SPESS F
Document Preparation Profile (DPP)
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1. IDENTIFICATION

Document Category: **Safety Guide**

Working ID: **DS530**

Proposed Title: **The Management System for the Safe Transport of Radioactive Material**

Proposed Action: **Revision of IAEA Safety Standards Series No. TS-G-1.4, The Management System for the Safe Transport of Radioactive Material, which was published in 2008**

Review Committee(s) or Group: **TRANSSC, NSGC**

Technical Officer(s): **Eric H. Reber (NSRW)**

2. BACKGROUND

IAEA Safety Standards Series No. TS-G-1.4, The Management System for the Safe Transport of Radioactive Material, was published in 2008. TS-G-1.4 provides guidance on implementing the requirements established in IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities (2006), for establishing, implementing, assessing and continually improving a management system for the transport of radioactive material. It also provides guidance on implementing the requirements established in IAEA Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material (2005), on quality assurance and quality assurance programmes within the management system for transport.

Since the publication of TS-G-1.4, the two publications in the Safety Requirements category that it supports have been revised once in the case of GS-R-3, and three times in case of TS-R-1. Revision of TS-G-1.4 is proposed to take account of revisions to several relevant publications, and issues that have impacted the areas of its purview since its publication in 2008, including:

— Revisions of the publications in the Safety Requirements category that it supports;

— Revisions of other publication cited as references, e.g., IAEA Safety Standards Series No. TS-G-1.1, ISO 9001:2000, and ISO 14001:1996;

— Technological changes, and changes to the nature and scope of the transport of radioactive material;

— Operational experience in Member States with the use of TS-G-1.4; and

— Consideration of the safety/security interface.

3. JUSTIFICATION FOR THE PRODUCTION OF THE DOCUMENT

Users of this publication will benefit from an updated version of the document that is based on current safety standards, and takes account of recent operating and regulatory experience and current technology. The revision of this publication will include more information about management systems for transport activities outside the nuclear industry, including those that apply to packages that do not require approval by the competent authority.

The revision of TS-G-1.4 is part of an initiative to review and revise all safety guides directly related to the safety requirements publication SSR-6 (Rev. 1), which was published in 2018. Furthermore, TRANSSC33 concluded that TS-G-1.4 should be revised upon consideration of the recommendation of a working group that was convened to consider whether a revision is necessary. The report of this working group, which also proposed changes to the text of TS-G-1.4, is included as Annex I. During TRANSSC35, a working group was convened to consider proposed changes to the text of TS-G-1.4. The report of this working group is included as Annex II.

4. OBJECTIVE

The objective of this safety guide will be to provide guidance on implementing the requirements in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety (2016), for establishing, assessing, sustaining and continually improving effective leadership and management in organizations associated with, and involved in the transport of radioactive material. It will also provide guidance on implementing the requirements established in IAEA Safety Standards Series No. SSR-6 (Rev. 1). Regulations for the Safe Transport of Radioactive Material (2018 Edition), concerning the management system for transport.

The target audience for this publication is organizations associated with, and involved in the transport of radioactive material, including, but not limited to, organizations that design, manufacture, maintain and repair packagings, and prepare, consign, load, carry (including in-transit storage), ship after storage, unload, receive or otherwise use a package in connection with the transport of radioactive material. This publication will also be useful for competent authorities for the transport of radioactive material.

5. SCOPE

This safety guide will apply to management systems for all activities related to the transport of radioactive material, including the design, testing, manufacture, modification, maintenance, and repair of packagings, and the preparation, consignment, loading, carrying (including in-transit storage), shipping after storage (including consideration of ageing management), unloading, receiving or otherwise using a package in connection with the transport of radioactive material.

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

The proposed publication will be a specific safety guide in the group of safety standards on the safe transport of radioactive material. The development of this safety guide will take account of other safety guides that provide recommendations on meeting the requirements of GSR Part 2 that are being revised [i.e., DS513 (generic guidance on meeting the requirements of GSR Part 2) and DS477 (Leadership, Management and Culture for Safety in Radioactive Waste Management)].

The drafting process for this publication will be managed by the Regulatory Infrastructure and Transport Safety Section (RIT) in NSRW. The Nuclear Security of Materials and Facilities Section (MAFA) in NSNS will be consulted concerning the safety/security interface.

