SPESS F
Document Preparation Profile (DPP)
Version 4.0 06/05/2025

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:	**RASSC, TRANSSC, WASSC, EPReSC, 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 It was updated in 1962 and 1973 but it is now superseded, predominantly by IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, but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,.
- GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.
- 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 Requirements, 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

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