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AGENCY INFORMATION NOTICE 09-02

RELEASE OF PATIENTS TREATED WITH RADIOPHARMACEUTICALS

Addressees

All medical use licensees authorized to administer radiopharmaceuticals to patients or human research subjects.

Purpose

The Massachusetts Radiation Control Program (Agency) is issuing this information notice to provide guidance to medical licensees who need to meet the regulatory requirements as specified in 105 CMR 120.540 relating to the release of patients containing unsealed radioactive material.

While no written response is required, it is expected that recipients will review the information for applicability to their activities and consider implementing appropriate actions that may be needed.

Background

Issue 1 - Radiation and contamination exposure to infants and children.

In May 2008, the US Nuclear Regulatory Commission (NRC) issued *Regulatory Issues Summary* (RIS) *2008-11, Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration Of Iodine-131*. A copy of the pertinent text from this document is attached as Appendix 1. The RIS describes a recent finding by the International Commission on Radiological Protection that the internal dose to the thyroid for infants and young children who may come in contact with a patient recently administered therapeutic quantities of I-131, such as oral sodium iodide I-131, could be significant. NRC's guidance for medical institutions on patient instructions recommends, among other things, that medical institutions not release patients if there is a risk that infants or children would be exposed should the patient go home.

Issue 2 - Detection of contaminated items in household trash

Many solid waste management facilities in Massachusetts and elsewhere, such as landfills and transfer stations, are performing radiation surveys on arriving vehicles hauling household trash. As a result, the Agency is receiving an unacceptably large number of legally-required notifications of the detection of radioactive materials in these loads. Each instance of detection is investigated by the Agency and the involved city/town or waste hauler to identify the radioactive material causing the alarm and to ensure that it is controlled and disposed of properly. The large number of these events (around 120 each year) has resulted in significant resource impacts to all parties involved.

These investigations usually include dismantling the trash load and opening, examining and sampling the contents of the trash bags which contain the radioactive material, potentially exposing investigators to conventional and biological hazards that are in addition to any radiological hazards. Most of these occurrences turn out to be due to excreted medical radioisotope contamination on items discarded by nuclear medicine patients in their household trash. In many cases, the individual patient may be identified by other items found in the trash bag, such as discarded mail. When this occurs, Agency inspectors typically visit the household to counsel the patient or his/her family against discarding radiologically contaminated material in household trash. Some municipalities and transfer stations are considering passing on the costs associated with these investigations and cleanups to the responsible party.

In a recent case, a large tractor trailer truck belonging to a Massachusetts municipality carrying 28 tons of trash was turned away from a solid waste handling facility when radiation was detected in the load. The radioactive material was located near the front of the trailer, and almost the entire 28 tons of trash had to be dumped out at the town facility and searched by Agency and town employees. Eventually, a trash bag containing a dozen or so radioactive adult diapers was found and segregated.

Action Requested

Issue 1 - Recommendations for reducing exposures to infants and children

Please review your written and oral patient release instructions to ensure they contain appropriate precautions regarding exposure to infants and children from radiation and contamination. Consideration should be given to extending a patient's stay if acceptable alternatives are not available to avoid contact with infants and children following therapeutic administration of radiopharmaceuticals. There are documented cases from other states regarding medical institutions recommending that patients check into a hotel for a period of time to avoid contact with children; the Agency discourages physicians from suggesting patients use hotels as a means of separating them from infants or young children, since that practice has proven to cause significant contamination of hotel property and raises concerns on the issue of exposures to housekeeping staff and guests.

Issue 2 - Clarifications on waste disposal by patients administered radiopharmaceuticals

Please ensure that your written and oral patient release instructions contain a section cautioning the patient against discarding any potentially contaminated excreta into their household trash. Disposal through the sanitary sewer should be emphasized as the appropriate alternative, because excreta from patients undergoing medical diagnosis or therapy is expressly exempted from the limitations on sewer disposal found in 105 CMR 120.253(A). Instructing the patient to bag and store waste items that cannot be flushed to the sewer would also be an acceptable alternative to disposal in regular trash, provided that the patient is given an estimate of when the material will have decayed so that it can be treated as regular trash. In addition to minimizing public dose and investigation costs, it would also help protect the privacy of a patient, which is frequently compromised during a search of his or her trash. It would also minimize the unnecessary exposure to investigators from other hazardous materials, and would minimize the possibility that an individual patient or a medical facility might be invoiced by a waste management facility for their cost of the investigation.

