2017
~~2016~~ JUN 26 PM 5:14

PUBLIC SUBMISSION

As of: 6/26/17 4:43 PM
Received: June 23, 2017
Status: Pending_Post
Tracking No. 1k1-8x4l-9e3z
Comments Due: June 27, 2017
Submission Type: Web

Docket: NRC-2017-0094
Patient Release Program

Comment On: NRC-2017-0094-0004
Patient Release Program; Extension of Comment Period

Document: NRC-2017-0094-DRAFT-0080
Comment on FR Doc # 2017-11027

Submitter Information

4/11/2017
82FR17465

Name: Barbara Hamrick
Address:
2828 Boa Vista Drive
Costa Mesa, CA, 92626
Email: bhamrick@uci.edu

94

General Comment

I am attaching my comments in response to Information Collection request on Part 35 (NRC-2017-0094). These are my comments as an individual and as a certified professional health physicist, working in the field for 25 years.
These comments were originally developed by the Health Physics Society, and reflect my professional opinion on the matter.

Sincerely,

Barbara L. Hamrick, JD, CHP

Attachments

Final NRC Patient Release Program Comments HPS

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= D-B Hoare (DBH)

Docket ID **NRC-2017-0094**

Background:

On April 11, 2017 the NRC published a Request for Comment in the Federal Register (NRC-2017-0094) regarding the Patient Release Program under 10 CFR 35. The regulation and guidance that comprise this program have been the standard since the 1990s when NRC published a radiation dose (risk) based rule permitting the release of patients from licensee control after the administration of radioactive materials. The NRC revised the regulations to permit a risk informed basis for releasing patients from licensee control which has been in place now for more than 20 years. The current system permits release of patients provided that the dose to the highest exposed individual (exclusive of the patient) is not likely to exceed 500 mrem from that particular administration or implantation of material. In addition, the rule requires patient instructions if the dose received by another individual may exceed 100 mrem, and includes special provisions regarding breastfeeding.

The existing regulation has permitted improvements in patient care and quality of life while providing adequate protection to the public. There have however been evolutions in medical practice and better methods are now available for radiation dose assessment. These improvements should be incorporated into common practice, and updated guidance from NRC on how to best comply with the existing regulations may be warranted. There are also opportunities for improved consistency between licensees and programs in messaging, patient information and related methodologies.

It is necessary and appropriate to have a framework and rationale for assessing the safety of releasing patients from licensee control following administration or implantation of radioactive material. The NRC has recently noted in IN -2017-02 that the existing framework appropriately balances public safety with access to medical treatment. Therefore the theoretical benefit that might be obtained by implementing more restrictive regulations are outweighed by other considerations such as unnecessary utilization of healthcare resources by patients who do not require hospitalization for medical reasons and the benefits of patients and families being able to spend time in a more comfortable and supportive environment than hospital isolation.

The likely doses to members of the public who are not caregivers are within the variance in the natural background radiation dose levels within the United States. As noted in the Health Physics Society position statement, Radiation Risk in Perspective, "below levels of about 100 mSv above background from all sources combined, the observed effects in people are not statistically different than zero" and "radiogenic health effects have not been consistently demonstrated below 100 mSv ". There is no evidence that family members or the general public have been harmed under the current release criteria.

During the NRC sponsored public meetings on this subject several concerns were raised and examples given of practices experienced by patients which do not conform to the prevalent practice standards espoused by nationally recognized bodies or by the NRC in the recent IN 2017-02. Examples included inadequate patient education (inadequate content and/or lack of any discussion with the patient) and not evaluating patient suitability for outpatient therapy prior to the day of treatment. NRC has issued

clarified guidance on this issue which, if coupled to licensee operations during the licensing and inspection processes, would seem to address these practice issues.

Another issue raised was concern about potential risks from patients staying in hotels after treatment, specifically with radioiodine. This issue has been studied by the NRC Advisory Committee on the Medical Use of Isotopes, and has been published in the literature. In addition NRC has already made it perfectly clear in RIS 2011-01 that licensees must address such release and attendant radiation exposures as part of their evaluation and release determination. Compliance with this existing requirement is, again, a matter more in keeping with enforcing the existing requirements and improved education than additional rulemaking.

Specific responses to the proffered questions are below.

A. Development of an Activity-Based Patient Release Threshold - Question: Should the NRC develop an activity-based patient release threshold?

NRC should not revert to an Activity-Based Patient Release Threshold.

