UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555
August 31, 2006

NRC REGULATORY ISSUE SUMMARY 2006-18 REQUESTING EXEMPTION FROM THE PUBLIC DOSE LIMITS FOR CERTAIN CAREGIVERS OF HOSPITAL PATIENTS

ADDRESSEES

All NRC medical licensees.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance on requesting exemption from the dose limit for members of the public for certain caregivers of hospitalized patients. Licensees in Agreement States should contact their appropriate State office if they wish to utilize this guidance, because the details and requirements may vary, and in some cases the State may not grant such an exemption.

BACKGROUND

Patients undergoing medical diagnostic or therapeutic procedures involving the use of radioactive materials may be released from the hospital, even though they represent sources of potential radiation exposure to members of the public, if they meet certain release criteria. These criteria are specified in 10 CFR 35.75. Patients who do not meet these release criteria must remain in the hospital until they do satisfy them. Aside from failure to meet release criteria, patients with administered or implanted radioactive materials may remain in the hospital for reasons such as ongoing diagnosis or treatment. Such patients are usually visited in the hospital by family and friends, and these visitors are considered members of the public, subject to the dose limit specified in 10 CFR 20.1301 for members of the public. This limit, normally 1 mSv (0.1 rem) per year, and in some cases 5 mSv (0.5 rem) per year, is easily observed for the vast majority of visitors.

In some cases, however, this dose limit is insufficient to accommodate situations in which a member of the public, who will be referred to in this RIS as a caregiver, is directly involved in the care of a patient containing radioactive material. Caregivers are usually members of

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the patient's family, or someone close to the family or the patient. They do not include hospital staff, who are considered to be occupationally exposed individuals subject to occupational dose limits that are much higher than the limits for members of the public. The role of caregivers often involves close contact with the patient, sometimes for prolonged periods of time, with the result that the radiation doses they receive may be much higher than the dose limit that would normally apply to members of the public.

To address this situation, NRC staff proposed to the Commission that dose limits for caregivers be established on a case-by-case basis by the licensee, and that their doses be limited only by the demands of their care-giving functions and the needs of the patient, provided the dose not be permitted to be high enough to present an immediate danger to the health of the caregiver or to increase the potential long-term risks resulting from radiation exposure to unacceptable levels. The rationale behind this approach is that dose limits are normally imposed for the protection of persons who are exposed either involuntarily, as in the case of exposures to members of the public, or who are exposed as a result of their occupations, such as hospital staffs and others whose occupations necessarily involve exposure to radiation. The caregiver situation is different in that it involves a voluntary decision by the caregiver, with the approval of the attending medical staff, to incur radiation exposure, and its potential risks, as an incidental consequence of the need to perform the caregiving function in the interest of the patient. The justification for incurring the exposure is that it is beneficial, or possibly essential, to the well-being of the patient, and may therefore be considered an extension of the patient's medical treatment.

The Commission approved the staff's proposal, and directed that a graded approach be used in controlling doses to caregivers. This approach would initially approve a default limit that experience has indicated would be adequate for most caregiver situations, and the Commission recommended that this default limit be set at 20 mSv (2 rem). The limit may subsequently be increased if it proves too low for a particular case. This RIS provides guidance for NRC licensees who may encounter such caregiving situations at their facilities and who may wish to apply for exemption from the dose limits in 10 CFR 20.1301. Requesting this exemption is not different in any essential way from any other exemption request, except that the Commission has already approved it in principle, and its approval by the staff in a specific case only requires a determination that a valid caregiver situation exists and that adequate controls will be implemented once the exemption is granted.

SUMMARY OF ISSUES

Licensees have always been permitted to request exemptions from any part of the regulations by applying to the NRC and providing adequate justification to support the request. Such exemptions are granted if the NRC considers the reasons provided to be sufficient to justify the exemption. Exemption of a caregiver from the dose limits applicable to members of the public may also be treated in the same manner as any other exemption, and such exemptions have been approved in the past. However, one characteristic of the caregiver situation that may make it different from other exemption requests is that the situation requiring the exemption may arise with little prior notice and may therefore require quick approval. For example, the patient's condition may change in a manner that requires additional testing using radioactive materials, or the unanticipated initiation or continuation of the use of radioactive materials in

treatment or therapy, or the patient may be dying. Caregivers may at that time elect to involve themselves directly in the care of the patient, and medical considerations may also indicate that such direct involvement may be beneficial, or even essential, to the patient. Hence the need for a rapid exemption from the dose limit for members of the public that may have been enforced up to that point.

