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General Comment

Question: Should the NRC develop an activity based patient release threshold?

No. An activity-based release threshold would still be based on a number of assumptions (e.g. time and distance from the patient, occupancy factors, uptake, etc.). The only difference from the current system is that the assumptions would then be static rather than dynamic. This would limit the flexibility of the patient care facilities without providing provable gain to the patients or their families.

Question: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing individuals?

Not without hard data on the radiation exposure family members are actually receiving from patients. Our feeling is that the current calculations of exposure to individuals living in the home are not supported by real data and that these calculated estimates are grossly conservative. In addition, our experience is that only about 10% of patients receive an additional dose

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add = D-B Home (DBH)

within the same year. It is not clear and obvious to us that the regulation should be changed due to a small minority of patients. Dose tracking and exposure reconstruction, as well as NRC enforcement are challenging given that the patient may change caregivers and even geographic locations between treatments, and because there is often a significant time gap between treatments. Given the lack of real exposure data and epidemiological evidence of harm, this change is not justified.

Note: Should the NRC have access to real exposure data to family members, etc. from well designed studies that have statistically significant sample sizes, we would welcome the opportunity to review them and invite the NRC to share them with the regulated community. We would also welcome the opportunity to review epidemiological studies of harm to individuals receiving 500 mrem of ionizing radiation exposure.

Question: Should the NRC continue to apply the same dose criteria to 5 mSv to all members of the general public including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?

Yes. Without significant and reproducible evidence of harm from this level of exposure, a change in the regulations is not warranted. In addition, to limit the exposure of a particular group (say caregivers or family members) effectively limits the exposure to all groups because the occupancy factors and commensurate patient instructions would have to accommodate the group required to receive the least exposure. Otherwise the patient instructions become overly complicated, given that different categories of people would be allowed different levels of exposure. An added difficulty is that there is no clear enforcement mechanism for this proposed change.