U.S. Nuclear Regulatory Commission Responses to Questions in October 13, 2009 Letter

Questions related to patient release criteria:

Question 1:

> **Do you plan to revisit the issues raised in Mr. Crane's petition? If so, please detail your plans. If not, please explain why you believe it makes sense for the U.S. regulations on this important public health matter to be so much less protective of public health than the European Union's.**

Response 1:

At this time, the U.S. Nuclear Regulatory Commission (NRC) is not planning to revisit the issues raised in Mr. Crane's petition. The NRC does not consider the U.S. regulations to be less protective of public health than the European Union's. A key consideration in NRC's conclusion is the 2006 National Council on Radiation Protection and Measurements (NCRP) Report No. 155, which summarized the work of numerous investigators who had published on the subject of patient release. The report stated 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 [millisievert] (0.5 rem) *provided that adequate instructions are provided at discharge to the patient and the family members*" [Emphasis added]. This statement directly supports the NRC requirement in 10 Code of Federal Regulations (CFR) 35.75(b) for the provision by the licensee of instructions, including written instructions, on actions recommended to keep doses to other individuals as low as reasonably achievable (ALARA), if the total effective dose equivalent (TEDE) to any other individual is likely to exceed 1 millisievert (0.1 rem).

Question 2:

> **It is my understanding that International Basic Safety Standards on radiation protection lists one of the criteria for an acceptable radiation protection regime to be the hospitalization of patients with more than 30 millicuries of I-131 in their bodies. Why did the NRC choose to promulgate a rule that was not consistent with these international radiation safety standards?**

Response 2:

The International Atomic Energy Agency (IAEA) is currently considering revisions to its standards in "The International Basic Safety Standards for Protection Against Ionizing Radiation," which was last revised in 1996. Relevant international standards, such as those in the International Basic Safety Standards (BSS), are considered when NRC promulgates domestic rules; the NRC does not simply adopt non-binding standards. The NRC, in its rulemaking activities, uses relevant factors and considers various international standards and informational documents as points of reference. When appropriate, the NRC may choose to adopt international standards.

In 1996, the NRC regulations related to patient release were consistent with the provisions in the BSS. However in 1997, the NRC updated its requirements to a more risk-informed and performance-based approach. Accordingly, the NRC considered it appropriate to revise the patient release requirements in 10 CFR 35.75 to be dose-based, rather than to maintain the quantity-based criteria that had previously been in place. The NRC believes that this dose-based requirement provides for adequate protection of members of the public.

Question 3:

> **At the time it promulgated the new rules, in 1997, NRC stated that releasing a patient with more than 30 millicuries of radiopharmaceutical content, would require an individualized analysis of the patient's living situation to determine the probable dose to others. Only if that dose did not exceed 500 millirem could the patient be released. But in recent issuances, NRC has been silent on the individualized analysis, suggesting this evaluation is not mandatory. Does NRC enforce the requirement of an individualized analysis and calculation of radiation dose for administrations of I-131 and other radioisotopes in excess of 30 millicuries, and if so, how?**

Response 3:

The NRC regulations in 10 CFR 35.75 permit the licensee to authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material, if the TEDE to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem).

The release of the patient can be based either on administered activity, measured dose rate, or patient-specific dose calculations based on individualized living situations. Therefore, the NRC does not require specific dose calculations for all patients. The 2008 NRC guidance found in NUREG-1556 Volume 9, Revision 2 describes acceptable criteria that a licensee can use to release a patient administered byproduct material or implants containing byproduct material in accordance with regulatory requirements.

Using the current inspection guidance found in the NRC's Inspection Procedure 87131 published in 2002, inspectors evaluate the licensee's program for patient release to verify compliance with NRC requirements in 10 CFR 35.75, including 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. If the NRC concludes that the licensee was not in compliance with the regulations, enforcement actions can be taken in accordance with Revision 6 of the NRC's Enforcement Manual dated December 22, 2008. Additionally, the NRC can require the licensee to implement corrective actions to prevent future occurrences.

Question 4:

How is it possible to justify sending individuals who have been treated with I-131 to hotels, where cleaning staff and subsequent guests would have no way of knowing that the occupied room was contaminated? Isn't it possible that all the linens in the hotel would risk becoming contaminated if the linens used by the treated individual are laundered with the rest of the hotel's laundry? Isn't it possible that some of the resultant exposed individuals would be pregnant women, infants or young children?

