ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION RESPONSE
TO JANUARY 14, 2010, INFORMATION REQUEST

U.S. Nuclear Regulatory Commission (NRC) Response to January 14, 2010, Information Request

Question 1:

In your letter to me you cite the 2006 report of the National Council on Radiation Protection (NCRP), No. 155, which found that with "adequate instructions," no member of the public is likely to be exposed to more than 5 millisieverts (mSv) of radiation by a released patient. However, NCRP No. 155 also says that for children and pregnant women, the acceptable dose rate is not 5 mSv, but one-fifth that: "Pregnant women and 'children *shall not* exceed 1 mSv." Later in your response, you state that "There is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children," yet you also state that NRC's release requirements are consistent with NCRP. Can you please clarify the NRC position on this? Does NRC agree with the NCRP's recommendation for a lower dose limit to pregnant women and children? If not, why not? If so, then how is that recommendation factored into NRC's regulations regarding the release of patients treated with radionuclides?

Response 1:

The NRC's dose limit to all members of the public from radiation from patients is 5 mSv. This is higher than the NRC's public dose limit of 1 mSv from other sources of radiation and NCRP's recommended level for pregnant women and children. The NRC incorporated this difference in dose limits into its regulations in response to several petitions received from the medical community between 1991-1994 that indicated lowering the dose limits from the release of patients would place an unacceptable burden on the medical community and interfere with medical treatment. These regulations were finalized in 1997.

In 2005, the agency received a petition for rulemaking that requested, among other things, that the NRC revoke the 1997 amendment, insofar as it allows the release of patients from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their bodies, and particularly mentioned the impacts on family members and children. In May 2008, the NRC denied the petition and stated that the rules did not require revision but that guidance on maintaining doses as low as reasonably achievable (ALARA) to other individuals would be strengthened.

The NRC believes it has incorporated the NCRP's objective into its regulations, which is to provide a reasonable set of measures to achieve adequate public protection. The NRC has done this by requiring 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 ALARA if the total dose equivalent to any other individual is likely to exceed 1 mSv. The NRC believes that the application of the dose limits together with the principle of keeping all radiation exposures as low as reasonably achievable, results in an adequate degree of protection and a degree of protection that is significantly greater than could be attained by relying on the dose limit alone. This is one reason that NRC regulations under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," not only establish a dose limit for patient release but also a requirement to provide instructions on actions recommended to keep doses to others ALARA.

At the direction of the Commission, the agency is currently in the process of engagement with stakeholders and interested parties to obtain feedback on key issues and to develop the technical basis for possible revision of the NRC's radiation protection regulations, as appropriate and scientifically justified. A set of facilitated public workshops are planned for later this year. The staff has noted to the Commission that this topic may be raised by stakeholders as a point of discussion.

Question 2:

How many iodine-131 (I-131) licensee facilities are there in the United States?

Response 2:

There are an estimated 500 NRC and 3,200 Agreement State medical use licensees that use I-131 in therapeutic quantities (i.e., quantities that exceed 30 microcuries, which require a written directive).

Question 3:

How often does the NRC perform sampling inspections at each of these I-131 licensee facilities?

Response 3:

The NRC inspects its medical licensees that administer therapeutic doses of I-131 every two to three years. Inspection frequencies are based upon the type and scope of the program. Typically, large medical institutes and university-run medical facilities hold Medical Institution Broad Scope licenses. These licenses require an inspection frequency of once every two years. Another type of medical license that administers therapeutic doses of I-131, referred to as a Medical Institution - Written Directive Required, requires an inspection frequency of once every three years.

Question 4:

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 4:

The NRC specifies the inspection criteria for a facility requiring written directives, including those facilities that administer I-131, in Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required" (Attachment 1). Regarding 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 NRC patient release criteria in 10 CFR 35.75. NRC inspectors also verify that the licensee's evaluation for release of the patient meets the requirements in 10 CFR 35.75. The inspectors review a sample of the licensee's written instructions to the patient to determine if the instructions meet current NRC requirements.

Question 5:

Appendix B of NCRP Report No. 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." 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 NRC given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 5:

NRC guidance to medical use licensees, NUREG-1556 Volume 9, Revision 2, Appendix U "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials," provides general objectives rather than prescriptive directions as provided in NCRP Report No. 155. The NRC requires the instructions to include actions that the licensee recommends to patients to meet the general objective of maintaining doses to other individuals as low as reasonably achievable. There are many ways of meeting these objectives, and the NCRP approach is one possible way. There is nothing that precludes the licensee from adopting the NCRP guidance.

