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General Comment

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Attachments

NRC-2017-0094 Commenst on Patient Release Program (05-25-2017)

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COMMENTS ON PATIENT RELEASE PROGRAM

A. *Development of an Activity-Based Patient Release Threshold*

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

Response: There is no need to develop an activity-based release threshold. The existing licensing guidance for medical facilities (NUREG 1553, Vol. 9) allows licensees to use tabular values for patient release utilizing conservative assumptions. Alternatively, patient release calculations, using various assumptions of uptake, occupancy, etc., based upon the patient's specific living and working conditions are acceptable and have been used successfully by many licensees. It has been noted even with the calculation method, several assumptions and default values used for those calculations result in conservatively high estimates of dose to those who come into close proximity to these patients. Patients benefit by being allowed to return to their home environment and the public is adequately protected when licensees go through the evaluation process to estimate potential doses to the public.

B. Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals

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? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider?

Response: There is no doubt the current regulations are somewhat ambiguous regarding the time frame associated with the current dose limit. As such, it would be wise to clarify this time frame. The appropriate time frame and limit would be 500 mrem (5 mSv) to members of the public and other family members per administration. There are several reasons for utilizing a per administration limit. According to clinicians, multiple administrations of radiopharmaceuticals or permanent implants within one year are rare. Unless a patient received multiple administrations by the same licensee, it would be difficult for licensees to know if patients had received previous administrations within the past year (assumed to be within the past 365 days). Furthermore, even if the licensee did know such administrations had occurred, unless the previous licensee had actually calculated the potential dose to a member of the public, it would not be possible to know how much additional dose a member of the public would be allowed to receive within that same year. From the radiation risk standpoint, the **"ASSUMED"** risk associated with receiving 500 mrem in a given year and then another 500 mrem 366 days later would be no different than receiving 1,000 mrem within 365 days. While dose rate does have some bearing on biological effects, at these

levels either 500 mrem or 1,000 mrem delivered over a few weeks would be considered low dose rate.

Note in the previous statement, the word "assumed" is emphasized. There is no data from reputable sources that indicates 1,000 mrem causes any statistically significant increase in risk – risk at this level is assumed by extrapolation from considerably higher doses using some form of the linear no threshold (LNT) hypothesis. In the May 2016 revision of the Health Physics Society's position statement entitled "Radiation Risk in Perspective," the following statement appears: "Substantial and convincing scientific data show evidence of health effects following high-dose exposures (many multiples of natural background). However, below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero." Thus, even exposures that are 2X the 500 mrem (5 mSv) limit are 1/10th of the amount that may result in an increase in risk that can be demonstrated with some statistical certainty. As such, receiving 500 mrem to 1,000 mrem within a one year or two year time frame is irrelevant in terms of risk.

The benefit to the patient is even in the rare occurrence a patient might receive repetitive administrations within one year; they still have the benefits of returning to their home environment. While there is no direct benefit to the public, as indicated above, there is also no demonstrable risk.

C. *Appropriateness of Applying the Same Limit on Dose From Patient Exposure to All Members of the General Public*

Question: Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), 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?

Response: Applying the same dose limit for all of those listed is appropriate, based upon risk. As stated above, radiation risks of less than 100 mSv (10,000 mrem) have not been shown to statistically increase risk. This general statement applies to adults. Of course, pregnant women and children can be looked upon as special cases; however, NCRP Commentary No. 9 – "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child" includes the following statement: "If the dose to the embryo, fetus, or nursing child from an unintended exposure is less than or equal to an effective dose of 50 mSv, there is no harm from deterministic effects and the risk of stochastic effects is less than one percent." The stochastic effects (e.g. cancer and/or leukemia) estimate is again based upon data associated with exposures that were much higher than 50 mSv and this risk estimate is no doubt based upon an extrapolation from the higher dose data. According to the BEIR VII report, the normal risk of cancer in the adult population (only exposed to background radiation) is about 46% in males and 37% for females. Thus, the cancer risk from an exposure to either a conceptus or a young

child to 1/10th of the value cited above would be statistically insignificant, even when applying the extrapolated risk estimate.

During a recent NRC webcast requesting public input on these questions, there was some discussion regarding the appropriate limit and the inconsistency between the 10 CFR 35.75 limit of 500 mrem and the 10 CFR 20.1301 limit of 100 mrem/year limit to members of the general public – a difference of 400 mrem. In an EPA document published on July 14, 2005 entitled "Assessment of Variations in Radiation Exposure in the United States", it is indicated that the national average dose equivalent in the US from background radiation (e.g. cosmic, terrestrial, and Rn sources) is 294 mrem per year. In the same publication, it is stated the average annual dose equivalent to a Colorado resident is 700.1 mrem/year – a difference of 406 mrem. Pregnant women and children in Colorado are also exposed to this higher level. Obviously, these numbers accumulate arithmetically over several years. While it is understood these background levels vary considerably (especially Radon) from one location to the next, the point is unless there have been scientific papers published that show a statistically significant increase in stochastic effects to Colorado residents this commenter is unaware of, the lack of such evidence of an increased risk from radiation exposure variations over a few hundred mrem illustrates the futility of trying to establish limits at such low levels, based upon conjecture as opposed to good science. From the emotional standpoint, we try to protect our children, including unborn children; however, we must draw the line at some point and include science in the decision-making process.

