



Council on Radionuclides and Radiopharmaceuticals, Inc.

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Henry H. Kramer, Ph.D., FACNP
Executive Director

4/27/05
70 FR 21684

June 21, 2005

(1)

Michael Lasar
Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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RULES AND DIRECTIVES
BRANCH
USNRC

RE: Regulations for the Safe Transport of Radioactive Material; Solicitation of Comments on Proposed Changes. Federal Register Vol. 70, No. 80, page 21684. April 27, 2005.

Dear Mr. Lasar:

These comments concerning the proposed changes to the International Atomic Agency's Regulations for the Safe Transport of Radioactive Materials are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medial applications.

The general comment we would like to express is that based on the overall nature of the proposed revisions, the IAEA should reconsider the frequency of its review cycle. The changes proposed do not appear to reflect any significant need to improve worker or public safety and, as we have expressed in some of the specific comments attached, a number of proposed changes aren't needed at all. Unless there is a recognized need to make improvements warranted by concerns over the safety of radioactive materials transport, the IAEA, competent authorities, regulated community, workers and the public would be better served by a less frequent review cycle. A more appropriate revision frequency would be four or five years. That would allow our limited resources to focus on other more worthwhile priorities such as material security and accountability.

Our specific comments are provided as attached on the standard comment form that was specified for use in the Federal Register notice of May 2, 2005.

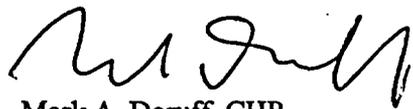
E-RJDS = ADM-03

adm = J. Cook (SRC)

SISp Review Complete
Template = ADM-013

CORAR appreciates the opportunity to express these comments. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Doruff', written in a cursive style.

Mark A. Doruff, CHP
Chairman, Transportation Committee
Council on Radionuclides and Radiopharmaceuticals

**2004-2005 Review/Revision Cycle
Comments on Proposed Change to TS-R-1 "IAEA Regulations
for the Safe Transport of Radioactive Material"**

NOTES:

1. Please, do not submit comments to indicate agreement with any Proposed Change;
2. Please, complete one Comment Form for each Proposed Change on which comment is provided;
3. For all submissions please provide the rationale for response to the Proposed Change (item 5 below);
4. The Change Number (item 1 below) for a Proposed Change is found in column 1 of the document entitled, "Proposed changes for 120 day review".

1. Change Number (See Note 4): 2
2. Comment submitted by: Name: Mark Doruff Organization: Council on Radionuclides and Radiopharmaceuticals Address: 3911 Campalindo Drive, Moraga, CA 94556-1551 Tel.: 925-283-1850 Fax: E-mail: corar@silcon.com
3. Date of comment: June 21, 2005
4. Response to the Proposed Change (mark appropriate box) (see Note 1): <input checked="" type="checkbox"/> Agree subject to the amended Proposed Change in item 6 below: <input type="checkbox"/> Reject
5. Rationale for response to the Proposed Change: Need to complete the proposed Table IX to specify the appropriate UN marking for Overpack containing only excepted packages (other than consignments accepted for international movement by post).
6. Amended Proposed Change, if any: Insert the following statement in row four, column two of the proposed Table IX: United Nations number, preceded by the letters "UN", and the proper shipping name.

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4. The Change Number (item 1 below) for a Proposed Change is found in column 1 of the document entitled, "Proposed changes for 120 day review".