NRC rightly moved away from the activity based system for determining suitability of releasing patients during the last major revision to the rule. Activity is only one factor in determining the radiation hazard posed by a given patient. Other factors include for example the type of therapy, excretion kinetics, patient living and working situation, general health status, radionuclide, chemical and physical form, body habitus and ability to follow basic safety and dose minimization instructions. Moving back to an activity based constraint by regulation would be taking a step backwards, away from risk informed regulation and sound science. Such a move, which decouples basic radiation science from regulatory compliance, is insupportable.

While the current guidance provided by NRC in regulatory guide 8.39 and NUREG 1556 Volume 9 Revision 2 does provide for use of administered activity (derived from the simple NRC dose model) as an acceptable pathway for demonstrating compliance with the radiation dose limit, this is very different than a mandate to use that method which is not appropriate in many cases. Licensees use the activity based release criteria for most diagnostic studies as well as some treatments for thyroid disease due to convenience – the administered activities calculated by the attendant methodology or provided in the guidance are below those requiring that patients be confined and in most cases are also below the threshold for requiring special patient instructions. These activity values are derived based on a very conservative model which is known to not accurately represent the likely radiation dose to a member of the public – in most cases the estimated radiation dose calculated using this simple model will greatly over-estimate the radiation dose (risk).

Under the current regulations, licensees are also permitted to release patients based on individualized instructions and patient specific dose calculations to demonstrate compliance with the existing dose limit. Since the dominant exposure pathway is external radiation from

proximity to a patient, distance isolation is the primary key to dose reduction. Internal dose to others from radioactive contamination is generally considered to amount to a small fraction of the dose received from external radiation for most scenarios, especially in the presence of adequate instruction. As a result patients may safely self-isolate at home or in other suitable environments. This benefits patients and society in general by providing flexibility in care and housing arrangements when medical care is not required.

B. Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) - 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?

NRC should make no changes in the time period covered by the dose limit in 10 CFR 35.75(a) and how it has been interpreted – meaning that it should stay as a per release limit.

The application of the dose limit codified in the regulations and interpreted as a "per administration" or "per release" limit has been the case for more than 20 years. We are unaware of any peer reviewed scientific study demonstrating actual harm from this practice. On the other hand using an annual dose limit is problematic for so many reasons that it may not be practical for many licensees to comply with such a regulation in any meaningful way. In addition such a limit is likely to have a negative impact on patient care and access to medical procedures that use radioactive materials. Costs of providing healthcare will increase due to the bookkeeping and data collection efforts necessary to collect and track patient related public dose across multiple providers and procedures. In addition there is a likely increase in the need for housing patients in the hospital solely for the purposes of regulatory compliance. It may not be possible to obtain the necessary data to estimate radiation doses in a reasonable fashion retrospectively for many patients to determine compliance with an annual limit.

For example, many patients receive care from multiple licensees, sometimes across multiple states or even national boundaries over the course of a year. It is not clear which licensee would be responsible for determining compliance with the dose limit. This is compounded by the variability in the possible assumptions that could be used to determine the likely receptor dose for purposes of demonstrating compliance. It is well known the instruction content, restriction times and methodology for calculation are licensee specific and can vary substantially because of the way the current system is structured. One can envision cases where a hospital would be required to confine a patient after administration of diagnostic radiopharmaceuticals or implantation of permanent brachytherapy sources when accounting for the dose to the public from all administered or implanted radioactive materials during the current calendar year.

In addition, it is not clear what dose is to be tracked or assigned. Is the licensee to use the Regulatory Guide 8.39 simplified methodology to determine the estimated dose to each person

routinely encountered? Will the licensee be permitted to adopt more realistic dose estimation techniques? Will licensees be required to overhaul the medical records systems to track assigned doses from release? What will happen if a licensee cannot obtain sufficient data to estimate dose from past procedures? If one licensee estimates a dose using the simple method in Regulatory Guide 8.39 can a different licensee redo the calculation with patient specific values to adjust the assigned dose to be more realistic? In addition, many licensees have adopted the NCRP 155 method for determining restriction times to be provided for patient instructions. This method relies on the use of dose constraints as an input to determine appropriate restriction times for inclusion into patient instructions. It is unclear how this method would best be applied in the context of an annual limit and over multiple administrations of radioactive material.

Also, there is no evidence that the risk to a family member who receives more than 500 mrem during the course of a year is greater than a family member who receives the same dose during two different years. The decision regarding the timing of retreatment should be based on medical need rather than radiation isolation issues.

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?

The existing 500 mrem limit in conjunction with existing requirements for precautions to keep exposures ALARA is adequately protective and no changes are necessary.

