Duran-Hernandez, Doris

From:	Opila - CDPHE, Jennifer <jennifer.opila@state.co.us>
Sent:	Wednesday, June 07, 2017 1:06 PM
To:	Howe, Donna-Beth
Cc:	OAS Executive Board (oasboard@agreementstates.org); oasvotingmembers@agreementstates.org; James Grice; James Jarvis
Subject:	[External_Sender] Colorado Comments on Patient Release Program
Attachments:	Colorado comments on NRC Patient Release 060717.pdf

Ms. Howe,
Please accept the attached comments from the Colorado Radiation Program on the Patient Release Program (Docket ID NRC-2017-0094).

Thank you,
Jennifer T. Opila, MPA
Radiation Program Manager
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Add= D-B. Howe (DBH)

COLORADO
Department of Public
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Dedicated to protecting and improving the health and environment of the people of Colorado

June 7, 2017

Donna-Beth Howe
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Docket: NRC-2017-0094, Patient Release Programs

Ms. Howe,
On behalf of the State of Colorado Agreement State Program, we respectfully submit the following responses and comments regarding NRC's patient release programs as discussed in Docket NRC-2017-0094. Our comments follow the order of questions in the NRC request for comment.

A. **Regarding whether NRC should develop an activity-based patient release threshold.**

The Colorado radiation program does not support the concept of a strict activity-based release criteria with an associated requirement to maintain the patient at a facility under the licensee's control.

While radiation safety is the foremost concern for our program, a strict activity-based release limit would present challenges and may be overly limiting to licensees. While implementation of activity based limits would likely be easier for licensees to follow, such an approach would likely and unnecessarily increase medical costs due to retaining patients in the hospital for non-medical reasons.

The current regulations and guidance provide a variety of patient release options for licensees.

An activity-based patient release requirement may not adhere to the concepts of the international radiation safety community as outlined in IAEA (International Atomic Energy Agency) Safety Report Series No. 63 (2009). With the exception of special considerations for protection of infants and young children, the IAEA report endorses a patient release process that is based on individual assessment of various patient specific factors and conditions and not strictly by activity-based release criteria. Additionally, as outlined in some early research evaluating exposures and thyroid uptakes by family members of patients treated with Iodine-131, a more important factor impacting dose to family members appears to be patient behavior and adherence to isolation instructions and other related information.

B. **Regarding whether NRC should clarify the time covered by the current dose limit in 10 CFR 35.75(a) for releasing individuals.**

The Colorado radiation program recommends that NRC regulations be clarified to specify a time frame for which the current dose limit in 10 CFR 35.75 applies. Colorado program recommends that the limit should be clarified as an annual limit.

Justification for an annual limit is consistent with the approach used for other regulatory limits which are often based on an annual criteria. Additionally, an annual limit approach is consistent with recommendations of other national and international bodies (National Council on Radiation Protection and Measurements, Publication 116; International Commission on Radiological Protection 60) as discussed in NRC Regulatory Issue Summary 2008-07.

While Colorado believes applying an annual limit is the approach consistent with other dose limits, we recognize that it could be challenging for licensees to implement. Specifically, those instances where a patient receives an initial treatment at one location and then within the same year receives another treatment at a different licensed facility may be challenging. Licensees would be required to spend resources to assess the dose estimate information in order to comply with an annual limit requirement. NRC should evaluate the additional resources that would needed by licensees to determine whether clarification of the rules as an annual limit would be risk-informed and cost effective.

As part of a pre-screening/patient release process that may need to be incorporated into guidance, consideration may need to be given to incorporate one or more questions pertaining to prior administrations of radioactive materials within the prior calendar year. The licensee would then need to perform an assessment of any prior procedures and their associated doses to members of the public following release.

Perhaps NRC should consider limiting such an annual dose only to therapy related procedures, which would expected to be much less frequent that other procedures involving radioactive materials (e.g., diagnostic procedures).

Whether requirements are based on an "annual" limit or a "per event" limit, it must be realized that any dose received by persons exposed to a released patient are only estimates. Such estimates are likely to have a wide margin of error due to the many factors and assumptions involved.

C. Regarding the appropriateness of applying the same limit on dose from patient exposure to all members of the general public.

The Colorado radiation program supports the concept of applying the same limit on dose from patient exposure to all members of the public.

While the concept of applying different dose values may have some limited benefit from a radiation safety perspective under some instances, unless NRC were to develop very specific situational criteria, the application of different dose limits for different exposed populations would seemingly present significant challenges for licensees to implement and regulators to evaluate for compliance.

