3 is structured around three different types of exposure situations (i.e., planned, emergency, and existing). The concept of exemption in planned exposure situations and application of reference levels for existing exposure situations are both included in GSR Part 3, but supporting guidance has not yet been developed. RS-G-1.7 needs to be updated to take account of these changes.

Section 5 of RS-G-1.7 on the application of the values for exemption needs to be updated to reflect use of the graded approach, in particular in the light of the conservative nature of the values. The values for exemption of moderate amounts of material were not considered in RS-G-1.7 and existing guidance needs to be modified to take this into account. There is also a need to provide guidance on the exemption process itself, ensuring consistency with what is contained in SSG-36 that addresses exemption specifically as it applies to consumer products. However, as the values for exemption (and clearance) of bulk quantities given in RS-G-1.7 are now incorporated into the BSS, it is no longer necessary to retain them in this new safety guide. However,

In addition, this Safety Guide will address the request of the General Conference resolution GC(59)/RES/9 “to further develop a technical document on a harmonized framework for the current international standards relating to radioactivity in commodities.” As previously mentioned, it would appear that the generic values for the exemption and clearance of bulk material given in GSR Part 3 would be appropriate for this purpose and this should be clarified in the proposed Safety Guide.

There is also a need to develop numbers for and provide guidance on the application of exemption to surface contaminated non-food commodities. It is noted that values for surface contamination of packages are provided in the IAEA Transport Regulations and this Safety Guide will need to consider their applicability to surface contaminated non-food commodities. An objective would be to resist the development of an additional set of values for trade non-food commodities.

**4. OBJECTIVE**

The objective of the Safety Guide is to provide guidance on exemption issues in the framework of planned exposure situations and application of reference levels in existing exposure situations for national and international trade in contaminated non-food commodities. The safety guide will cover similar subject matter to that in RS-G-1.7, but use the newer concepts and definitions, such as exposure situations and reference levels given in *GSR Part 3*. As the values for exemption (and clearance) of bulk quantities given in RS-G-1.7 are now incorporated into GSR Part 3, it is no longer necessary to retain them in this new safety guide.

The document will be of particular value for regulatory bodies in Member States to assist them the applying the GSR Part 3 requirements on the exemption of a source or practice from regulatory control. The application of this safety guide will promote the harmonization of national reference levels for contaminated non-food commodities and therefore support international trade.

**5. SCOPE**

The scope of this new Safety Guide is to describe the process of exemption from regulatory control. It will also provide guidance on the application of the requirements in GSR Part 3 relating to commodities in existing exposure situations (e.g. those that may have been contaminated as a consequence of a nuclear or radiological emergency). Emergency exposure situations will not be addressed.

Guidance will be provided on the management of surface contaminated non-food commodities, including the development of new values. The applicability of values for surface contamination of

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packages as provided in the IAEA Transport Regulations will be considered for surface contaminated non-food commodities. An objective would be to resist the development of an additional set of values for trade in non-food commodities but instead to confirm the applicability of existing values for exemption to the management of such commodities. The corresponding screening and detection methodologies and dosimetric modelling will be also discussed.

The issue of exclusion will be addressed in the introductory sections of the proposed new safety guide using text that will be duplicated in the new safety guide on clearance. The text will explain the principle of exclusion as well as its relationship to exemption and clearance, but no specific guidance will be provided.

### **6. PLACE IN THE OVERALL STRUCTURE OF THE RELEVANT SERIES AND INTERFACES WITH EXISTING AND/OR PLANNED PUBLICATIONS**

The proposed safety guide will be one of a set of documents supporting GSR Part 3 *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*. Being part of the revision of RS-G-1.7, the present safety guide development should be closely coordinated with the proposed new safety guide on the clearance of radioactive material.

The safety guide will also take account of IAEA-TECDOC-1679, *Exemption from Regulatory Control of Goods Containing Small Amounts of Radioactive Material* and SSG-36, *Radiation Safety for Consumer Products*, as well the discussion of RASSC and WASSC during their November 2015 and June 2016 meetings and material coordinated through the RASSC Electronic Working Group.

