Organization of Agreement States Meeting

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Introduction to the International Atomic Energy Agency's "Regulations for the Safe Transport of Radioactive Material" (SSR-6, Rev. 2)

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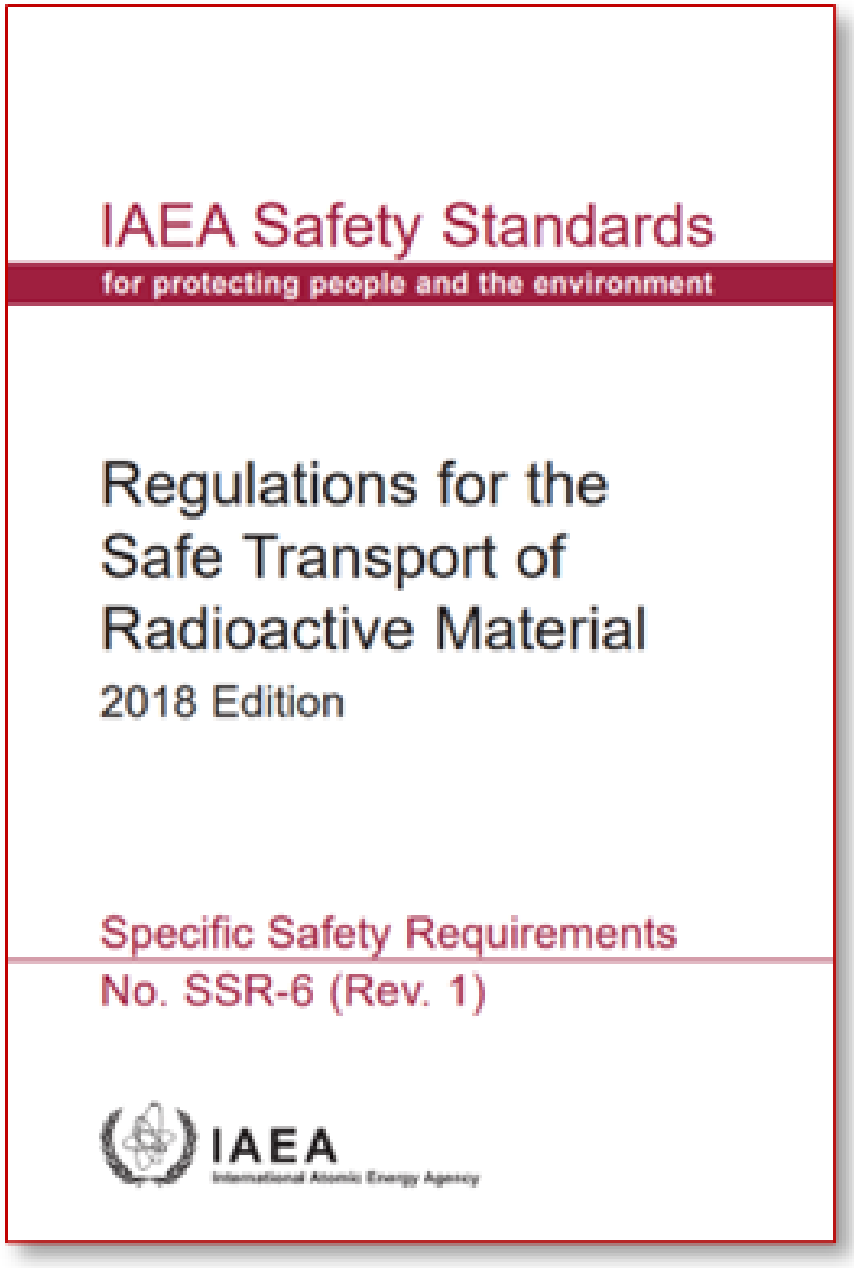
Objective and Scope of SSR-6

The objective of SSR-6 is to establish requirements that must be satisfied to ensure safety and to protect people, property and the environment from harmful effects of ionizing radiation during the transport of radioactive material.

SSR-6 applies to the transport of radioactive material by all modes on land, water, or in the air. Transport comprises all operations and conditions associated with, and involved in, the movement of radioactive material.



