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April 14, 2010

The Honorable Edward J. Markey
Chairman, Subcommittee on Energy and Environment
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Rep. Markey:

This letter is in response to your request dated March 18, 2010, seeking additional information on Wisconsin's regulation and inspection of facilities that treat patients or human research subjects with radioactive iodine (I-131). Please note that the Wisconsin Administrative Code chapter on Radiation Protection (DHS 157) can be found on our website at http://dhs.wisconsin.gov/dph_beh/RadioactiveMat/Index.htm. The state of Wisconsin assumed regulatory authority over byproduct materials, which includes Iodine-131, in August 2003. Prior to that time, the Nuclear Regulatory Commission regulated the use of I-131 in Wisconsin. All responses in this letter cover the time period August, 2003 to present. Wisconsin's program has been found to be adequate to protect public health and safety and compatible with U.S. Nuclear Regulatory Commission (NRC) regulations.

The authority to regulate the safe use of radiation is with the Radiation Protection Section (RPS) which is part of the Wisconsin Department of Health Services. The RPS licenses and inspects the use of radioactive materials, registers and inspects x-ray machines, as well as maintains emergency preparedness and environmental monitoring programs related to multiple nuclear power plants.

If you need additional information or need further clarification, please do not hesitate to contact me via phone (608-267-4792) or email at paul.schmidt@wi.gov , or Cheryl Rogers via phone at (608-266-8135) or email at cheryl.rogers@wi.gov . Thank you for your letter.

Sincerely,

Paul Schmidt

Paul S. Schmidt, Chief
Radiation Protection Section
Wisconsin Department of Health Services

Question 1: How many I-131 licensee facilities are overseen by your State?

Response 1: Wisconsin has 59 medical licensees authorized to administer I-131 in therapeutic quantities. Of these, 53 are authorized to administer I-131 for thyroid carcinoma therapy.

Question 2: How often does your State perform sampling inspections each of these I-131 licensee facilities?

Response 2: Wisconsin inspects its medical licensees that administer therapeutic doses of I-131 every one to three years. Inspection frequencies are based on the type and scope of the program and are sometimes more frequent than the NRC's. Large medical institutes and university-run hospitals hold Medical Broad Scope licenses and are inspected every 1-2 years (compared to the NRC frequency of 2 years). Other medical licensees who administer therapeutic doses of I-131 have an inspection frequency of once every three years.

Question 3: What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 3: Wisconsin follows all applicable NRC guidance outlined in Inspection Manual Chapter 2800 (IMC 2800). For medical facilities that administer I-131, Wisconsin's inspection policy meets the criteria given in NRC Inspection Procedure 87131 "Nuclear Medicine Programs, Written Directive Required" (IP 87131). Inspections are "performance based" and include observations of the licensee's use of radioactive material, interviews with individuals who handle or oversee the use of radioactive material, and review of selected records. With respect to the release of patients, IP 87131 requires, in part, that the inspector determine by direct observations and, if needed, review of selected records that the licensee is knowledgeable about patient release criteria and is in compliance with the Wisconsin patient release criteria in DHS 157.62(8). Inspectors also verify that the licensee's evaluation for release of the patient meets the requirements in DHS 157.62(8). The inspectors routinely review a sample of the licensee's written instructions to the patient to determine if the instructions are adequate to meet Wisconsin rule requirements.

Question 4: NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients"[4]. For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 4: The decision to release the patient is the authorized user physician's decision based on his or her discussion with the patient. Part of this decision is an evaluation by the physician that the patient is able and willing to follow instructions, including radiation precautions. DHS provides patient release guidance to licensees in WISREG-1556, Vol. 9, Rev. 1, Appendix U. This document is equivalent to NRC's NUREG-156, Vol. 9, Rev 2, Appendix U. Wisconsin's version can be found at http://dhs.wisconsin.gov/dph_beh/RadioactiveMat/Index.htm. This

document provides licensees with general objectives rather than prescriptive directions to use in their instructions. The objectives include maintaining distance from people, minimizing time spent in public places, precautions to reduce the spread of radioactive contamination and the length of time each of the precautions should be in effect. WISREG-1556, Vol. 9, Rev. 1, Appendix U requires more specific instructions for patients who might be breast-feeding, including the biological consequences to the child for failing to interrupt or discontinue breast-feeding. As part of the licensing process, most medical licensees commit to following the patient release guidance in WISREG-1556, Vol. 9, Rev. 1, Appendix U.

In addition, Wisconsin has issued to our licensees the same generic communications that NRC has issued, such as Information Notice (IN) 2003-22, Supplement 1, which was issued in July 2009 and Regulatory Issue Summary (RIS) 2008-11 "Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131, dated May 12, 2008. Wisconsin's dose limits and restrictions are required to be compatible with those of the NRC's.

