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FILE

MEMO TO : North Dakota Medical Radioactive Material Licensees

FROM : Terry L. O'Clair, P.E.
Director
Division of Air Quality

RE : NRC Regulatory Issue Summary 2005-24: Control of Radiation Dose to Visitors of Hospital Patients

DATE : January 23, 2006

Enclosed is a copy of the United States Nuclear Regulatory Commission (NRC) Regulatory Issue Summary (RIS) 2005-24 as titled above. Under an agreement with the NRC, North Dakota has assumed regulatory authority of certain uses of radioactive material within its borders. Regulations comparable to 10 CFR are contained in North Dakota Administrative Code 33-15. North Dakota maintains compatibility with the NRC by having comparable regulations and conducting adequate enforcement to maintain compliance.

This RIS provides guidance on methods that may be used to estimate and control radiation doses to visitors of hospitalized patients who have been administered radioactive material. Guidance is also provided regarding information collection for visitor exposure cases requiring dose reconstruction.

Please review this information for applicability to your licensed activities and consider actions, as appropriate, to ensure the safe and legal use of radioactive material and associated documentation in the State of North Dakota.

This notice is for your information only. Neither specific action nor written response is required. If you have any questions concerning this issue, please contact the Radiation Control Program at (701)328-5188.

TLO/CJS:saj

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

November 23, 2005

NRC REGULATORY ISSUE SUMMARY 2005-24 CONTROL OF RADIATION DOSE TO VISITORS OF HOSPITAL PATIENTS

ADDRESSEES

All medical licensees.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance on methods that may be used to estimate and control radiation doses to visitors of hospitalized patients who have been administered radioactive material. Guidance is also provided on information collection in visitor exposure cases requiring dose reconstruction. No specific action nor written response is required.

BACKGROUND

In 2002, several members of the public were inadvertently permitted to receive radiation doses in excess of the regulatory limit. The individuals received the doses when they visited a family member who was confined to the hospital after receiving radioactive material. The licensee was not required to individually monitor the doses received by each of the visitors, and none of the visitors were provided with dose-monitoring devices. The licensee was required, however, to perform surveys and take other measures to ensure that none of the visitors received a dose in excess of the dose limit for a member of the public. The licensee discovered the inadvertent exposures a few weeks after they had occurred, and it attempted to estimate the doses received. However, lacking the data to accurately and directly assign doses to the visitors, it was necessary to retrospectively estimate the doses using a combination of survey data, records of radioactive material administration, interviews with persons involved with the case, and dose calculations. Because these efforts were initiated a considerable time after the exposures had taken place, there were uncertainties regarding the details of the case and the conditions under which the exposures occurred. The final dose estimates necessarily reflected these uncertainties, and consequently involved wider margins of uncertainty than are normally desirable in such assessments.

The NRC identified several factors that indicated a lack of sufficient awareness of the status of the visitors' accumulated doses during the visits to ensure compliance with applicable regulations, including applicable dose limits. A contributing factor that resulted in a dose above the applicable limit in the case of at least one of the visitors was a reluctance, on the part of the visitor, to comply with the licensee's instructions that were designed to minimize these doses.

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Important questions also arose regarding the use of data obtained from radiation surveys conducted in the patient's room to retrospectively estimate the doses received by the visitors. These concerns prompted an examination of the methods that may be used in controlling exposures of visitors, and in estimating the doses they receive during these visits. This RIS provides some guidance in these areas.

SUMMARY OF ISSUE

Patients undergoing nuclear medicine procedures, either diagnostic or therapeutic, as well as patients with brachytherapy implants, may be released from the hospital only if they meet certain conditions specified in NRC's regulations [10 CFR 35.75]. Patients failing to meet these conditions must be kept in the hospital until the radiation fields emanating from them diminish to the point where they meet the release conditions.

During their confinement in the hospital, patients are usually visited by family members and friends. Such visitors are considered to be members of the public, subject to the dose limits applicable to members of the public [10 CFR 20.1301]. The hospital's radiation protection staff are required to ensure that doses do not exceed these limits, and that all reasonable measures are taken to keep doses ALARA, given the circumstances of the case. Ensuring compliance with the dose limits implies that either the licensee has prospectively determined that conditions cannot lead to doses in excess of the limit, or the accumulated dose to date for each visitor is monitored, and appropriate controls are imposed based on the degree to which the accumulated dose approaches an action level or a limit. It should be pointed out that the success of these controls depends on the cooperation of the visitors and on their compliance with the licensee's instructions for minimizing the doses received.