1. Change Number (See Note 4): 4
2. Comment submitted by: Name: Mark Doruff Organization: Council on Radionuclides and Radiopharmaceuticals Address: 3911 Campalindo Drive, Moraga, CA 94556-1551 Tel.: 925-283-1850 Fax: E-mail: corar@silcon.com
3. Date of comment: June 21, 2005
4. Response to the Proposed Change (mark appropriate box) (see Note 1): <input type="checkbox"/> Agree subject to the amended Proposed Change in item 6 below: <input checked="" type="checkbox"/> Reject
5. Rationale for response to the Proposed Change: There is no need in paragraph 105 for additional emphasis on implementation of an adequate radiation protection programme to assure the safety of the public and workers in the transportation of radioactive materials. There are other aspects of compliance with the regulations (e.g. proper packaging, marking and labeling, limitations on activity, radiation levels and surface contamination) that are more fundamental and significant with respect to assuring safety. None of these are highlighted and there is, therefore, no need for the proposed additional emphasis on radiation protection programmes. In many cases where radioactive materials are in transport, there is no need for any formal application of a radiation protection programme as other measures relevant to compliance afford satisfactory protection of workers and the public. This additional wording is unnecessary.
6. Amended Proposed Change, if any: In section 105, remove the following proposed wording: " , including through the correct implementation of an adequate radiation protection programme"

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3. For all submissions please provide the rationale for response to the Proposed Change (item 5 below);
4. The Change Number (item 1 below) for a Proposed Change is found in column 1 of the document entitled, "Proposed changes for 120 day review".

1. Change Number (See Note 4): 14
2. Comment submitted by: Name: Mark Doruff Organization: Council on Radionuclides and Radiopharmaceuticals Address: 3911 Campalindo Drive, Moraga, CA 94556-1551 Tel.: 925-283-1850 Fax: E-mail: corar@silcon.com
3. Date of comment: June 21, 2005
4. Response to the Proposed Change (mark appropriate box) (see Note 1): <input type="checkbox"/> Agree subject to the amended Proposed Change in item 6 below: <input checked="" type="checkbox"/> Reject
5. Rationale for response to the Proposed Change: The proposed change in wording in 648 (b) (ii) from "ensure the retention of" to "enclose completely the" is not appropriate. Containment systems are part of package design to ultimately ensure the retention of liquid contents, a point that is adequately made by the current wording. The proposed wording is redundant in nature and less rigorous in its intent.
6. Amended Proposed Change, if any: Replace the proposed wording in 648 (b) (ii) from "enclose completely the" to the current wording, "ensure retention of the."

**2004-2005 Review/Revision Cycle
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4. The Change Number (item 1 below) for a Proposed Change is found in column 1 of the document entitled, "Proposed changes for 120 day review".

1. Change Number (See Note 4): 26
2. Comment submitted by: Name: Mark Doruff Organization: Council on Radionuclides and Radiopharmaceuticals Address: 3911 Campalindo Drive, Moraga, CA 94556-1551 Tel.: 925-283-1850 Fax: E-mail: corar@silcon.com
3. Date of comment: June 21, 2005
4. Response to the Proposed Change (mark appropriate box) (see Note 1): <input checked="" type="checkbox"/> Agree subject to the amended Proposed Change in item 6 below: <input type="checkbox"/> Reject
5. Rationale for response to the Proposed Change: The proposed change in wording in paragraph 549 (now 551) would add the statement that " the consignor is responsible for ensuring that an overpack has the relevant overpack mark. " This change is acceptable as long as it is made in the context of the need for some clarification on the definition of an overpack. The concern is that some regulators may take the position that packages consolidated onto pallets or into rigid carrier enclosures for the ease of handling are in fact overpacks. The proposed change in 549 should reinforce the position that the consignor shall have the responsibility for determining when a consolidation becomes an overpack and shall then follow all of the relevant requirements for proper marking, labeling, etc.
6. Amended Proposed Change, if any: Amend paragraph 229.2 of TS-G-1.1 as follows in bold text: <i>A consignment is an overpack when the responsible consignor designates a consolidation as such. A rigid enclosure or consolidation of packages, such as those stacked on a pallet or placed inside a freight wagon, for ease of handling is such a way that package labels remain visible for all packages need not be considered as an overpack unless advantage is taken by the consignor of the determination of the TI of the overpack by the direct measurement of the radiation level.</i>