

SPESS F
Document Preparation Profile (DPP)
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1. IDENTIFICATION

Document Category	Safety Guide
Working ID:	DS556
Proposed Title:	Radiation Safety in the Use of Unsealed Sources
Proposed Action:	New publication
Review Committee:	<u>RASSC</u>, TRANSSC, WASSC, EPRReSC, NSGC
Technical Officer:	J. Bosnjak (NSRW/RIT)

2. BACKGROUND

Unsealed radioactive sources are used for various purposes in medicine, industry, agriculture, education and research. Unlike sealed sources, in which the radioactive material is permanently sealed in a capsule, or closely bound and in a solid form, unsealed sources are in a liquid, gas or dispersible solid form and can pose radiation exposure risks if not handled properly. Therefore, it is essential to provide recommendations to ensure protection of people and the environment, and safety of unsealed sources.

The first IAEA Safety Series publication was a manual on Safe Handling of Radioisotopes, issued as IAEA Safety Series No. 1 in 1958 (SS-1). It was updated in 1962 and 1973 but it is now superseded, predominantly by IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, but also by other safety standards. However, the part of SS-1 covering unsealed sources is not fully addressed in any existing safety standards.

Several Safety Guides have been published (see Section 6 of this DPP) that provide recommendations on implementing the requirements of GSR Part 3 on radiation protection and safety of facilities and activities, including some recommendations on unsealed sources, such as GSG-7, Occupational Radiation Protection; GSG-8, Radiation Protection of the Public and the Environment; SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation; SSG-59, Radiation Safety of Accelerator Based Radioisotope Production Facilities; and SSG-87, Radiation Safety in the Use of Radiation Sources in Research and Education.

However, the existing Safety Guides do not provide recommendations for all facilities and activities involving unsealed sources.

3. JUSTIFICATION FOR THE PRODUCTION OF THE PUBLICATION

Acknowledging the above-mentioned requirements and recommendations on the use of unsealed sources, Member States have expressed, through their representatives at the Radiation Safety Standards Committee (RASSC), the need for recommendations on the use of unsealed sources. During the RASSC-52 meeting, in June 2022, the decision was made to develop a new Safety Guide that would provide recommendations on the safe use of unsealed sources, including the classification of laboratories and

other areas where unsealed sources are used, considering different categories of unsealed sources (see Annex).

The potential scope of the Safety Guide was initially identified through a gap analysis, a questionnaire ‘RASSC Survey on Safe handling of unsealed sources – SS-1 update’ to obtain feedback from Member States, and a subsequent consultancy meeting in April 2022. A second consultancy meeting was held from 22 to 26 April 2024, to prepare a DPP for the proposed Safety Guide.

There are a few Safety Guides that have been published relating to safe use of unsealed sources in specific facilities and activities. However, these do not provide recommendations for all facilities and activities involving unsealed sources. In addition, a mechanism for implementing the graded approach, such as the classification of laboratories, which was addressed in SS-1, is missing from the existing Safety Guides.

Several options to fill the gaps in current recommendations were considered and it was concluded by RASSC that the optimal solution would be to develop a new Safety Guide rather than revising existing Safety Guides. RASSC has included the development of this Safety Guide among its priority topics in its 2024–2026 work plan.

4. OBJECTIVE

The objective of the proposed Safety Guide is to provide recommendations on implementing the requirements of GSR Part 3 in relation to the protection of people and the environment against exposure due to the use of unsealed sources, in accordance with a graded approach. The aim is to support consistency in protection and safe use of unsealed sources, in a varied range of facilities and activities.

The proposed Safety Guide is intended for use by regulatory bodies, operating organizations and interested parties.

5. SCOPE

The proposed Safety Guide will provide recommendations for implementing the requirements in GSR Part 3 in relation to facilities and activities where unsealed sources are produced, processed or used in medicine, industry, agriculture, education and research. It will also address the interface between safety and security measures related to unsealed sources.

An unsealed source is defined in GSR Part 3 as a radioactive source in which the radioactive material is neither a) permanently sealed in a capsule nor b) closely bonded and in a solid form. The scope of the proposed Safety Guide includes the use of unsealed sources in the form of liquid, gas, or dispersible solids (with the exception of bulk amounts of naturally occurring radioactive material).

The proposed Safety Guide will not duplicate specific recommendations provided in other Safety Guides but will provide necessary reference to these Guides and give context in the overall framework.

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

The proposed Safety Guide will provide recommendations on the implementation of the requirements of:

- GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, which establishes requirements for the governmental, legal and regulatory infrastructure for safety of facilities and activities, including those associated with unsealed sources.
- GSR Part 3, which establishes requirements for the protection of people and the environment and safety of radiation sources, including unsealed sources.
- GSR Part 5, Predisposal Management of Radioactive Waste.
- GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency.