In many situations involving exposure of visitors in patient rooms, the visitors are not provided with radiation-monitoring devices, such as self-reading pocket dosimeters, to measure the doses they receive during the visits, nor is such monitoring required by regulation. This is adequate if it is prospectively determined that the doses to visitors, under the specific conditions of the case, are unlikely to exceed any limit or action level. Otherwise, the hospital radiation protection staff should either issue personnel-monitoring devices to the visitors or must rely on the radiation survey data routinely conducted in the patient's room to estimate and monitor visitor doses in real time. Under certain conditions, and where adequate data are available, the doses received by the visitors may be calculated, but such calculations are complex, require a considerable amount of input data, and are normally performed only if it becomes necessary to undertake a retrospective dose assessment. The calculations are generally not suitable for controlling an ongoing exposure situation.

This RIS discusses some of the measures that may be used to maintain control and minimize doses to visitors, and also discusses the types of information that may be needed if a retrospective dose assessment becomes necessary. In addition, it provides guidance on the use of radiation survey data to estimate visitor doses in those cases where visitors are not provided with personnel-monitoring devices. This discussion and guidance is provided in the Appendix to this RIS.

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

This RIS does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C., 3501 et seq).

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.

Patricia K. Holahan, for /RA/
Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Attachments:
1. Appendix: Controlling Visitor Exposures
2. "List of Recently Issued NMSS Generic Communications"

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APPENDIX

CONTROLLING VISITOR EXPOSURES:

To assist in maintaining compliance with regulatory requirements, and in assessing doses to visitors when necessary, the following measures are recommended:

1. It has sometimes proven useful to mark the floor of the patient's room with clearly visible tape of an appropriate color to indicate areas where visitors may stand or sit without being in excessively high-dose-rate areas. Conversely, appropriately colored tape may be used to indicate areas that visitors should not enter, or should avoid whenever possible, because of high dose rates.

2. In planning for visitor exposures and for performing surveys, consideration should be given to the fact that the radiation fields around the patient could vary rapidly with location around the patient, depending on where the radioactive material is located within the patient's body and the nature and energy of the radiation. Frequently, the radiation field may be much higher on one side of the patient, compared with the other side. In nuclear medicine procedures, consideration should also be given to the fact that the radioactive material will generally move inside the body, with time, after administration of the dose. This movement within the body could cause significant changes over time in the radiation fields surrounding the patient, and therefore to the doses received by visitors. The distribution of radiation fields around the patient can be easily and quickly determined by appropriate surveys using a standard survey instrument. Survey locations and frequencies should be planned to identify these changes as they occur, allowing timely action in controlling visitor activities.

3. In cases where it is anticipated that the dose to a visitor will approach a substantial fraction of the applicable limit, it is important to increase control of exposures to avoid exceeding that limit. The limit is normally 0.1 cSv (0.1 rem), but in some cases may be 0.5 cSv (0.5 rem) or a higher pre-approved value. In such cases, it is usually prudent to provide affected visitors with self-reading pocket dosimeters that are checked periodically. These periodic dosimeter readings are added to previous readings to obtain each visitor's total dose to date. The reading of the dosimeter in roentgen or rad in such cases may be taken as a sufficiently accurate indicator of the person's dose in rem. Action must be taken if the running total dose for any visitor approaches a pre-established action level. These actions may be, for example, attempting to restrict visit durations or frequency, increasing the use of shielding, and/or confining the visitor to locations within the room that are not too close to the patient. An alternative approach to keeping a running total dose might be to attempt to restrict the total duration of all visits by a visitor to a time period based on a conservative estimate of the dose rate to which the visitor may be exposed. The time period would be chosen such that the total dose received during that period, assuming a conservatively high dose rate, will not cause any dose limit to be exceeded. Additional measures might include increased surveillance by the radiation protection staff, and training of the visitor in ways to

minimize radiation exposure. If for any reason it appears that a visitor's dose may exceed the applicable regulatory limit, the licensee should notify the NRC promptly to consider appropriate measures. Notification of the NRC is required if the dose has, or may have, exceeded any applicable limit. It should be noted that attempts to control visitor activities, such as restricting visit frequency and duration, may in some cases be difficult or impossible if the visitor refuses to cooperate. Explaining the risks from radiation exposure and the need to keeps doses within regulatory limits for health and safety reasons may be useful in some cases. However, as indicated above, the licensee should immediately notify the NRC if a situation develops in which a failure by a visitor to follow the licensee's instructions could to lead to doses that exceed the applicable regulatory limit.