The issue of these types of patients being released to hotel rooms has generated much undue concern. The two populations mentioned during a recent NRC webcast were occupants of hotel rooms adjacent to rooms where an I-131 patient might be located. A paper published by D. Dewji, et.al. (Med. Phys. 42(4), April 2015) considered a number of exposure geometries associated with these patients, one of which was a patient and another hotel occupant seated back-to-back on an adjacent wall and the other with the patient and hotel occupant lying head-to head on an adjacent wall. The initial exposure rate for the back-to-back position was 1 x 10-5 mSv/MBq·h. Thus, for a patient with 200 mCi (7,400 MBq) in his/her body, the exposure rate would be 0.074 mSv/h or 7.4 mrem/h. Thus, for an 8 hour period, for someone seated directly opposed to that patient in the adjacent room (assuming no decay or biological elimination), the calculated dose equivalent would be 7.4 mrem/h x 8 h or 59 mrem.

For the head-to-head geometry, the initial dose equivalent rate from the patient to the adjacent hotel occupant was 2.25 x 10-6 mSv/MBq·h. Thus, the initial exposure rate and 8 hour integrated cumulative dose equivalent to the adjacent hotel occupant for a 200 mCi patient under the same conditions as described above would be 0.017 mSv/h (1.7 mrem/h) and 14 mrem in 8 hours. Given the conservative assumptions and the aforementioned calculations, it can be reasonably stated these patients housed in a hotel room provide no significant radiation hazard to adjacent occupants.

With respect to hotel workers, these patients would likely not be in the room when hotel workers are cleaning the room. Even if they were, their time spent in close proximity to the patient would be brief. Furthermore, concern has been raised about contamination and the possibility hotel workers would come into contact with contamination from the patient. While there could be some contamination on linen (sheets and towels), calculations could show transfer of those low levels of contamination would result in very little skin contamination or intake by hotel workers. Intermingling slightly contaminated linen with other linen during laundering would result in significant dilution of the contamination and would likely be undetectable. The highest level of contamination (based upon vast experience by the commenter many years ago when hospitalizing the patients was mandatory) is the toilet. Presumably, hotel staff wear disposable gloves when cleaning the toilet for a number of reasons that have nothing to do with radioactivity. As such, they would be adequately protected from skin contamination and assuming standard hygiene habits are used, internal contamination would be of no concern as well.

In summary of this most lengthy response, dose limits should be based on science and not conjecture or extrapolations of risk from higher levels with a certain level of conservatism to assure exposures don't approach levels that indeed are demonstrably hazardous. Regarding the inconsistency between the 100 mrem/year public limit and the 500 mrem limit to individuals who come into contact with these patients, one could argue that both limits should be 500 mrem. However, establishing a higher limit to those exposed to these patients recognizes that there is a direct benefit to those patients and to their family members by allowing those patients to return to their home environment and the risk associated with the difference in to two limits is too small to quantitate.

Many cite the ICRP and NCRP with respect to their recommendations on limits; however, both organizations acknowledge they base their limits on LNT while acknowledging doses at such low levels cannot be statistically verified – it is the ultimate conservative approach. It is interesting while some European countries adopt the ICRP recommendations as their radiation exposure limits, they don't have speed limits on some of their highways. That seems to be somewhat of a contradiction in terms of real versus perceived risks. In fact, if we were to treat speed limits as we do radiation limits, we could reduce the number of traffic deaths by reducing the speed limits on all highways to 10% of what they are now – that would no doubt decrease the number of traffic deaths, but would likely be unacceptable to the public (i.e. the benefit outweighs the risk).

D. *Requirements for Releasing Individuals Who Are Likely To Expose Young Children and Pregnant Women*

Question: Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?

Response: The answer to this question is a qualified "yes." The requirement should be the written instructions licensees provide to patients should include some information on the **potential** risks associated with exposing pregnant women and children and simple instructions to avoid close proximity to those individuals for a few days following treatment. In fact, that information should be included with all written instructions, not just when it is "likely" that children or pregnant women will be exposed. Situations may arise (e.g. riding on a bus or sitting in a theater next to a pregnant woman or child) that may not be considered "likely", but could happen just the same. If the patient is provided some simple information in the instructions regarding maintaining an "arms-length" distance from obviously pregnant women or children (e.g. don't sit next to them on the bus or in a theater), that would be more than adequate to address the potential risks. As indicated in previous responses, the real hazard to pregnant women and children is likely to be negligible; however, it is something that can generally be accomplished quite easily.

One recommendation I have would be the requirements for written instructions include a requirement documentation be maintained where the patient acknowledges by signature they have received the instructions, agree to follow the instructions, and have been provided the opportunity to ask questions.

E. Requirement for Timely Discussion With the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning

Question: Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?

Response: The answer to this question is a qualified "no." The NRC's responsibility is to assure the licensee meets the requirements of 10 CFR 35.75 and the licensee is responsible to meet that requirement. If the licensee does not give patients adequate time to make isolation arrangements, they will either have to wait to treat the patient until arrangements are made or make arrangements themselves to hospitalize the patient. In either case, the licensee will learn failure to provide patients adequate time to prepare for isolation causes problems and will likely modify their procedures to do so in the future. In order to prevent licensees from making this mistake, providing patients sufficient time to make isolation arrangements should be strongly suggested in licensing or other NRC guidance.

F. *Requirement to Ensure Patients Are Given Instructions Prior to the Procedure*

Question: Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?

Response: The response to this question is similar to that for the previous question (E.). The timing of when instructions are provided to the patient should be left up to the licensee; however, including a specific recommendation for the timing of providing the instructions in NRC guidance would be helpful.