Response 4:

The NRC believes the current regulation provides adequate protection to members of the public. The regulation does not limit the location to which the individual may be released nor does it specifically address the release of patients to hotels. The NRC has determined that the dose-based limit of 5 millisievert (0.5 rem) does not pose an unacceptable risk to any member of the public, and that the dose to any member of the public from a patient treated with I-131 and released in a manner that complies with the regulation would not likely approach the dose-based limit.

It is possible for linens to become contaminated, and it is possible for the contamination to result in exposure to pregnant women or young children. But the NRC believes that the resultant dose from contamination would be very low and would not pose a significant safety hazard.

Question 5:

A European Commission document entitled "Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)" states that "sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days. After two or three days, however, the patients' residual activity will be sufficiently low to justify their discharge from the hospital."

a. Does the Commission agree or disagree with this statement? If the Commission disagrees, why?

b. If the Commission agrees with the statement made in this EC document, then why has it approved a rule which would allow for such exposures?

Response 5:

The NRC disagrees with this statement. Sending patients home immediately after the administration of I-131 can be justified in certain situations because the resulting excretion and external radiation do not result in high doses to other individuals in contact with the patient.

The NRC established criteria based upon the individual most likely to receive the highest dose from the patient. The NRC recognized that some patients, during the course of their daily lives,

do not come in close contact with the other individuals for very long or very often, and these patients could return home more quickly. The NRC also recognized that other patients would be motivated to isolate themselves for short periods of time, if it meant the patient could be released from the hospital sooner. The NRC believed this motivation, combined with information on how to reduce radiation exposure to others, would be sufficient to prevent high doses to other individuals. The NRC determined that in certain instances it would be appropriate to release these patients, but in other instances the physician may determine that it is in the patient's best interest to remain in the hospital. The NRC requirements in 10 CFR 35.75 are intended to allow physicians and licensees to assess each situation, thereby providing the best overall treatment for the patient.

Question 6:

> **In its 1997 rulemaking, the Commission stated that "In the case of the released patient at home, therapeutic administrations usually occur no more than once in a year and probably no more than once in a lifetime; but in the case of a hospital, large therapeutic administrations are done repeatedly on many patients. Therefore, areas in hospitals have the potential for contamination from many patients, and people who frequent the hospital (e.g., clergy or a hospital orderly) have the potential to be exposed to contamination from many patients."**
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> **a. Aren't hospitals better equipped to control the extent of radioactive contamination (i.e., by placing the patient, linens, etc., under radioactive isolation and barring access to clergy and other non-essential personnel) and decontaminate areas and items than would most typical residential homes? Why or why not?**
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> **b. Aren't hospitals better equipped to control the extent of radioactive contamination (i.e., by placing the patient, linens, etc., under radioactive isolation and barring access to clergy and other non-essential personnel) and decontaminate areas and items than would most typical hotels, especially since hotel management would not necessarily know that such contamination was occurring in the first place? Why or why not?**

Response 6:

Although hospitals may be better equipped to control contamination, as stated in the Supplementary Information accompanying the final rule amending the patient release criteria in 10 CFR 35.75 in January 1997 (62 FR 4120), "the mere fact that a home cannot control contamination as well as a hospital does not mean that the contamination control achieved in homes is not adequate." As discussed in an NRC regulatory analysis (NUREG-1492) published in February 1997, actual measurements of dose to household members from contamination show that dose from contamination is low, demonstrating that the degree of contamination control that was achieved is adequate.

Through interviews and observations conducted during routine inspections, the NRC verifies that licensees are providing relevant information to patients and their guardians about the dangers patients may pose to others, and the precautions that patients should take. The NRC believes that the instructions can be followed by many patients to minimize the spread of contamination at

home and that there are benefits to allowing patients to be released after administration. However, the authorizing physician has the primary responsibility for assessing the patient's condition and the unique living situation, and evaluating on a case-by-case basis the ability of the patient to comply with the dose limit of 5 millisievert (0.5 rem) to others. These same considerations would apply to patients who go to hotels after release.

Question 7:

> **Are "safe" levels of radiation exposure different for pregnant women and young children? If so, on what basis is the exposure (witting or unwitting) to radioactive isotopes (particularly I-131) of these individuals justified?**

Response 7:

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 in 10 CFR Part 35. The release requirements provided in 10 CFR 35.75 are consistent with the recommendations of the NCRP and the International Commission on Radiological Protection (ICRP) at the time that the final rule was published in January 1997. The NRC believes these dose limits and release criteria adequately protect all members of the public, including pregnant women and young children.