4. Some licensees have adopted the practice of routinely issuing self-reading pocket dosimeters to all visitors who enter the patient's room, even in those cases where the doses received by the visitors are not expected to be significant. This practice has many advantages, including providing reliable control and easy monitoring of visitor doses, as well as producing a reliable record showing compliance with applicable limits. This option may be especially attractive if the licensee already uses such dosimetry for other purposes, but may be expensive to implement if the dosimetry is not already in use at the facility.

5. If it appears, in prospective assessments, or in re-evaluations during the visiting period, that circumstances are such that it may not be feasible to remain within the regulatory limit for some of the visitors, then several actions should be considered. The NRC Regional Office, or equivalent State regulatory authority, should be immediately notified of the situation and guidance sought on the appropriate regulatory mechanisms to be used for that situation. Close monitoring of the visitor using a self-reading dosimeter would be advisable. The key elements in these measures are that visitor doses should be estimated prospectively, and that dose trends be carefully monitored and action taken before any pre-established action level or limit is reached.

6. In the case of unsealed sources, such as those used in nuclear medicine procedures, there is the potential that the patient's room may become contaminated. The contamination may be on surfaces, or it may be airborne. The licensee should determine, in any given case, whether there exists a potential for such contamination. If there is such a potential, then appropriate surveys may be required to establish if the contamination exists, and if so, its magnitude. Should it be determined that visitors may have been exposed to unsealed radioactive material, suitable measurements and internal dose calculations should be considered, and the calculated internal doses added to the external doses to estimate the visitor's total effective dose equivalent (TEDE), to show compliance with 10 CFR Part 20 dose limits.

DATA COLLECTION IF RETROSPECTIVE DOSE ASSESSMENT IS ANTICIPATED:

A detailed retrospective dose assessment should be considered whenever available information suggests that the dose to any person may have exceeded an applicable limit, and when there is insufficient reliable data to directly assign a dose to the exposed visitor. The type of

assessment will depend in part on the degree to which the dose may have exceeded the limit, and also on the type and quality of the data available on which to base the assessment. Estimating dose retrospectively may be as simple as reviewing survey or dosimeter readings, if such data are of adequate quality and quantity. Alternatively, and especially if the measurements are inadequate or if the dose received may be high, calculations may be performed to estimate the doses.

The success and accuracy of any retrospective analysis depends on the availability of adequate information and data to permit a reliable reconstruction of the exposure situation and reasonably accurate estimation of the resulting dose. Therefore, as soon as it is realized that a retrospective dose assessment may be required, the licensee should assemble as much relevant information on the case as is possible. The types of information that should be assembled include, but are not limited to, the following:

a. All relevant survey data, including the survey readings, location of each survey, the time and date each survey was conducted, the type of instrument used, and the name of the person who conducted the survey. The models and serial numbers of the instruments used should be recorded, as well as the calibration date and calibration due date for each instrument.

b. If the affected persons were monitored with personal dosimeters, then the readings of the dosimeters should be provided, as well as the calibration certificates, the processor reports if the dosimeters were processed, and descriptions of where the dosimeters were placed on the monitored persons.

c. Details on the radioactive material involved, activity or amount administered (or implanted), date and time of administration, and initial surveys after administration. For implants, their shapes, sizes, and locations should additionally be provided.

d. Data on excretion of radioactive material by the patient if the material was administered in unsealed form. Although excreta are not normally collected and analyzed, any data on excretion patterns that may be available would be useful. These data may include volumes excreted (fecal and urinary), how collected, activity contained in the excreta or a measurement of the radiation fields emitted by these excreta, date and time excreted, and any surveys performed on the excreta. This type of information may help in retrospective assessment by permitting a better estimate of the amount of radioactive material that was retained in the patient's body during various periods of visitor exposures.

e. As much detail as possible on the movements of the exposed persons during the periods of exposure. This would include location with respect to the patient; time spent; and orientation with respect to the patient, (e.g. facing the patient and leaning on the bed, sitting on a chair, with side to the patient, and so on).

f. In the case of unsealed sources, any information that is useful for understand the

distribution of the radioactive material in the patient's body as a function of time. This may be obtained from the medical staff and/or the results of radiation surveys conducted close to the patient. The patient's medical condition at the time may significantly alter the pattern distribution and excretion of radioactivity, and this should be taken into account.

g. Detailed records and notes of any interviews that may have been conducted with affected persons, including the exposed persons, other visitors, and licensee and other staff. These interviews should be conducted as promptly as possible after the decision is made to retrospectively estimate doses.

h. Any information that indicates the level of contamination in the patient's room or that indicates the absence of such contamination. The information could also include any data from bioassays that may have been performed on a visitor.

