

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL
MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

March 27, 2008

NRC REGULATORY ISSUE SUMMARY 2008-07
DOSE LIMIT FOR PATIENT RELEASE UNDER 10 CFR 35.75

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Material Licensees. All Radiation Control Program Directors, and State Liaison Officers.

INTENT

The NRC is issuing this regulatory issue summary (RIS) to inform all addressees that the NRC intends to pursue rulemaking to clarify the 0.5 millisievert (mSv) (0.5 rem) limit in 10 CFR 35.75 as an annual limit, rather than a per-release limit. This rulemaking is being pursued because the NRC has determined that the regulation as it is now written does not incorporate the NRC's intent in having promulgated this regulation.

BACKGROUND

10 CFR 35.75 (a) provides:

A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent [TEDE] to any other individual from exposure of the released individual is not likely to exceed 5 mSv (0.5 rem).

The dose-based criterion in 10 CFR 35.75 for release of patients or human research subjects to whom byproduct material has been administered was established in 1997, when the NRC amended its regulations to provide for a dose-based rather than activity-based limit for release of these individuals who have been administered unsealed byproduct material or implants containing byproduct material (see 62 FR 4124). Licensees have asked whether, in cases in which an individual is given a series of administrations over time, the dose-to-others criterion applies to each of the administrations separately, or whether the dose-to others criterion for release of the individual is an annual dose limit. While the regulatory history of the 1997 addition to 10 CFR Part 35 that established the patient release criteria in §35.75 supports the intent of an annual dose limit interpretation, the wording of the regulation, which has not been changed since 1997, is ambiguous.

ML063030572

SUMMARY OF ISSUE

As explained in the Supplementary Information accompanying the final rule (62 FR 4124, January 29, 1997) the NRC proposed to adopt a new 10 CFR 35.75(a) to change the patient release criteria from 1,110 megabecquerels (30 millicuries) of activity in a patient, or a dose rate of 0.05 millisievert (5 millirem) per hour at 1 meter from a patient, to a TEDE not to exceed 5 millisieverts (0.5 rem) in any one year to an individual from exposure to a released patient. The Supplementary Information states that this release limit was consistent with the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection," and the National Council on Radiation Protection and Measurements (NCRP) in NCRP Report Number 116, "Limitation of Exposure to Ionizing Radiation." Each of these recommendations provided a basis for allowing individuals to receive annual doses up to 5 millisieverts (0.5 rem) in a given year in situations when exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) per year for a long period of time, as would be the case for doses from released patients. Current ICRP and NCRP recommendations on doses to individuals from exposure to a released patient are still consistent with the above-cited earlier recommendations from these advisory organizations.

The wording of §35.75, which does *not* indicate that the dose limit is an annual limit, was based on the presumption, appropriate at the time the regulation was being developed, that an individual who received a therapeutic radiopharmaceutical dosage or a therapeutic sealed source permanent implant and was released under the restrictions of §35.75 was highly unlikely to receive another treatment and again be released under §35.75 within a year, i.e., to receive multiple administrations and to undergo multiple releases within a given year. The presumption that patients receive single administrations of therapeutic doses in a given year, which is the basis used in developing the wording for the dose limit in §35.75, is no longer valid. Several licensees have described patient treatment protocols involving multiple therapeutic administrations, and in some cases multiple patient releases under §35.75, in a given year.

If multiple administrations or applications in a single year are planned, anticipated, or potentially may be required for an individual, the decision about releasing that individual following each of the administrations should, in NRC's view, be based on the cumulative TEDE from all administrations or applications in a given year not exceeding 5 mSv (0.5 rem) for the maximally exposed other individual.

The position of the NRC, supported by the recommendations of both national and international organizations, remains that there should be an annual limit on the dose to other individuals from the release of an individual under the provisions of 10 CFR 35.75.

Therefore, NRC intends to pursue rulemaking to establish the 0.5 millisievert (mSv) (0.5 rem) limit in 10 CFR 35.75 as an annual limit. The normal procedures for rulemaking, including opportunity for public comment, will be followed.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

In accordance with the Congressional Review Act, the NRC has determined that this RIS is not a major rule, and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) has confirmed this determination.

PAPERWORK REDUCTION ACT STATEMENT

This RIS references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval number 3150-0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact one of the individuals listed below or the appropriate regional office.

/RA/

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Enclosure:
List of Recently Issued FSME
Generic Communications

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List of Recently Issued FSME
Generic Communications

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OFC	DMSSA/MSEA	TechEd	DMSSA/MSEA	DMSSA/MSEA	DMSSA/MSEA
NAME	RZelac:smh	EKraus FAX	CFlannery	MLO for AMcIntosh	SWastler
DATE	10/02/07	10/31/06	10/02/07	12/11/06	10/12/07
OFC	OIS	OGC	OGC	DMSSA	
NAME	TDonnell	FCameron	TRothschild	RLewis	
DATE	12/04/07	11/08/07	11/15/07	2/27/08	/ /08

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List of Recently Issued FSME Generic Communications			
Date	GC No.	Subject	Addressees
10/04/07	RIS-07-22	Status Update For Implementation Of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission materials licensees, radiation control program directors, State liaison officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes.
10/04/07	RIS-07-23	Date For Operation Of National Source Tracking System	All licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.
12/05/07	RIS-07-27	Improving Public Understanding of the Risks Associated with Medical Events	All U.S. Nuclear Regulatory Commission medical use licensees. All Radiation Control Program Directors, and State Liaison Officers
12/07/07	RIS-07-28	Security Requirements for Portable Gauges	U.S. Nuclear Regulatory Commission portable gauge licensees and Agreement State Radiation Control Program Directors and Liaison Officers
12/14/07	RIS-07-38	Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users	All U.S. Nuclear Regulatory Commission medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
02/01/08	RIS 2008-02	Actions to Increase the Security of High Activity Radioactive Sources	All U.S. Nuclear Regulatory Commission Materials and Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
<p>Note: This list contains the six most recently issued generic communications. A full listing of generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p>			