Review/Revision of SSR-6

- SSR-6 is reviewed every two years
- “The decision on the revision and publication will be made based on the decision of TRANSSC”
- If TRANSSC considers that a proposal for change stemming from a review cycle is sufficiently important for safety to necessitate publication as soon as possible, the Secretariat will initiate the revision process

Overview of Proposals for Change

- The IAEA issued a Note verbale seeking Member State comments
- 306 proposals received from Australia (3), Belarus (5), Belgium (1), Canada (10), France (70), Germany (11), IATA (12), ISO (3), Italy (7), Japan (17), Morocco (7), Oman (3), Pakistan (2), Russia (11), Sweden (15), Switzerland (28), WNTI (79), TIC (5), UK (8), USA (6)
- 294 unique proposals were assigned to primary TTEGs

TTEG	Primary
TTEG-C	37
TTEG-OM	177
TTEG-PPA	62
TTEG-RP	18

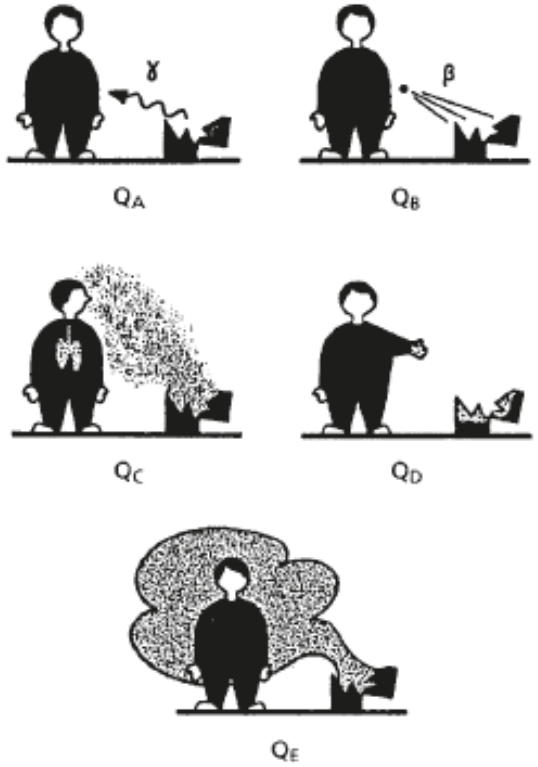
Revision Cycle Overview

Activity	Start	End
STEP 1: Preparation of DPP	July 2022	18 August 2022
STEP 2: Internal review of the DPP (Approval by the Coordination Committee)	11 August 2022	18 August 2022
STEP 3: Review of the DPP by the Review Committees	26 August 2022	2 December 2022
STEP 4: Review of the DPP by the CSS (approval by CSS)	23 March 2023	23 May 2023
STEP 5: Development of revised manuscript of SSR-6 (Rev. 2)	December 2022	24 July 2023
STEP 5: Development of modified text for proposals that were designated as “Accepted, but modified” during T-45	December 2022	20 April 2023
STEP 5: Review of revised text at TRANSSC 46	5 June 2023	9 June 2023
STEP 6: First internal review of SSR-6 (Rev. 2) (Approval by the Coordination Committee)	24 July 2023	24 August 2023
STEP 7: First approval of the draft publication by the Review Committees	31 August 2023	December 2023
STEP 8: Soliciting comments by Member States	December 2023	May 2024
STEP 9: Addressing comments by Member States	April 2024	July 2024
STEP 10: Second internal review of the draft publication (Approval by the Coordination Committee)	July 2024	August 2024
STEP 11: Second review of the draft publication by the review Committee(s) (Approval of the draft)	September 2024	December 2024
STEP 12: Editing of draft in MTCD and endorsement of the draft by the CSS, establishment by the Publications Committee and editing	December 2024	April 2025
STEP 12: Silence approval of the final edited text by TRANSSC	May 2025	May 2025
STEP 13: Approval by the Board of Governors	June 2025	September 2025
STEP 13*: Submittal of SSR-6 (Rev. 2) to UNECE	October 2025	March 2026
STEP 14: Publication	October 2025	January 2026