There were no cosponsoring organizations for TS-G-1.4, and to date, no organizations have expressed an interest in cosponsoring this revision.

It is expected that at least the following IAEA safety standards and other publications will be referenced in the revised guide (the list is not exhaustive):

- 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).
- INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition), IAEA Safety Standards Series No. SSG-26 (Rev. 1), IAEA, Vienna (20XX). [As of November 2021, SSG-26 (Rev. 1) is in the final stages of preparation for publication, and it is anticipated that it will be published in early 2022.]

— INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).
— INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006). [Under revision as DS513]
— INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership, Management and Culture for Safety in Radioactive Waste Management, IAEA Safety Standards Series No. DS477 [Revision and combination of GS-G-3.3 and GS-G-3.4]
— INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material, IAEA Safety Standards Series No. SSG-65, IAEA, Vienna (20XX).
— INTERNATIONAL ATOMIC ENERGY AGENCY, Security of Radioactive Material in Transport, IAEA Nuclear Security Series No. 9-G (Rev. 1), IAEA, Vienna (2020).
— INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems: Requirements, ISO 9001:2015, ISO, Geneva (2015).
— INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Environmental Management Systems—Requirements with guidance for use, ISO 14001:2015, ISO, Geneva (2015).
— NUCLEAR REGULATORY COMMISSION, Packaging and Transportation of Radioactive Material, Quality Assurance, 10 CFR 71, Subpart H, US Govt Printing Office, Washington, DC (2004).

7. OVERVIEW

The structure of the safety guide will follow that of GSR Part 2, Leadership and Management for Safety. The requirements in GSR Part 2 will be quoted so that readers can easily grasp the basis of the transport specific recommendations that are provided.

1. INTRODUCTION

   BACKGROUND
   OBJECTIVE
   SCOPE
   STRUCTURE

2. RESPONSIBILITY FOR SAFETY

3. LEADERSHIP FOR SAFETY

4. MANAGEMENT FOR SAFETY

   RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM
      Responsibility of senior management for the management system
      Goals, strategies, plans and objectives
      Interaction with interested parties
   THE MANAGEMENT SYSTEM
      Integration of the management system
      Application of the graded approach to the management system
      Documentation of the management system
   MANAGEMENT OF RESOURCES
      Provision of resources
   MANAGEMENT OF PROCESSES AND ACTIVITIES
      Management of processes and activities

Management of the supply chain

5. CULTURE FOR SAFETY

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

APPENDIX: GRADED APPROACH FOR MANAGEMENT SYSTEMS FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

REFERENCES

ANNEX I: COMPARISON OF APPLICABLE STANDARDS FOR THE MANAGEMENT SYSTEM
ANNEX II: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR AN INDUSTRIAL RADIOGRAPHY COMPANY
ANNEX III: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR A RADIOPHARMACEUTICAL COMPANY
ANNEX IV: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR A DESIGNER OF EXCEPTED, INDUSTRIAL OR TYPE A PACKAGES
ANNEX V: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR A DESIGNER OF TYPE B (U) PACKAGES
ANNEX VI: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR A MANUFACTURER OF EXCEPTED, INDUSTRIAL OR TYPE A PACKAGINGS
ANNEX VII: EXAMPLE OF DOCUMENTATION OF THE MANAGEMENT SYSTEM FOR A MANUFACTURER OF TYPE B (U) PACKAGINGS
ANNEX VIII: EXAMPLE OF AN INTERNAL AUDIT PROCEDURE FOR A SMALL ORGANIZATION

8. PRODUCTION SCHEDULE: Provisional schedule for preparation of the publication, outlining realistic expected dates for each step *(fill the column corresponding to your proposed publication and delete the other columns)*:

	A*	B*	C*
STEP 1: Preparing a DPP	DONE	DONE	DONE
STEP 2: Internal review of the DPP (Approval by the Coordination Committee)	Q4, 2020		
STEP 3: Review of the DPP by the review Committee(s) (Approval by review Committee(s))	Q2, 2021		
STEP 4: Review of the DPP by the CSS (approval by CSS) or information of the CSS on the DPP	Q4, 2021		
STEP 5: Preparing the draft publication	Q1 – Q2, 2022 No TMs are planned.		
STEP 6: First internal review of the draft publication (Approval by the Coordination Committee)	Q3, 2022		
STEP 7: First review of the draft publication by the review Committee(s) (Approval for submission to Member States for comments)	Q4, 2022		
STEP 8: Soliciting comments by Member States	Q1, 2023		
STEP 9: Addressing comments by Member States	Q2, 2023		
STEP 10: Second internal review of the draft publication (Approval by the Coordination Committee)	Q3, 2023		
STEP 11: Second review of the draft publication by the review Committee(s) (Approval of the draft)	Q4, 2023		
	Q2, 2024		

STEP 12: (For Safety Standards) Editing of the draft publication in MTCD and endorsement of the draft publication by the CSS (For nuclear security guidance) DDG's decision on whether additional consultation is needed, establishment by the Publications Committee and editing			
STEP 13: Approval by the Board of Governors (for SF and SR only)	N/A		
STEP 14: Target publication date	Q4, 2024		

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- *Column A for Safety Fundamentals, Safety Requirements and Safety Guides.*
- *Column B for Nuclear Security Series publications*
- *Column C for TECDOCs, safety reports and other publications*

9. RESOURCES

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

Three one-week consultancy meetings

Three six-week home based assignments

Secretariat: 20 person-weeks

Annex I: Feedback Analysis Report–Report of Working Group 2 on Revision of TS-G-1.4 (TRANSSC33)

TRANSSC33 Nov 2016 Working Group 2 – TS-G-1.4

The Management System for the Transport of Radioactive Material

Chair – David Pstrak (USA)

Secretary – Iain Davidson (UK)

Attendees: Frank Wille (Germany); Adelia Sahyun (Brazil); Ito Daiichiro (WNTI); Nathalie Cordier (France); Julie Krochmaluk (France); Ben Dekker (WNTI); Pierre Malesys (ISO); Fernando Zamora (Spain); Christophe Karasinski (Belgium); Ikoma Yutaka (Japan); and Gerhard Wortmann (ISSPA).

Summary:

1. Group agreed to consider the proposed changes from SSR-6 and SSG-26 i.e. 2018 editions for TS-G-1.4 revision considerations.
2. Reference to shipment after storage/ageing may be useful (see (1)).
3. Paragraphs 106 and 306 of SSR-6 define the scope for TS-G-1.4. Paragraph 1.4 of the introduction may benefit from review e.g. to narrow the focus to SSR-6 requirements rather than the fairly broad focus of facilities and (all) activities, which included in a general way health, environment, economic element considerations.
4. Recognition of developments in 'Human Factors' (HF) may be useful to add. TRANSSC to consider a member state to present on HF in the future.
5. If not included in the new version of SSG-26, augment the paragraphs on document retention, data management etc. which is becoming more of an issue in ageing facilities.
6. Need to update all references for current revision(s) and any consequential changes plus any new references that need to be included.
7. Recommendation to the TS-G-1.2 (EP&R) working group to cover the latest thinking on Management Systems (so that it is not needed in TS-G-1.4). [How do we get the balance right between referencing out and providing a useful document and duplication of info?]
8. Concerning the graded approach, consensus was that more examples would be useful for duty holders not involved in the nuclear fuel cycle (terminology that everyone agrees with for this community may be needed!)
9. Recommend that Table 3 of the Appendix for Graded Management Controls be reviewed and revised as necessary to reflect current standards/thinking.
10. To help the target audience, the document should be rationalized and simplified where possible. [do we need more intelligence from IAEA on who the users/target audience of the document are?]

Consensus to revise to reflect 2018 standards and other improvements identified.

Discussion

France - Shipment after storage/ ageing should be included to reflect recent amendments.

Spain – TS-G-1.4 is adapted to 2005 edition but 2012 exists – should we look at this or 2018 edition? Group agreed to look forward to 2018 edition.

UK – need to make sure that we don't repeat what may go in SSG-26 but refer to ageing?

Germany – used TS-G-1.4 for its own guidance.

Spain – need to bear in mind TRANSSC secretariat advice to keep in mind the less developed/ nonnuclear sector.

Germany – re para 1.4 is everyone happy with 'management system' rather than 'QA' and/or CA?