The above information may not be needed in all cases involving retrospective dose assessment. However, the licensee should judge the scope of the expected assessments and collect the information as appropriate. The information should be collected promptly, because delays will blur recollections, and certain information may be short-lived, and may not be available if collection of that information is delayed. In addition, certain tests, such as internal contamination measurements, may not be possible after a certain time period has elapsed after the exposure. If these tests are to be successful, the decision to order them must be made soon after the exposures.

It should be clear from the above that mechanisms should be in place that promptly alert the licensee of an event that would initiate data collection and preparations for retrospective assessments. A procedure should also be in place to indicate the types of information to be assembled.

ESTIMATING VISITOR DOSES USING SURVEY DATA:

In February 2003, NRC issued a RIS entitled, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessment" [RIS 2003-04]. This RIS encouraged licensees, in certain situations, to use the effective dose equivalent in place of the deep dose equivalent (DDE) in the 10 CFR Part 20 definition of the total effective dose equivalent (TEDE). The reason was that in situations other than uniform whole body exposures, the effective dose equivalent is more closely related to the risks from radiation exposures than is the DDE. The aforementioned RIS noted that the guidance applies to all situations except those involving monitoring of individuals using personal dosimetry. This exception arises from the fact that special methods are required for interpreting the dosimetry results, so as to obtain reliable estimates of the effective dose equivalent, and the NRC reserved the right to approve each of these methods individually before authorizing its use.

The effective dose cannot be measured directly, and it is therefore necessary to estimate its value in any given situation on the basis of an appropriate measured quantity. In many situations involving visitor exposures, the only available measured quantity is the exposure rate, in roentgens (R) per hour, obtained from the required periodic surveys of the patient's room.

To determine the relationship of the survey readings to visitor dose, NRC has made detailed calculations of the radiation fields around a patient lying on a hospital bed and containing radioactive material administered during nuclear medicine or brachytherapy procedures. The calculations estimated the relationship between the readings of a survey instrument, in R/hr, at specified locations around the bed, and the effective dose rate that would be received by a person present at that location. These calculations serve as the technical basis for the guidance provided in this section. The details of this study were presented in Health Physics Journal, Volume 89, Number 3, 2005.
Based on these calculations, NRC will consider it acceptable to use the reading of a calibrated and correctly functioning survey meter, in R/hr, as directly indicating the effective dose rate to a visitor, in centisievert per hour (cSv/hr, rem/hr), who may be present at the survey location. The surveys should be performed without the presence of the visitor, and the survey instrument should be held at some distance (e.g. at arm's length) from the body of the person performing the surveys. Failing to take these precautions will lead to high survey readings and will, in turn, cause the effective dose rate based on these readings to be overestimated. This is a result of backscatter from the person's body contributing to the survey reading. Assuming no internal exposures, the effective dose determined in this manner may be considered to be equal to the TEDE for purposes of showing compliance with applicable dose limits.

It will be noted, on reviewing the Health Physics Journal article referred to above, that the results indicated that the effective dose may be underestimated by as much as a factor of 2 under certain exposure conditions if the survey readings in R/hr are equated directly to the visitor dose in cSv/hr (rem/hr). The results also showed that the effective dose may be overestimated in some circumstances. However, the calculations in the study were based on the assumption that the visitor was exposed while directly facing the patient. Exposure in other orientations, such as with one side or the back toward the patient, will result in significantly lower visitor doses for a given radiation field. Therefore, if the reasonable assumption is made that visitors will generally be exposed from varying directions during their visits, using a one-to-one correspondence between the survey readings and the visitor doses is not likely to significantly underestimate or overestimate the visitor's dose, and is expected to yield estimates of the effective dose with an accuracy considered acceptable for this type of assessment.