NRC's Appendix U provides licensees with areas to consider in the instructions that they provide to patients who have received radiopharmaceutical administrations or implants. The instructions should be specific to the type of treatment, include information for individual situations, and include the name and telephone number of a knowledgeable contact person, in case the patient has any questions.

The guidance suggests that licensees provide instructions to patients on maintaining distance from other persons, including separate sleeping arrangements; minimizing or avoiding time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events); precautions to reduce the spread of radioactive contamination; and the length of time each of the precautions should be in effect. It also provides guidance concerning breast-feeding, and sample calculations to assist licensees in performing patient release calculations.

Additionally, in response to ICRP Publication 103 and to highlight concerns involving protection of infants and young children, the NRC provided supplemental guidance to NUREG-1556 Volume 9, Revision 2, Appendix U. This guidance is contained in 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. The supplemental guidance recommends that in order to protect infants and young children from possible I-131 contamination, the licensee should recommend to patients that they avoid direct or indirect contact with infants and young children and maintain an adequate living space (bedroom and bathroom) that can be used exclusively by the patient. The RIS also recommends that licensees inform patients of potential consequences, if any, from failure to follow these recommendations. The supplemental guidance also highlights that licensees should consider not releasing patients administered I-131 whose living conditions may result in the contamination of infants and young children.

Also, in July 2009, the NRC issued Supplement 1 to NRC Information Notice (IN) 2003-22 "Heightened Awareness for Patients Containing Detectable Amounts of Radiation From Medical

Administrations" to provide additional information regarding medical-use licensees' provision of instructions and information to individuals released in accordance with 10 CFR 35.75 and to remind licensees of the importance of various NRC requirements, guidance, and communications on this topic. The IN stresses that under current regulations, a licensee may release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, 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.

Furthermore, over the years the NRC has worked with the Society of Nuclear Medicine and the Centers for Disease Control and Prevention (CDC) to enhance and better understand patient release issues. In 1987, the NRC and the Society of Nuclear Medicine co-published a pamphlet that provided information for patients receiving treatment with radioiodine, which contained blanks for the physician to fill in the length of time that each instruction should be followed. The NRC also collaborated with the CDC in 2006 and 2007 to assess how health care facilities informed patients released in accordance with 10 CFR 35.75 about radiation and public security checkpoints, such as border crossings. The findings from the study, which appeared in *The Journal of Nuclear Medicine* in December 2007, were the impetus for the NRC issuing IN 2003-22, Supplement 1, in July 2009.

Question 6:

> **In the past ten years, how many times has NRC, 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 6:

During every inspection of I-131 programs at medical use facilities using quantities that require a determination of whether to release the patient under 10 CFR 35.75, NRC inspectors evaluate the licensee's patient release program to verify compliance with NRC 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. Further documentation is requested if deficiencies are noted. These documents are reviewed at the licensee's site during the inspection. NRC does not keep a record of how many times inspectors have requested records.

Question 7:

> **In the past ten years, how many times has NRC, 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 7:

The NRC does not require licensees to keep a copy of the instructions provided to patients unless the patient is a breast-feeding female, and the dose to the infant or child from continued breast feeding would exceed 5 mSv; retention of these instructions in such a situation is required by 10 CFR 35.75(d). If the licensee does keep a copy of the instructions provided for an individual

patient, the inspector may review it when the release methodology is reviewed. Also, many licensees have examples of the guidance they provide on hand for inspection. When the licensee does not keep copies of instructions for each patient or appropriate instruction models are not available at the licensee's facility, the inspector determines if the licensee is knowledgeable about release criteria and communicating adequate instructions to patients to determine if the licensee is in compliance with the regulations. NRC does not keep a record of how many times inspectors have requested records.

Question 8:

> **In the past ten years, how many times has NRC 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 8:

In the past 10 years, the NRC has found a small number of 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. However, retrospective dose analysis has shown that the patients were allowed to be released per 10 CFR 35.75.

When these cases were identified, the NRC took enforcement action and required the licensee to implement corrective actions to prevent future occurrences. For example, the NRC issued Severity Level IV violations of 10 CFR 35.75 against the following licensees that failed to perform individualized analyses: South Jersey Hospital-Millville, Bridgeton, Newcomb (2001), Forbes Regional Hospital (2005), and Central Jersey Radiologists (2008). See Attachment 2 for detailed information on these violations.