The Colorado radiation program supports applying the current/same dose criteria of 5 mSv (0.5 rem) to all individuals potentially exposed to the treated patient. While studies confirm the potential for additional exposure to radiosensitive populations through transfer of contamination, most studies appear to indicate that the dose to these populations is generally lower than estimated. Studies have also generally shown that where patient instructions are closely adhered to, most doses to radiosensitive populations are below the 1 mSv (0.1 rem) limit for members of the public. Providing for a specific lower limit for more radiosensitive populations would perhaps result in additional hospital time and expense for the patient for a savings of a few hundred millirem that may not be warranted. Again, NRC would be encouraged to evaluate this on a cost-benefit basis.

As discussed in other comments herein, NRC is encouraged to consider additional regulatory requirements that apply a stronger patient evaluation process and guidance that more fully evaluates the patient's potential to expose others.

D. Regarding requirements for releasing individuals who are likely to expose young children and pregnant women.

The Colorado radiation program supports the concept of a requirement to provide additional information pertaining to the release of a patient who is likely to expose young children or pregnant women.

Due to the increased radiosensitivity of young children and the fetus, additional efforts should be made to make patients aware of potential increased risks to these populations. While the Colorado radiation program would not necessarily recommend a separate or unique dose limit for these populations, a requirement for providing the patient with additional information and limitations on exposing these populations would be warranted.

Any evaluations of potential exposure to young children and pregnant women should fully consider the patient's living situation, occupation, and ability to follow directions regarding their likelihood of exposing young children and pregnant women. NRC should consider additional detailed guidance in the form of an updated questionnaire (as a "model" form) that help assess the patient's living and social situation and would be provided to patients as part of the pre-procedure/treatment planning process.

E. Regarding proposing a requirement for timely discussion with the patient about patient isolation to provide time for licensee and patient planning.

The Colorado radiation program supports the concept for a pre-administration requirement to discuss the isolation limitations with the patient.

A requirement for providing a discussion of the patient isolation requirements to patients and their families in advance of the procedure is believed to be in the best interest of the patient and public safety and would be expected to help ensure patients and their family are fully informed and aware of any isolation requirements prior to the procedure taking place.

The Colorado Radiation Program believes a requirement for licensees to have a discussion regarding isolation requirements at least one to two days in advance of the treatment would be prudent. Although not necessarily regulatory driven (and most likely out of procedural necessity), there are numerous instances where medical treatments or procedures dictate certain preparations by the patient prior to a given procedure, so this would not be expected to be a burden. An exception could be provided for emerging medical conditions using language similar to that found in 10 CFR 35.40 pertaining to written directives.

F. Regarding a requirement to ensure patients are given instructions prior to the procedure.

The Colorado radiation program supports the concept for a requirement that licensees be required to provide instructions prior to the procedure involving radioactive materials.

Similar to question E above, a requirement for providing instructions to patients in advance of the procedure is believed to be in the best interest of the patient and public safety and would be expected to help ensure patients and their family are fully informed and aware of the requirements prior to the procedure taking place. This is especially critical for those patients who rely on others to care for them (e.g., nursing homes, assisted living facilities, etc.) or who otherwise may have difficulty in adhering to the directions. The Colorado Radiation Program believes a requirement for licensees to provide instructions to patients at least one to two days in advance of the treatment would be both reasonable and appropriate. As discussed in the prior question, there are numerous instances where medical treatments and procedures dictate providing instructions to the patient well before the procedure.

During Colorado's participation in the recent NRC stakeholder meetings on the patient release process, it was noted that some meeting participants - typically licensees - expressed concern over pre-treatment requirements that would result in delays of a patient's same day treatment. While Colorado does not have data to support this, we anecdotally suspect that most patient treatments do not occur on the same day as diagnosis.

Colorado believes that if NRC were to establish a requirement for licensees to provide instructions to patients before the treatment and within a specified timeframe (a number of hours or days), the approach/language used for written directive changes in 10 CFR 35.40(a)(1) could be used to give licensees additional flexibility in those cases where there is a short time period between diagnosis and treatment. Language from 35.40 could be incorporated into such a requirement that would allow deviation from the requirement "because of the emergent nature of the patient condition". If such language is used, NRC may also wish to consider the need for a requirement to document deviations from a new requirement.

As a final comment pertaining to the patient release process in general, NRC has over the years, issued a number of information notices and regulatory information summaries on this topic. As NUREG-1556 Vol 9, Revision 2 is currently published for comment, NRC should consider incorporating these guidance documents and other applicable recommendations and technical research papers into the final NUREG Vol. 9.

The Colorado Radiation Program appreciates the opportunity to provide comments on NRC's patient release program and looks forward to our continued cooperation with NRC in the regulatory and rulemaking process.

If you have any questions regarding this letter, please contact me at 303-692-3403 or jennifer.opila@state.co.us.

Jennifer T. Opila

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