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General Comment

Question A: No. NUREG 1492 Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material published in February 1997 analyzed the risks and benefits of continuing with the existing activity-based release threshold or adopting dose-based release criteria. NUREG 1492 justified the use of a dose-based release. In addition, the NRC (in Federal Register Vol. 62, No. 19 January 29, 1997) included the following supporting statements:
The new criteria are consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP).The Advisory Committee on the Medical Use of Isotopes (ACMUI) Patient Release Report Dated December 13, 2010 provided a comprehensive review of patient release issues included the following statements: Today, the Subcommittee affirms the thorough analysis found in NUREG-1492 and its rational evaluation of the three alternatives. The NRC's final decision to implement Alternative 3 as the patient release criteria found in 10 CFR 35.75 appropriately balanced the three fundamental radiation protection principles for use of radioactive materials in medicine. (Alternative 3 referred to the 5 mSv (500 mrem) dose limit. The NRC is adopting a dose-based limit rather than an activity- based limit because the dose-based limit better expresses the NRC's primary concern for the public's health and safety.
Question B: No. We support the NRC's stance as found in the analysis published in the Federal Register Vol. 62, No. 19 January 29, 1997, as follows:"The NRC is establishing a dose limit of 5 millisieverts (0.5 rem) total effective dose equivalent to an individual from exposure to the released patient for each patient release.

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This dose limit is consistent with the underlying risk basis of the current 10 CFR 35.75 (50 FR 30627; July 26, 1985), the recommendations of the NCRP and the ICRP, and the provisions in 10 CFR 20.1301(c) pertaining to temporary situations in which there is justification for a dose limit higher than 1 millisievert (0.1 rem)." "Each patient release is to be treated as a separate event, and licensee knowledge of previous administrations is unnecessary."

Question C: No. (but ambiguous question) NRC regulations (10CFR35.75) require that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem). However, the NRC also requires the licensee to provide written instructions to the patient on ways to keep the radiation dose ALARA or less than 1 mSv (100 mrem) to children, pregnant women, and non-caregivers. In addition, the 5 mSv (0.5 rem) is meant for the most highly exposed individual, as noted in the Federal Register Vol. 62, No. 19 January 29, 1997. In it, the NRC states that "Using a dose-based system based on a dose to the most highly exposed individual of 5 millisieverts (0.5 rem) would, in some circumstances, allow release of a patient with more than 1,110 megabecquerels (30 millicuries) of activity." The "most highly exposed individual" wording is found in other NRC documents related to the development of the dose-based release approach. Therefore, the "dose criteria" is not 5 mSv (0.5 rem). The regulation is 5 mSv (0.5 rem). The dose criterion is 100 millirem for children, pregnant women, and non-caregivers. In addition, the NRC uses this criterion (100 millirem) when deriving the recommendations for breastfeeding infants. The NRC should continue to require that the likely dose to individuals other than adult caregivers should be as low as reasonably achievable and below 100 mrem as reflected in guidance documents.

Question D: Unfortunately, Regulatory Guide 8.39 lacks guidance on precautions and instructions for individuals who may expose children (family members or otherwise) and pregnant women. Additional guidance is necessary.

Question E: No - If "specific requirement" means a regulation.

Patient isolation instructions are addressed in Regulatory Guide 8.39. As noted in the response to Question D, some additional guidance is necessary. As far a sufficient time prior to the administration to make plans to hold the patient, if this is not already in place, the facility should not be in the business of offering in-house therapies.

Question F: No, a specific time frame should not be regulated. The timing of providing instructions to patients and their household members and/or caregivers is a clinical decision and will vary from patient to patient. However, common sense dictates that instructions should be given prior to the procedure.

Respectfully submitted, Christopher Poeschl BSRT, CNMT, ARRT(NM)(CT)