The NRC recognizes that pregnant women and young children are more sensitive to radiation, and provides additional guidance on maintaining doses as low as is reasonably achievable to these individuals in Regulatory Issues Summary (RIS) 2008-11, dated May 12, 2008. Specifically, the RIS states that in order to protect infants and young children from possible I-131 contamination, the licensee should provide the patients with additional instructions and consider not releasing patients administered I-131 whose living conditions may result in contamination of infants and young children. The RIS further states that the additional instructions should include: recommending patients avoid direct or indirect contact with infants and young children for a specific period of time (including considering having children stay outside the home with other family members); recommending patients have adequate living space that can be used exclusively by the patient for a specific time; and recommending that licensees provide information to patients on potential consequences from failure to follow recommendations. The information contained in RIS 2008-11 is based on radiation safety recommendations found in ICRP Publication 103, which was published in February 2008.

Question 8:

In 2001, the Illinois Department of Nuclear Safety wrote to the NRC to warn of the problems posed by radioactive patients. Stating, "simply because NRC does not keep records on such events does not mean that such events are not occurring." In response, the NRC Commissioners considered and voted down a proposal under which, if a licensee became aware that a released patient had caused a member of the public or family member to receive a dose ten times allowable limits, this would have to be reported to NRC. 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 8:

In 2002, the Commission, in a Staff Requirements Memorandum (SECY 02-0111) stated that it was not necessary to amend 10 CFR Part 35 to require licensees to notify the NRC when a member of the public received radiation exposure of 10 times (50 millisievert or 5 rem) the allowable limit in 10 CFR 35.75. At that time it was noted that the likelihood of an individual receiving a dose of this magnitude from a released patient appeared to be very low.

Questions related to incidents occurring at the Philadelphia Veterans Affairs Medical Center:

Question 1:

Does the Commission still concur with its earlier finding that if a doctor alters a treatment plan retroactively in order to cover up an error, the incident in question doesn't have to be reported or acted on? Why or why not? Please fully describe NRC's current policy in this area, as well as any proposed or planned revisions to this policy that might be undertaken in the future.

Response 1:

The Commission has not changed its position on allowing revisions to written directives. While certain modifications to written directives are permitted under current regulations, it was never the Commission's intent that such changes be used to cover up errors in treatment.

Under the current regulations in 10 CFR 35.40, a written revision to an existing written directive may only be made before the administration of a brachytherapy procedure. However, certain information may be entered into the written directive after implantation but before the completion of the procedure. Specifically, before implantation, the treatment site, radionuclide and dose must be entered; however, after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose) may be entered to more accurately reflect what actually occurred.

Therefore, under these regulations, if an authorized user entered into the written directive the number of seeds that were actually implanted into the target organ after implantation but before the patient left the operating room, this in itself would not constitute a reportable event.

Recent events involving therapeutic use of byproduct material, along with advice from the Advisory Committee on the Medical Uses of Isotopes (ACMUI), prompted the NRC to reconsider the appropriateness and adequacy of the regulations for medical events and written directives. Among the issues identified was the lack of clarity as to when and how certain information is to be entered into the written directive. A proposed rule has been published in the *Federal Register* (73 FR 45635) that would amend the regulations regarding reporting of medical events involving permanent implant brachytherapy to address this and other issues. In this rulemaking process, the NRC must work to balance the flexibility physicians may need to adjust treatment plans based on actual patient conditions, which might not be evident until the treatment is commenced, with a need for the NRC to be aware of true errors in treatment that should be reported. Development of the final rule is in progress. On March 30, 2009, the NRC issued a Special Inspection Report on the medical events at the Philadelphia, Pennsylvania Department of Veterans Affairs Medical Center (PVAMC). The NRC is considering the results of this inspection report, along with other issues raised during the public comment period and input received from the ACMUI and Agreement States, as it prepares the final rule.

Question 2:

> **It is my understanding that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) has advocated for a *relaxation* of medical reporting procedures, stating that "To the extent possible, NRC's ME reporting and follow-up procedures should be designed to not increase Licensee liability." Does the Commission believe that the purpose of medical reporting is to protect patients from unsafe practices and incompetent physicians or to protect licensees and incompetent doctors from being sued? Please fully explain your response.**

Response 2:

The purpose of the NRC's regulation of the medical use of byproduct material is to provide for the radiation safety of patients, workers, and the public. A licensee's or physician's potential liability is not considered by the NRC in promulgating its regulations. In discussing public comments on its Medical Use Policy Statement, which was published in the *Federal Register* in 2000 (65 FR 47654), the NRC clearly states that "NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients. Moreover, there is nothing in the Commission's regulatory approach to medical use regulation that would in any way modify the legal rules governing malpractice suits arising out of the medical use of byproduct material."