Sincerely,

Robert Walker

Robert Walker, Director
Radiation Control Program

Encl (1)

APPENDIX 1

Excerpt of Pertinent Information From NRC Regulatory Issue Summary 2008-11

PRECAUTIONS TO PROTECT CHILDREN WHO MAY COME IN CONTACT WITH PATIENTS RELEASED AFTER THERAPEUTIC ADMINISTRATION OF IODINE-131

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

NRC is issuing this regulatory issue summary (RIS) to inform licensees of supplemental guidance to NUREG 1556, Volume 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses" on the precautions that should be taken to protect infants and young children who may come in contact with patients released after administration of therapeutic amounts of iodine-131 (I-131), such as oral sodium iodide I-131. No specific action or written response is required. NRC is providing this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate.

BACKGROUND

On January 29, 1997, NRC published a final rule in the *Federal Register* on the "Criteria for the Release of Individuals Administered Radioactive Material" (62 FR 4120). This rule amended the patient release criteria in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," replacing the activity-based or dose-rate-based release limit with a limit based on projected radiation doses to other individuals exposed to a patient released after therapeutic administration of radionuclide, such as oral sodium iodide I-131. These dose-based release limits used assumptions that the internal doses for individuals who may come in contact with released patients were very small compared with doses from external exposures. Also, these criteria were consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) at the time.

However, in ICRP Publication 94 "Release of Patients after Therapy with Unsealed Radionuclides," published in 2004, ICRP cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," which states

that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

SUMMARY OF ISSUE

The regulations in 10 CFR 35.75 permit a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)." However, as described in the Background section of this RIS, for some I-131 therapies, such as oral administration of sodium iodide I-131, the ICRP cautions that the internal dose to infants and young children who may come in contact with a released patient could be significant.

NRC has developed guidance on recommended instructions that licensees should give I-131 therapy patients who are about to be released from licensee control and who will or may have contact with infants and young children. The guidance recommends that licensees consider not releasing patients, administered I-131, whose living conditions may result in unnecessary exposure of infants and young children.

The guidance mentioned above may be found in Enclosure 1 of this RIS and at the NRC's Web page entitled "Medical Uses Licensee Toolkit" at ttp://www.nrc.gov/materials/miau/med-usetoolkit.html. Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses."

CONTACT

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

/RA/
Robert J. Lewis, Director
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and State Agreements
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Enclosures:

1. Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131

Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131

The Nuclear Regulatory Commission (NRC) regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)." For this guidance document, the individual or human research subject to whom the radioactive material has been administered is called the "patient." Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses."

NRC's current patient release criteria were based, in part, on the assumption that internal doses to an individual from a patient released after therapeutic administration of a radionuclide, such as oral sodium iodide I-131, was small compared with doses from external exposures.

However, in 2004, the International Commission on Radiation Protection (ICRP), in ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides," cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," which states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

Section 35.75(b) of 10 CFR Part 35 requires the licensee to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In consideration of the more recent ICRP recommendations described above, the licensee, in implementing the requirements on written instructions in 10 CFR 35.75(b), should take into account whether the released patient may come in contact with infants or young children. In such a situation, in order to protect infants and young children from possible I-131 contamination, the licensee should provide the patient with additional instructions. These additional instructions should include:

- A recommendation to have patients avoid direct or indirect contact (e.g., indirect contact includes contamination from shared living space) with infants and young children for a specific period of time (e.g., consider having children stay outside the home with other family members).
- A recommendation for patients to have adequate living space at home (e.g., bedroom, bathroom) that can be used exclusively by the patient for a specific period of time.

- Information on the potential consequences, if any, from failure to follow these recommendations.

Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children