This RIS provides guidance to licensees on the means that they may use to obtain an exemption for the caregiver situation, whether there is ample time to follow routine application procedures or there is a need for a quick exemption. To ensure that the information needed by the NRC staff is available at the time of the exemption request, and that the regulatory conditions that are likely to accompany an exemption are known beforehand to the licensee, this RIS provides a list of the information that should accompany the exemption request, and provides a discussion of the control measures that are likely to be a condition for approval of the exemption request. These conditions have been reviewed by NRC's regional staff, who considered them adequate as a basis to issue the exemption. The exemption request becomes, in essence, a request by the licensee to initiate the pre-approved conditions upon acceptance by the NRC of the pre-approved list of information that would be considered sufficient to justify immediate issuance of the exemption. The procedures to be followed in Agreement States, and the conditions that the States may wish to impose, may differ from those described in this RIS, and licensees in these States should contact their State officials for additional information.

It should be emphasized that exemption from a pre-established regulatory dose limit for caregivers does not in any way imply that radiation safety and control of dose is no longer necessary. The potential that a caregiver may receive doses much higher than those normally permitted for members of the public, or possibly for occupationally exposed persons, and also that doses may be accumulated at a rate that is much higher than normally encountered in radiation exposure situations, points to the need for a carefully planned and executed radiation monitoring and control program, and this is an essential condition underlying the approach to the caregiver exemption described in this RIS. It should also be emphasized that the normal inspection and enforcement programs applied to any licensed operation continue to be in effect after the exemption is granted.

APPLYING FOR THE EXEMPTION

NRC licensees may apply for the exemption described in this RIS by contacting the NRC Regional Office that issued the license. The licensee should ensure that the necessary telephone numbers are available for use when needed, as well as the appropriate fax numbers, to permit transmitting the licensee's request to the Regional Office in written form. It is possible, however, that conditions may develop that require an exemption during periods when the cognizant NRC staff are not available, such as during the night or outside normal working hours, on weekends, or during holidays. If this occurs, licensees may proceed as though the exemption has been approved, provided that the pre-established conditions described in this RIS are implemented, and the NRC Operations Center is immediately notified of the action. The telephone number of the NRC Operations Center is (301) 816-5100. The NRC staff should be contacted as soon as possible during normal working hours, and in any case, a written request should be forwarded to the NRC by the end of the next business day after Operations Center notification. If the licensing staff determines that there are issues with a licensee's

actions that occurred during periods when cognizant NRC staff are unavailable, enforcement discretion will be considered, on a case-by-case basis, provided that the licensee has implemented the control measures described in this RIS before allowing caregivers to receive exposures above the regulatory limits.

The same approach may be used if the licensee finds that the limit approved in a previous exemption proves to be insufficient for a particular case and that a higher caregiver dose limit is needed. In any case, if the request is made by telephone, the request for the exemption should be followed by documentation, provided to the region, that describes the manner in which the elements of the caregiver protection program, as described in this RIS, will be implemented. It should be noted that the caregiver limits referred to in this discussion are in fact controls imposed on the caregiver's radiation exposure to avoid accumulating high doses at rapid rates, without adequate and carefully considered justification. Additionally, the dose that the caregiver is ultimately permitted to receive is determined by the patient's needs and the caregiver's informed willingness to incur the resulting potential radiation risks. Exemptions may be granted to hospital departments, such as the nuclear medicine department, rather than to a particular caregiver situation, but the required justification and radiation controls remain the same. It should be noted that the caregiver situation must be invoked and approved prior to the caregiver receiving a dose in excess of the public dose limit. Exceeding the public dose limit prior to the existence of a formal caregiver situation would be considered a violation of the conditions of the license.

INFORMATION THAT SHOULD ACCOMPANY THE EXEMPTION REQUEST

The following may be considered to be the minimum information to be provided to NRC's regional staff to permit them to evaluate the merits of the request and determine whether to grant the exemption. The information should be as complete as possible to make it unnecessary for the staff to request additional information and hence delay approval. The list below is not exhaustive, and the licensee should provide any additional information that may help clarify the situation and explain the justification for the request. The NRC Regional offices will issue the exemption on the basis of the licensee's statement that these conditions have been implemented, and the adequacy of implementation will be verified during subsequent NRC reviews or inspections.

1. The name of the licensee, the license number, the authorized user involved, and the names of physicians or staff who made the determination that a caregiver situation should be invoked.

2. Name and telephone number of a contact person or persons in case the NRC needs additional information, and for notification of approval or denial of the request. Any written exemption requests should be signed by a person authorized to represent the institution in matters pertaining to the NRC license, or by the authorized user who prescribed the dosage.

3. A description of the situation that necessitates the request, the radioisotope, form, and activity of radioactive material administered to the patient, and the anticipated number of caregivers.

4. The expected duration of the requested exemption, and the needed starting date for the exemption.

5. The expected dose that may be incurred. A limit of up to 20 mSv (2 rem) will be approved initially. A second exemption request for a higher dose may be made if the need arises. Experience with care giver situations has demonstrated that virtually all such cases can be accommodated within the 20 mSv (2 rem) limit.

6. A description of the control program that will be implemented to meet the requirements described in the section below on exposure controls. This program description is not a description of the licensee's normal radiation control program, but only the additional measures that will be used to monitor and control the caregiver's exposures.