The purpose of medical event reporting as required in 10 CFR 35.3045 is to provide to the NRC and to the involved individuals information about occurrences in which the end result of a medical use of radioactive material is significantly different from what was intended, for whatever reason(s). The NRC investigates each of these medical events to determine whether the occurrence involved a generic issue related to procedural problems; resulted from a deliberate action or error; or was due to equipment problems that should be promptly brought to the attention of other medical use licensees and Agreement State regulators. The NRC notes that the occurrence of a medical event does <u>not</u> necessarily mean that the patient or research subject involved has been harmed or even that the individual has an increased potential for harm. However, in those cases where there has been apparent

harm to the patient or increased potential for such harm, the NRC routinely takes actions against the involved licensee and, if necessary, its employees.

ACMUI provides the NRC recommendations on a variety of issues impacting the medical community that use byproduct material. The quoted ACMUI statement regarding medical event reporting and follow-up procedures suggests this approach be taken only to the extent possible, and should not be interpreted as suggesting a relaxation of the NRC's medical event reporting procedures.

Question 3:

> **The ACMUI has historically had a "Patient's Rights Advocate" position. However, for the past decade, this position has been held by a variety of individuals who do not appear to be actual patients rights advocates (such as individuals who work for the medical isotopes industry). Do you think that the Patient's Rights Advocate should be someone free of actual or perceived conflicts of interest with the nuclear medicine industry or practitioners? Why or why not? What plans do you have to fill this position with someone who might be more able to objectively carry out its intended purpose?**

Response 3:

With regard to the perception that members of the ACMUI may have conflicts of interest because they work in the medical community and related industries, the NRC seeks to fill positions on the ACMUI with individuals who have medical expertise because they are best able to advise the Commission with regard to issues related to the medical use of byproduct material. The NRC values input from the patient's perspective, and for that reason there is a patients' rights advocate position on the ACMUI. Historically, the NRC has not received a large number of nominees when a vacancy for the patients' rights advocate position has been advertised in the *Federal Register*. The NRC staff relies heavily on nationally recognized professional organizations, which are engaged in ACMUI-activities, to nominate individuals for open positions on the ACMUI. While there are many groups nationally that advocate for medical patients and, more specifically, cancer patients, the NRC does not routinely receive nominations from such groups. Recently, in an effort to increase transparency, the NRC posted all ACMUI position descriptions, including a description of the patients' rights advocate position, on the NRC public website. The NRC intends to increase outreach efforts and welcomes suggestions for expanding the pool of potential patients' rights advocate nominees when the position becomes vacant.

Question 4:

Please provide an update on the case raised in the New York Times piece and the Commission's response. Did the NRC ever undertake an investigation to determine if there was a pattern of mistakes at the VAMC? Has NRC taken any actions related to the events described in the article or to determine whether similar problems could have occurred elsewhere? Please describe what if any actions have been taken.

Response 4:

The health and safety of all patients, including veterans, is of paramount importance to the NRC. The specific case raised in the New York Times article cannot be addressed because the NRC does not maintain personal privacy information about patients. The PVAMC provided the NRC a list of all the patients who received prostate implants, and the patients were identified by a number, not by name, in order to protect their personal privacy. The NRC retained a medical consultant to conduct an independent assessment of a representative sample of the medical events to determine any health consequences to the patients. The NRC responded aggressively and promptly to the reported medical events at the PVAMC.

The NRC conducted several comprehensive onsite inspections including a Special Inspection, at the PVAMC and at all of the Department of Veterans Affairs (VA) hospitals authorized to perform prostate cancer treatments. The NRC identified unreported medical events at some of the other VA hospitals, as well as similar incompatibilities between the VA computer systems and the treatment planning systems. However, the number of unreported medical events at the other facilities was fewer and represented a much smaller percentage of the procedures performed. The other VA facilities also developed interim measures to correct computer communication problems in a more timely manner. The root causes for these medical events were not the same as those at PVAMC; therefore, the NRC did not identify the same problems occurring at the other VA hospitals.

The NRC is taking strong action to ensure that the problems that led to errors at the VA hospitals are addressed. Based on the results of its inspections, the NRC will hold a pre-decisional enforcement conference for the PVAMC in the near future. The NRC issued a Demand for Information to a physician in order to obtain specific information regarding the physician’s current and future activities as they relate to the use of NRC-regulated byproduct material. The NRC is also in the process of updating its inspection procedures based on the outcome of the medical events at PVAMC.