While it is desirable to maintain doses to children and pregnant women as low as reasonably achievable, this should be accomplished with guidance that allows physicians the flexibility to meet the needs of each patient and his or her family. The occupational limit for dose to the fetus of a declared pregnant woman is 500 mrem and there is no justification for the dose limit to the child of a patient to be set lower. However, in accordance with the ALARA principle, patients should be encouraged to follow restrictions that will keep the doses to children and pregnant women below 100 mrem when reasonable, given the financial and emotional consequences of extended restriction periods.

Patients and families can incur real and lasting harm from over-zealous regulation and over application of the precautionary principle in this area, with a disparate impact on those who lack the resources to arrange and pay for special accommodations as may be required under a revised framework. It can be shown that using a 100 mrem dose limit as an input into the calculations for activities related to, for example, child care can result in quite lengthy restriction times after therapeutic use of radioactive materials (for example, up to several weeks when using NRC models suggested in Regulatory Guide 8.39 as inputs into the NCRP 155 method). The end result is that patients may be restricted from returning to work, participating in routine

household tasks and caring for children for extended periods with little, if any, attendant benefit.

In addition, application of a 100 mrem limit to certain populations is likely to increase the rate of hospital admissions solely for the purpose of patient confinement. Many patients who are currently treated as out patients will be forced to stay in a medical facility, even though they do not require medical care. This is inefficient, increases the burden on the health care system, and produces a net detriment to the public welfare by taking available bed space away from patients who require those services. To compound this issue, many medical centers no longer maintain shielded therapy rooms or have not replaced or expanded such facilities since the need was no longer there. Often such facilities that remain are limited in scope to accommodate the relatively small fraction of patients who are not releasable under the current regulations. Therefore there is a very real possibility that necessary cancer treatments and other medical procedures could be cancelled or delayed until such time as the limited space can be made available.

As mentioned before, the dose calculation method in Regulatory Guide 8.39 is overly conservative. The use of better dose estimation methods would produce more reasonable estimates of doses to other individuals from exposure to released patients. Many licensees use the systematic method presented by NCRP in report 155 to determine restriction times for various patient activities.

Before proceeding with formal rulemaking to lower the radiation dose limit NRC should conduct a formal analysis of the impact that this change will have on medical practice, access to care and over-all societal costs.

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?

No changes are necessary to the regulatory framework. However, updating the regulatory guidance to include more up to date methods of dose and risk assessment and determination of restriction times is warranted to assist licensees and patients in adequately managing this in a cohesive and more consistent manner that balances risk with accrued net benefit from restriction durations.

Licensees are already required to consider special exposure pathways and risk factors for these sensitive populations. For example, potential ingestion or inhalation by children of radioactive materials introduced into the environment by a patient should be considered and could be treated more deliberately and realistically in new NRC Guidance. This is an issue most properly addressed through enhanced guidance and inspection by NRC and the Agreement States to

ensure that licensees document evaluations properly, considering appropriate exposure pathways and scenarios for the patient populations.

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?

Timely and adequate patient education regarding any medical procedure is a very important issue and is a hallmark of quality medical care. However, it is questionable whether this issue warrants rulemaking by NRC. There are cases which occur where prescreening and pre counseling is difficult or not feasible at all and licensees should be able to maintain the flexibility to treat these patients. For example, hyperthyroid patients are often diagnosed and treated the same day, when the patient is able to comply with the recommended restrictions. Physicians should have the flexibility to work with patients to schedule treatment without an arbitrary time frame imposed. Adjusting the dose limit, requiring dose tracking and other necessary measures required by all of the preceding proposals, if adopted, will greatly exacerbate the patient education challenge.

Summary:

There is no need for rulemaking to change the current regulations regarding the release of patients under 10 CFR 35. The existing regulations are adequately protective of public health while affording licensees the flexibility to provide customized and patient-centered care. Anecdotal evidence brought forth by some commenters regarding inadequate education and other practices that do not conform to the prevalent standard of care and best practices are best addressed through the licensing, guidance and inspection processes of the NRC and Agreement States.

Selected References:

NRCP Report 155 – Management of Radionuclide Therapy Patients

NRC Information Notice 2017-02: Best Practice Concepts for Patient Release

NRC Regulatory Guide 8.39 – Release of Patients Administered Radioactive Material

NUREG 1492 – Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material (1997)

Radiation Risk in Perspective, Position Statement of the Health Physics Society (5/2016)

Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources, Position Statement of the Health Physics Society (3/2012)

NCRP Report 124 Sources and Magnitude of Occupational and Public Exposure from Nuclear Medicine Procedures (1996)