SPESS: Strategies and Processes for the Establishment of IAEA Safety Standards

Update of the Q System - correction of A_1/A_2 values

- The IAEA's Q System is used to derive A_1/A_2 values – upper limit of radioactive material in a Type A package; other uses in SSR-6 because the values would produce equivalent radiological consequences
- Under the Q System, A_1/A_2 values are the quantities of a radionuclide that would produce the reference doses of 5 rem (effective dose), 50 rem (equivalent dose to the skin) and 15 rem (equivalent dose to the lens of the eye) under five exposure scenarios, which are intended to represent potential doses resulting from accident conditions of transport
- The Q System was last updated in the 1996 Edition of the Transport Regulations (SSR-6)
- The TTEG-RP assessed the Q System and proposed new A_1/A_2 values



Justification Paper

- Conclusions of the A_1/A_2 Working Group
  - For certain radionuclides, the current A_1/A_2 values are incorrect in that the specified quantities of radionuclides would produce more than or less than the reference doses under the conditions of the five exposure scenarios of the Q System
  - Calculations using recently published dose coefficients, radiological data and modelling techniques produced A_1/A_2 values that are different than the current values for approximately 44% of the A_1 radionuclide values and 54% of the A_2 radionuclide values
  - For certain radionuclides, i.e. At-211, Bi-212, In-114m, Pb-202, Pb-210, Pb-212, Ra-224, Ra-225, Ra-228 and U-230 (fast lung absorption), the recalculation of the A_1/A_2 values revealed that the current values underestimate doses by greater than a factor of 10
- Impact on transport operations of the incorporation of corrected A_1/A_2 values into the draft SSR-6 (Rev. 2)
  - Step 8: comments AUS-1, -2, -3 and CDN-04; negative impact on the development and/or implementation of emerging radiopharmaceutical therapies, i.e. Targeted Alpha Therapy
  - Step 11: comments CDN-02 and USA-6; A_2 values for certain radionuclides (Ac-225, At-211, Pb-212, Ra-223, Ra-224, and Ra-225) that may be used in Targeted Alpha Therapy should not be changed
  - 35% of the corrected A_1 values and 35% of the corrected A_2 values are higher than the current values and the incorporation of these corrected values into SSR-6 (Rev. 2) would relax the requirements for the transport of the relevant radionuclides, which would include the following examples of radionuclides that are commonly transported: Am 241, Cd-109, Cm 244, Gd-153, I-125, I 131, Kr-85, Ni-63, P-32, Pu 238, Ra-226, Tc-99m and Tl 201

Justification Paper

- Safety Basis Considerations
  - Incorporation of the corrected A_1/A_2 values into the revised edition of SSR-6 (Rev. 1) and the acceptance of the updated Q System parameters are deemed to be necessary so that all A_1/A_2 values can be reliably derived and checked, each value being underpinned by an explicit and transparent safety basis that is based on current radiological data, modelling techniques and calculational methods and on a process that is thoroughly verified.
  - Requirement 3 of GSR Part 3 states that “The regulatory body shall establish or adopt regulations and guides for protection and safety and shall establish a system to ensure their implementation.”
  - Ensuring that safety regulations such as SSR-6 are based on the most up-to-date and transparent information demonstrates a commitment to fulfilling this responsibility and maintaining the public’s trust in regulatory bodies.
  - Transparent and scientifically grounded regulations help build public confidence in the safety measures being taken to protect members of the public from radiation risks. Based on these considerations, it seems that the corrected A_1/A_2 values should be incorporated into SSR-6 (Rev. 2).
  - Not including the corrected values would contradict IAEA policies and good practice and could also lead to a reputational risk to IAEA and loss of public confidence in Governments.

Why is this important?

The United States transport regulations are based on the IAEA's transport regulations

The NRC currently has a rulemaking with the Commission to harmonize with SSR-6 (Rev. 1)

Both NRC and DOT will assess SSR-6 (Rev. 2) for potential changes to the Code of Federal Regulations (Titles 10 (NRC) and 49 (DOT)

Questions and Answers