CONTROL MEASURES THAT SHOULD BE IMPLEMENTED

An exemption from a dose limit for the caregiver does not mean that no controls on the dose received will be required. The exemption simply means that the dose that the caregiver will be permitted to receive will be determined by the needs of the situation rather than beforehand by the regulatory agency, as is the case with other dose limits. Therefore, the exemption must be accompanied by a control program designed to minimize the dose received by the caregiver and to ensure that the selected dose limit will be observed. The general control measures that should be implemented are listed below, but the details will depend on the facility and the local conditions. These details should be provided with the exemption request, in addition to items one through six in the section above.

1. A description of the training and instructions to be given to the caregivers on the potential risks of radiation exposure, the applicable dose limit, and ways to minimize exposures. Information on the caregivers, in regard to their relationship with the patient and whether they are 18 or more years old, should also be provided. This will help the NRC staff ensure that the conditions that warrant approving the exemption have been met.

2. Copies of any consent forms signed by the caregiver and the responsible licensee personnel should be maintained on file. The caregiver should sign a declaration that she is not pregnant or, if pregnant, that she is aware of the risks to the embryo/fetus arising from radiation exposure. In general, pregnant women and minors should be discouraged from participating as caregivers if that can be avoided, even though there is little evidence that the risk of the embryo/fetus will be significantly increased at exposures up to the proposed 20 mSv (2 rem) limit. NRC regulations do permit occupationally exposed pregnant women who do not declare the pregnancy to be exposed up to the occupational dose limit of 50 mSv (5 rem) per year. In general, the eligibility of pregnant women to be caregivers may be determined by hospital policy.

3. A description of the radiation protection measures to be used in controlling dose to the caregiver, including methods for monitoring doses on a real-time basis. Real-time in this context means that the accumulated dose to the caregiver is updated with sufficient frequency to permit the licensee to take corrective action if the dose approaches a limit or is accumulating faster than anticipated. Dosimetry that must be sent for processing to determine the dose received, such as film badges, will not serve that function

because they are not capable of providing information on doses received over sufficiently small time intervals, so as to serve as a means of controlling that dose and anticipating the need for additional control measures.

It should be noted that the above controls will generally require careful consideration and planning to determine the specific approaches suited for the licensee's facility, such as, for example, the types of monitoring equipment that are available to monitor caregiver doses or, if necessary, the types that should be acquired to accomplish that function. Since design of such a control program is unlikely to be successfully completed under pressing emergency conditions, licensees who anticipate any possibility of invoking a caregiver situation should plan their control programs ahead of time, and acquire any instruments and develop any procedures that may be needed if such a situation develops.

FEDERAL REGISTER NOTIFICATION

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

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in the appendix to this RIS are covered by the requirements of 10 CFR Parts 20 and 35, which were approved by the Office of Management and Budget (OMB), approval numbers 3150-0014 and 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 or an information collection requirement unless the requesting document displays a currently valid OMB control number.

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

/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: "List of Recently Issued NMSS
Generic Communications"

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OFFICE	IMNS	NMSS	IMNS	IMNS	OGC
NAME	SSherbini	EKraus	RCorreia	TEssig	S.Treby
DATE	06/12/05	6/15/05	6/20/05	6/20/05	06/12/05

OFFICE	OIS/PRA	NMSS
NAME	BShelton	CMiller
DATE	6/20/05	08 /31 /06

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Recently Issued NMSS Generic Communications

Date	GC No.	Subject	Addressees
04/23/06	RIS-06-10	Use of Concentration Control for Criticality Safety	All licensees authorized to possess a critical mass of special nuclear material.
01/26/06	RIS-02-15, Rev. 1	NRC Approval of Commercial Data Encryption Products For the Electronic Transmission Of Safeguards Information	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
01/24/06	RIS-06-01	Expiration Date for NRC-Approved Spent Fuel Transportation Routes	The U.S. Nuclear Regulatory Commission (NRC) licensees who transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel (SNF)).
01/13/06	RIS-05-27, Rev. 1	NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review	All 10 CFR Parts 71 and 72 licensees and certificate holders.
07/10/06	IN-06-13	Ground-Water Contamination Due to Undetected Leakage of Radioactive Water	All holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor and those authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72 licenses to store spent fuel in water-filled structures.
07/06/06	IN-06-12	Exercising Due Diligence When Transferring Radioactive Materials	All materials licensees.
06/12/06	IN-06-11	Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures	All medical licensees.
03/31/06	IN-06-07	Inappropriate Use of a Single-parameter Limit as a Nuclear Criticality Safety Limit	All licensees authorized to possess a critical mass of special nuclear material.
03/21/06	IN-02-23, Supl. 1	Unauthorized Administration of Byproduct Material for Medical Use	All medical licensees.
01/19/06	IN-06-02	Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless- Steel-jacketed Electrical Cables	All holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under

Electronic Reading Room/Document Collections.