Question 9:

> **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 9:

The NRC staff believes that a licensee can calculate conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors.

Question 10:

Has the NRC 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 10:

The NRC does not maintain records regarding the destinations of released patients from medical institutions. Instead, during onsite inspections at medical facilities, inspectors review a 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 counseling the patient received. These reviews are used to verify that public safety was ensured regardless of the patient's final destination.

Question 11:

In patients with doses in excess of the default limits, has the NRC 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 NRC 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 11:

As discussed in response to questions four and six, NRC inspectors evaluate the licensee's program for patient release to verify compliance with NRC requirements. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. The NRC provides examples of violations of 10 CFR 35.75 in response to question eight.

Question 12:

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 12:

NRC guidance to medical use licensees provides general objectives rather than prescriptive directions. NRC 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 NUREG-1556, Volume 9, Revision 2, Appendix U describes in general terms how licensees can meet this performance-based objective. The NRC staff intends to review the guidance in this area, based on an existing internal commitment.

Question 13:

The health departments of Minnesota, Washington State, and New York City have all issued advisories warning licensees not to send radioactive patients to hotels. Is it the NRC's view that these advisories were uncalled-for? If not, why has the NRC issued no such guidance?

Response 13:

The NRC has determined that issuance of an advisory warning NRC licensees not to send radioactive patients to hotels is not necessary given the regulation's flexibility to be applied to a variety of individual patient situations. The NRC believes that the current regulations provide adequate protection to members of the public. NRC regulations do not limit the location to which an individual may be released and allow a licensee to release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, as emphasized in a generic communication to licensees in a supplement to IN 2003-22, 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. The NRC has provided other considerable guidance to licensees about completing the required dose assessments. The principal guidance document is NUREG-1556, Volume 9, Revision 2 "Program-Specific Guidance About Medical Use Licenses" . This document has been supplemented by a 2008 generic communication (RIS 2008-11), and NRC staff intends to review the guidance relating to the release of I-131 therapy patients to hotels.

Question 14:

In 2002, the NRC Commissioners voted against receiving reports of instances in which released I-131 patients caused radiation exposure to family members or members of the public. How can NRC be confident that its rule is not causing harm when it has declared its unwillingness to be notified of events in which harm occurs? Do you believe that this proposal should be reconsidered? Why or why not?

Response 14:

NCRP Report No. 155 summarizes the work of numerous investigators who have published on the subject of patient release. The report states that "the release of patients treated with therapeutic amounts of radiopharmaceuticals is not likely to expose any member of the public, inclusive of both external and internal dose contributions, [to] >5 mSv (0.5 rem) *provided that adequate instructions are provided at discharge to the patient and the family members*" [Emphasis added]. As such, the likelihood of a member of the public receiving a radiation exposure of 10 times (50 mSv or 5 rem) the allowable limit in 10 CFR 35.75 from a released patient appears to be very low. Therefore, the likelihood of a member of the public receiving a harmful radiation exposure (e.g., 1 Sv or 100 rem) is even more unlikely. As discussed in response to question four, the NRC does inspect to ensure patients are, in fact, given instructions. The Commission is not aware of any scenario in which a member of the public received a 50 millisievert (5 rem) exposure from a released patient. Based on this information, the Commission does not believe that this proposal should be reconsidered.

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 10 CFR 35.75 are missing or incomplete, this is considered to be a violation of NRC requirements and would be identified by NRC's inspectors. If the documentation is initially unclear, the inspector will ask additional questions to determine if a violation has occurred or not. Therefore, NRC's inspection reports provide a record of missing or incomplete documents.

Only a few cases were found where licensees violated 10 CFR 35.75. In some cases, licensees failed to perform surveys to assess I-131 patients prior to release. In other cases, licensees did not provide documentation for dose assessments because the licensee misinterpreted the guidance. These cases are documented in inspection reports in Attachment 2.

Two cases were identified in which patients were released to hotels. See Attachments 3-4 for detailed information on these cases.

Attachments:
1. NRC Inspection Manual – Inspection Procedure 87131
2. 10 CFR 35.75 Severity Level IV Violations for I-131 Therapy
3. Case 1 – Patient Release to Hotel
4. Case 2 – Patient Release to Hotel

There is an additional document that is Official Use Only that will come to you under separate cover.