NRC Response to October 20, 2010 Recommendations

1) The NRC should immediately commence a rulemaking to revise its 1997 regulations surrounding the treatment of patients with radionuclides, and ensure that these regulations are made to be consistent with and as protective of the most vulnerable populations as policies that are in place in other developed countries. Hospitalization should be mandatory for those patients who are treated with doses of I-131 above internationally accepted threshold limits.

The NRC continues to believe that current regulations are appropriately protective of the families of patients and the public at large. These regulations use a combination of dose limits and the principle of keeping all radiation exposures as low as reasonably achievable (through patient release instructions) to achieve adequate protection. In addition, the regulatory flexibility provided can be applied to a variety of individual patient situations while continuing to ensure radiological safety.

The NRC believes that the agency's patient release regulations and guidance are consistent in principle and practice with international scientific recommendations on the matter. As stated in the recent Advisory Committee on the Medical Use of Isotopes (ACMUI) Subcommittee report, "[t]he Subcommittee finds the current 10 CFR 35.75 release criteria to be consistent with the practical application of nationally and internationally recommended dose constraints and limits, and to be in harmony with public safety, humane patient care, and cost-effective delivery of medical treatment."

With regard to mandatory hospitalization, the NRC continues to believe that the need for and length of hospitalization needs to be evaluated on a patient-specific basis, considering a number of factors. As the ACMUI Subcommittee report points out, national and international advisory boards agree that the decision to hospitalize a patient should be determined on an individual basis, based on dose criteria, rather than residual-activity criteria. In addition, factors such as patient wishes and medical condition, patient ability to understand and follow instructions, family considerations, and cost also should be considered by a physician in deciding whether to release a patient.

2) The new regulations should ensure that patients who are released from the hospital after treatment are prohibited from recovering from such treatments in hotels or taking taxis or public transportation in the days that immediately follow treatment and that specific written and verbal guidance prohibiting such activities is provided both to medical licensees and to patients. Enforcement actions should be taken against licensees who fail to provide such guidance to patients, or otherwise fail to advise a patient planning to violate the prohibitions that the regulations do not permit such activities. In cases where the patients cannot identify a suitable outpatient facility in which to recover, NRC regulations should mandate in-patient stays.

The NRC strives to ensure that, prior to release, a patient's individual situation is thoroughly understood and that appropriate, clear, and easy-to-follow instructions based on NRC regulations and guidance are provided to patients for care following their release. The NRC and Agreement States take appropriate enforcement actions against licensees for violations of these requirements. However, the NRC, Agreement states, and medical licensees retain no control over what patients will actually do once they are released.

As we noted in our March 5, 2010, letter to you, the NRC is preparing a Regulatory Issue Summary (RIS) on release of patients to locations other than private residences that will supplement existing regulations and guidance. This guidance will address, but not unilaterally prohibit, release to locations such as hotels. The ACMUI Subcommittee evaluated this specific issue at the request of the NRC and concluded that "I[odine]-131 therapy patient release to a private residence should be encouraged, and that licensees should carefully evaluate patient release to other locations and communicate to the patient additional radiation safety precautions that may be appropriate for such locations."

Our regulations require that an assessment be completed to demonstrate that such releases are not likely to exceed required dose limits. We continue to believe that a regulatory framework that provides general requirements while providing flexibility to address a variety of patient circumstances and medical needs is appropriate. We expect to finalize and issue the RIS in the coming months and will forward a copy to you once it is completed.

3) The NRC should aggressively enhance its oversight of both its medical licensees and the Agreement States to better identify, track, and respond to potential regulatory violations. NRC should pay particular attention to whether New Hampshire, Arkansas, and Alabama are capable of implementing NRC regulations in this area, in light of these states' failure to respond to requests for information.

As with all of its regulatory programs, the NRC provides appropriate oversight of medical licensees. Specifically, the NRC conducts licensing, inspection, and other oversight activities based on the type and scope of the medical programs. In general, the NRC inspects its medical licensees that administer therapeutic doses of I-131 every 2 to 3 years.

With regard to Agreement States, we review their performance across all their areas of responsibility, including implementation of patient release requirements. We carry out our evaluation of the adequacy and compatibility of Agreement State activities through the Integrated Materials Performance Evaluation Program (IMPEP). IMPEP consists of regularly scheduled, structured reviews of both the NRC materials program with respect to its licensees, and the individual Agreement State materials programs. As a result of those efforts, we are confident that both NRC and the Agreement States have the necessary regulations in place and are implementing them in accordance with the Atomic Energy Act and in a manner that ensures adequate protection. As to the capabilities of New Hampshire, Arkansas, and Alabama, our most recent IMPEP reviews of their programs (2008, 2009, and 2010, respectively) indicate that their programs are adequate to protect public health and compatible with the NRC program. As additional guidance in the area of patient release is developed, we will work closely with our licensees and Agreement States to ensure its appropriate and full implementation.

4) NRC should immediately implement a reporting requirement for incidents that could have resulted in unintended radiation exposures from patients treated with radioactive isotopes, and ensure that data related to reports of such incidents are promptly made public in a centralized location such as the NRC website.

The likelihood of a member of the public receiving a harmful radiation exposure from medical use of radioisotopes is extremely low. The NRC believes the patient release requirements, which include the need for an assessment demonstrating that the total effective dose equivalent to other individuals is not likely to exceed 500 millirem and the requirement to provide instructions to patients to reduce the doses to other individuals if the total effective dose equivalent to any other individual is likely to exceed 100 millirem, provide adequate protection of

public health. Given the existing regulations and NRC guidance for implementation of those requirements, and considering the extremely low likelihood of the public receiving a harmful exposure from such medical uses, the Commission has concluded in 2002 that there is no need to revise the current reporting requirements.

While there is analytical information that indicates that our current requirements are protective, little empirical data exists to demonstrate actual doses to members of the public as a result of the release of patients following medical isotope treatment. The Commission expects to explore the utility of collecting additional data on public doses as a result of patient release.