The Safety Guides that are applicable to specific facilities and activities involving the use of unsealed sources are as follows:

- GSG-7, Occupational Radiation Protection
- GSG-8, Radiation Protection of the Public and the Environment
- GSG-17, Application of the Concept of Exemption
- GSG-18, Application of the Concept of Clearance
- RS-G-1.9, Categorization of radioactive sources
- SSG-45, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education
- SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation
- SSG-59, Radiation Safety of Accelerator Based Radioisotope Production Facilities
- SSG-87, Radiation Safety in the Use of Radiation Sources in Research and Education

IAEA has published TECDOCs, technical report series and Safety Reports, that provide practical examples, as follows:

1. TECDOC 1823: Use of Carbon Isotopic Tracers in Investigating Soil Carbon Sequestration and Stabilization in Agroecosystems
2. TECDOC 1856: Quality Control in the Production of Radiopharmaceuticals
3. TECDOC 1974: Application of a Graded Approach in Regulating the Safety of Radiation Sources
4. IAEA Technology Series No. 3: Application of Radiotracer Techniques for Interwell Studies
5. IAEA Technology Series No. 5: Radiotracer Generators for Industrial Applications
6. TRS-1002: Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources
7. Safety Report Series No. 58: Radiation Protection in Newer Medical Imaging Techniques PET/CT
8. Safety Report Series No. 63: Release of Patients After Radionuclide Therapy
9. Safety Report Series No. 104: Radiation Protection and Safety in Veterinary Medicine.

The proposed Safety Guide will interface with all of the above listed Safety Guides, TECDOCs, Technical Report Series and Safety Reports.

7. OVERVIEW

A Table of Contents has been developed for the proposed Specific Safety Guide. It will provide recommendations on how to implement requirements applicable to all facilities and activities involving unsealed sources, according to a graded approach.

TABLE OF CONTENTS

1. Introduction

The background, scope and objectives of the guide are set out in this section. The definition of ‘unsealed source’ is explained. The general properties of unsealed sources, special considerations in their use and potential exposure routes are also summarized. The range of facilities and activities involving unsealed sources is briefly described.

2. Framework for safe use of unsealed sources

Recommendations on the principles of radiation protection in relation to unsealed sources are provided in this section. Responsibilities of the regulatory body, the authorized party and other parties are specified. Management of protection and safety in relation to facilities and activities involving unsealed sources is covered in this section. The concept of the graded approach is introduced.

3. Radiation safety in the design of facilities activities and workplaces for producing, processing and using unsealed sources

Recommendations on the classification of laboratories and other areas where unsealed sources are produced, processed or used, considering different categories of unsealed sources, are provided. Recommendations on the siting, choice and design of facilities and workplaces are provided, with emphasis on engineered controls, such as furniture, floors, work surfaces, ventilation, lighting, plumbing, equipment design, shielding, access control, containment, manipulation, and washing/decontamination facilities.

4. Radiation protection and safety in the use of unsealed sources

This section provides recommendations on the management of unsealed sources, including safety assessment; and the components of the radiation protection programme associated with unsealed sources, such as working procedures, information instruction and training, protective clothing, protective measures and radiological monitoring of the area, environment, equipment and persons.

5. Regulatory control of unsealed sources

Recommendations on the regulatory control of facilities and activities involving unsealed sources are provided in this section, taking into consideration the application of a graded approach.

6. Other considerations in relation to the use of unsealed sources

Recommendations on other aspects to be considered when dealing with unsealed sources are provided in this section. This includes storage of unsealed sources, radioactive waste management, decommissioning, transport, and emergency preparedness and response.

Annexes

Relevant annexes will be included, such as examples of unsealed sources used in typical practices and application of a graded approach.

8. PRODUCTION SCHEDULE

Provisional schedule for preparation of the publication, outlining realistic expected dates for each step:

STEP 1: Preparing a DPP	DONE
STEP 2: Internal review of the DPP (Approval by the Coordination Committee)	September 2024
STEP 3: Review of the DPP by the review Committee(s) (Approval by review Committee(s))	November 2024
STEP 4: Review of the DPP by the CSS (approval by CSS) or information of the CSS on the DPP	May 2025
STEP 5: Preparing the draft publication	2025
STEP 6: First internal review of the draft publication (Approval by the Coordination Committee)	Q2 - Q3 2026

STEP 7: First review of the draft publication by the review Committee(s) (Approval for submission to Member States for comments)	November 2026
STEP 8: Soliciting comments by Member States	Q2 2027
STEP 9: Addressing comments by Member States	Q3 2027
STEP 10: Second internal review of the draft publication (Approval by the Coordination Committee)	Q1 2028
STEP 11: Second review of the draft publication by the review Committee(s) (Approval of the draft)	June 2028
STEP 12: (For Safety Standards) Editing of the draft publication in MTCD and endorsement of the draft publication by the CSS	Q2 2029
STEP 13: Approval by the Board of Governors (for SF and SR only)	
STEP 14: Target publication date	2029

9. RESOURCES

Estimated IAEA Staff resources required: 15 person-weeks;

Estimated Member States resources required:

- Home-based assignment: 3x5 person-weeks;
- Three consultancy meetings: 5 person-weeks/CM;
- One technical meeting 30 persons/3 day.

ANNEX

- Meeting Report – Consultancy Meeting on SS-1 Update, (25.04.2022)
- Summary of outcomes and agreements from 52nd Meeting of the RASSC
- RASSC Survey on Safe handling of unsealed sources Summary Data
- Gap analysis