Question 5: In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

Response 5: During inspections of I-131 programs at medical use facilities using quantities that require a determination of whether to release the patient under DHS 157.62(8), our inspectors routinely evaluate the licensee's patient release program to verify compliance with State of Wisconsin requirements. This includes determining if the licensee is knowledgeable about release criteria, maintains appropriate records to document the basis for authorizing the individual's release, and provides adequate instructions to patients. During inspections, the inspector reviews a representative sample of cases for compliance. Further documentation is requested if deficiencies are noted. These documents are reviewed at the licensee's site during the inspection. We do not keep a specific record of how many times inspectors have requested such records. The decision to release the patient is the authorized user physician's decision based on his or her discussion with the patient. Occasionally, the physician will decide to keep a female patient in the hospital for treatment due to small children living in the home.

Question 6: In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

Response 6: Wisconsin requires licensees to provide instructions to patients who are administered more than 7 millicuries of iodine-131 and routinely inspects to ensure this is accomplished. These instructions are signed by the patient acknowledging the release conditions according to the instructions they have been given. During inspections, the inspector reviews a representative sample of cases for compliance. Wisconsin does not keep a specific record of how many times inspectors have requested I-131 patient release records.

Question 7: In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 7: Wisconsin has not found any cases in which a required dose calculation was not performed by the licensee or the licensee did not provide written instructions to the patient on how to maintain doses to other individuals as low as reasonably achievable. In all cases reviewed, the licensees demonstrated that the patients were allowed to be released per DHS 157.62(8).

Question 8: In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8: Wisconsin believes that a licensee is capable of calculating conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors. The information concerning the patient's planned activities, housing, and who will be in the immediate vicinity is exchanged between the authorized user physician and the patient. In any case, licensees rely on the information provided by the patient.

Question 9: Has your State ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

Response 9: Wisconsin does not maintain records regarding the destinations of patients released from medical institutions. Instead, during onsite inspections at medical facilities, inspectors review a representative sample of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances whereupon the patient was released and the content of the instructions the patient received. These reviews are used to verify compliance with the regulations regardless of the patient's final destination. Wisconsin is aware that it is extremely rare for patients treated with I-131 to be kept in the hospital for additional time.

Question 10: In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Response 10: As discussed in responses above, Wisconsin inspectors evaluate the licensee's program for patient release to verify compliance with Wisconsin rule requirements. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. We have not found any situations where the dose calculations were not performed.

Question 11: What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

Response 11: Wisconsin does not have any disclosure rules for patients to give to hotels. Instead, we recommend that our licensees refer to the NRC's guidance for medical use licensees which contains general objectives rather than prescriptive directions. Wisconsin requires the instructions to include actions the licensee recommends that meet the general objective of maintaining doses to other individuals as low as reasonably achievable, but licensees are not required to give patients explicit instructions to provide to hotel management. Guidance in NRC's NUREG-1556, Volume 9, Revision 2, Appendix U describes in general terms how licensees can meet this performance-based objective. This document is reviewed and updated periodically by the NRC and we make changes at that time if any are necessary.

Question 12: Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels: If so, please provide copies.

Response 12: No. However, we do routinely send to our licensees, as applicable, any generic communications that NRC has issued, such as Information Notice (IN) 2003-22, Supplement 1, which was issued in July 2009. Licensees should consider the destination to which a patient may be released, consider the potential for exposure to others, and provide release instructions specific to the patient's circumstances and other considerable related guidance to licensees about completing the required dose assessments. The principal guidance document we refer licensees to is NRC's NUREG-1556, Volume 9, Revision 2 "Program-Specific Guidance About Medical Use Licenses", which has been supplemented by a 2008 generic communication (RIS 2008-11).

Question 13: Are your licensees required to report to you any instances in which released I-131 patients caused radiation exposure to family members or members of the public?

Response 13: Wisconsin does not require such a report. Once a patient is released under DHS 157.62(8), there are no further requirements for either the patient or the licensee.

Question 14: Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.

Response 14: The only correspondence we have is the routine review of our program through the Integrated Materials Performance Evaluation Program (IMPEP). These reports can be found on the NRC's website: http://nrc-stp.ornl.gov/rulemaking.html#WI

Question 15: Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Response 15: If documents required under DHS 157.62(8) are missing or incomplete, then it is considered to be a violation of Wisconsin requirements and would be identified and cited as such by inspectors. If the documentation is initially unclear, the inspector will ask additional questions to determine if a violation has or has not occurred. Therefore, it is reflected in the inspection report accordingly. Wisconsin is not aware of any cases where released I-131 patients went to a hotel.