France – helpful to have mgt system as this includes Human Factors etc. Spain – the nuclear Competent authority present does not regulate health, environment, economics, etc so difficult to implement this integrated concept (out of scope of SSR-6?) ISO – term was brought in to align with GS-R-3 rather than ISO 9001 (NB Quality Management System). Chair – Ref [3] talks of facilities and activities (which would include transport). Is the definition too broad/ too general for transport and therefore make applicability difficult? Germany – [1.6] is clear on the scope (add ageing). France - emergency preparedness and recovery and Spain - security?)

France/UK – keen to have recognition of Human Factors. The group thought that this may be too detailed for the guide. France to present at T34?

Japan – keen to augment record retention/data management paragraphs – wait for SSG-26 revision wording.

ISO – need to update all references for current revision(s) and any consequential changes plus any new references that need to be included.

General discussion - It was agreed that Emergency response management systems should be covered somewhere in TS-G-1.4 (if it is not clear in the new revision of TS-G-1.2). France – further explanation on the expectations of the graded approach for smaller users would be useful. UK suggested that a specific example for the medical sector might be useful as there are so many of these entities. Other examples within the range may also be useful to help the non-nuclear community.

Germany – is Table 3 of the Appendix for Graded Management Controls up-to-date, consistent and accurate?

Discussion on whether RPP management systems should be referred to – agreed that as reference to management systems was already in TS-G-1.3 (page 30) then not needed here.

Spain - could the document be rationalized with more use of tables of examples/ appendices (reference out to e.g. ISO 9001) rather than words? A long document is less useful to small users/ single entities in the transport chain. Simplicity!

UK – discussion on a need for an over-arching QP to cover a number of different interfaces that may be involved in a transport operation. Paragraph 5.48 seems to cover this.

Discussion on who might use TS-G-1.4 going forward and target the document and its potential revision to this audience. Target the small users/ countries under the IAEA regional approach programme, who would benefit most.

Decision to revise or not – consensus to revise to reflect 2018 standards and other improvements identified.

END.

Annex II: Feedback Analysis Report–Report of Working Group 1 on Proposed Changes to TS-G-1.4 (TRANSSC35)

TRANSSC 35 – WG 1 : TS-G- 1.4

Participants :

WILLE Frank, Germany (Chair)

IKOMA Yutaka, Japan

SAHYUN Adelia, Brazil delegation

HELLSTEN Santtu, Finland

PSTARK David, USA

NILSEN Mette, Norway

CABIANCA Tiberio, UK

BADR Mohamed Abdel Halim, Egypt

FULOFRd Greg, Canada

MILIN Mathieu, France

ITO Daïchiro, WNTI

KARASINSKI Christophe, Belgium (Secretary)

Minutes of the Working group

Due to the time given for the working group, it was decided to discuss the points of the previous WG (TRANSSC 33) instead of reviewing all the document.

After reviewing the minutes of the last WG (TRANSSC 33), there is a consensus about waiting for the final text of SSG-26 before reviewing TS-G-1.4. We see that the ageing management program will have an effect of the content of the TS-G-1.4.

The current structure of the document seems to be good but the content will need to reflect the most current international guidances on management system.

The document and detailed proposals for revision should be discussed in a consultancy meeting. Experts familiar with ISO-9000 standards family are welcome.

References (mainly ISO 9000 family) should be reviewed, and/or added on consequences of new approaches about e.g. quality management, manuals, process development.

Section 1.4 requires modification to become more transport specific. We should keep in 1.4 and chapter 2 the explanation of what is behind the term « Management system » and keep

information about history of development of the regulation. Reference to the IAEA GSG 3.1 (ref [3]) is not necessary in 1.4 and 2.3.

WG cannot address the details of the human factor but recommends that TRANSSC look further into this topic.

Clarification is needed about document retention, specifically if we have DPC or ageing management in mind.

It is recommended that the working group on ER&P (TS-G-1.2) has a look on the management system.

WG recommends that member states could be encouraged to submit national experiences about graded approach of management systems to be included in safety guides. It's important that the existing text (appendix of TS-G-1.4) is reviewed and revised to take account of current approaches of the member states.

Annexes should be reviewed on the point of the usefulness and deleted or amended if not useful. Examples of management systems applicable to bigger or smaller companies should be given.

WG strongly recommends that a consultancy meeting works on the revison of TS-G-1.4 after the final text of SSG-26.