The following documents are relevant to the issues to be covered by the new Safety Guide:

1. IAEA, Application of the Concepts of Exclusion, Exemption and Clearance (RS-G-1.7);
2. IAEA, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3);
3. IAEA, Regulations for the Safe Transport of Radioactive Material (SSR-6);
4. IAEA, Predisposal Management of Radioactive Waste (GSR Part 5);
5. IAEA, Decommissioning of Facilities (GSR Part 6);
6. IAEA, Radiological Aspects of Non-fixed Contamination of Packages and Conveyances (TECDOC-1449);
7. IAEA, Exemption from Regulatory Control of Goods Containing Small Amounts of Radioactive Material (TECDOC-1679);
8. IAEA, Radiation Safety for Consumer Products (SSG-36);
9. IAEA, Derivation of Activity Concentration Values for Exclusion, Exemption and Clearance (SRS-44)

## **7. OVERVIEW**

### **I. INTRODUCTION**

Background

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Objective

Scope

Structure

## II. THE CONCEPTS

Types of Exposure Situations

Concepts of Exemption and Reference Levels

Role of Exemption from Regulatory Control in Planned Exposure Situations

Authorization of practice

Graded Approach

Generic and Specific Exemption

Existing exposure situations: the derivation of measurable values for unrestricted international trade

## III. ROLES AND RESPONSIBILITIES

Government

Regulatory body

Applicant

(?) Organizational and administrative arrangements

## IV. GENERIC EXEMPTION

Application of GSR Part 3 values of activity concentrations for bulk quantities

Application of GSR Part 3 values of activity concentrations and total activities for moderate quantities

## V. SPECIFIC EXEMPTION

Safety Assessment

Exemption in planned exposure situations

“Type approval” exemption (see SSG-36)

Revoking or revision of the exemption

Management of materials non-complied to exemption

## VI. DEVELOPMENT OF LEVELS FOR SURFACE CONTAMINATION

Applicability of the transport (or other) values

## VII. IMPLICATIONS FOR INTERNATIONAL TRADE

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Application of GSR Part 3 values (Table I.2) for international trade of non-food commodities

Application of values for surface contamination: (e.g. use of IAEA Transport Regulations)

Harmonization of export and import of non-food commodities

## VIII MEASUREMENT APPROACHES

Calibration

Procedures

Uncertainty

Compliance

Record keeping

## ANNEX Dosimetric Modelling of Surface Contamination of Non-food Commodities

Comparison of three current modelling approaches (Japan, Korea and Netherlands)

Summary: approaches to conversion of generic reference dose level to surface activity concentration for different radionuclides

ANNEX NATIONAL EXPERIENCE – Routine practice (including known and unknown origin of radioactive material)

ANNEX NATIONAL EXPERIENCE – Chernobyl accident (decades after accident)

ANNEX NATIONAL EXPERIENCE – Fukushima accident (years after accident)

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**7. PRODUCTION SCHEDULE**

Provisional schedule for preparation of the document, outlining realistic expected dates:

STEP 1: Preparing a DPP	July 2016
STEP 2: Approval of DPP by the Coordination Committee	September 2016
STEP 3: Approval of DPP by the relevant review Committees	November 2016
STEP 4: Approval of DPP by the CSS	May 2017
STEP 5: Preparing the draft	June 2017 - June 2019
STEP 6: Approval of draft by the Coordination Committee	August 2019
STEP 7: Approval by the relevant review Committees for submission to Member States for comments	November 2019
STEP 8: Soliciting comments by Member States	December 2019 – March 2020
STEP 9: Addressing comments by Member States	April 2020
STEP 10: Approval of the revised draft by the Coordination Committee Review in NS-SSCS	October 2020
STEP 11: Approval by the relevant review Committees	June 2021
STEP 12: Endorsement by the CSS	November 2021
STEP 13: Establishment by the Publications Committee and/or Board of Governors (for SF and SR only))	March 2022
STEP 14: Target publication date	August 2022

**8. RESOURCES**

Estimated resources involved by the Secretariat (person-weeks) and the Member States (number and type of meetings)

- 6 CS meetings (3 consultants x 5 days for each CS meeting)
- 1 TM meeting (20 participants x 3 days)
- IAEA staff:
  - 1 Scientific Secretary – 30 weeks
  - 1 administrative assistant – 8 weeks

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