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General Comment

See attached file(s) Please contact me for further information - Bobbi Smith, American Thyroid Association, 703-998-8890

Comments of the American Thyroid Association regarding Proposed Changes to the Patient Release Program [NRC-2017-0094]

The American Thyroid Association (ATA) is the leading organization devoted to thyroid biology and to the prevention and treatment of thyroid disease through excellence in research, clinical care, education, and public health. Our members include pediatric and adult endocrinologists, nuclear medicine specialists, thyroid surgeons, and other medical professionals who care for patients with thyroid disorders. Patients with thyroid cancer, hyperthyroidism, and nodular goiter routinely undergo treatment with radioactive iodine (I-131) as part of their care.

The ATA has a longstanding commitment to ensuring that radioactive iodine treatment is provided in ways which adequately protect patients, their families, and the general public from potentially harmful effects of radiation exposure. In 2011 the ATA Task Force on Radioiodine Safety published "Radiation safety in the treatment of patients with thyroid diseases by radioiodine 131I: practice recommendations of the American Thyroid Association," a document intended to define best practices for complying with NRC safety

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regulations. These recommendations were endorsed by the Academy of Molecular Imaging (AMI), American Association of Endocrine Surgeons (AAES), American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), American College of Nuclear Medicine (ACNM), American Head and Neck Society (AHNS), Endocrine Society (ENDO), European Society of Endocrinology (ESE), International Radiation Protection Agency (IRPA), Latin American Thyroid Society (LATS), and Ukrainian Association of Endocrine Surgeons (UAES). In addition, the American College of Surgeons (ACS) and the American Congress of Obstetricians and Gynecologists (ACOG) acknowledged their support of the document.
The ATA has carefully reviewed the issues raised by the NRC related to the release of patients after I-131 administration. It strongly endorses the efforts to ensure that patients are informed about exposure issues in a thorough and timely way. However, as described below, the ATA has reservations about possible changes in the threshold-related requirements.

More on attached document.....

Attachments

ATA NRC Statement 5-17-17

Comments of the American Thyroid Association regarding Proposed Changes to the Patient Release Program [NRC–2017–0094]

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The ATA has a longstanding commitment to ensuring that radioactive iodine treatment is provided in ways which adequately protect patients, their families, and the general public from potentially harmful effects of radiation exposure. In 2011 the ATA Task Force on Radioiodine Safety published "Radiation safety in the treatment of patients with thyroid diseases by radioiodine 131I: practice recommendations of the American Thyroid Association,"[1] a document intended to define best practices for complying with NRC safety regulations. These recommendations were endorsed by the Academy of Molecular Imaging (AMI), American Association of Endocrine Surgeons (AAES), American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), American College of Nuclear Medicine (ACNM), American Head and Neck Society (AHNS), Endocrine Society (ENDO), European Society of Endocrinology (ESE), International Radiation Protection Agency (IRPA), Latin American Thyroid Society (LATS), and Ukrainian Association of Endocrine Surgeons (UAES). In addition, the American College of Surgeons (ACS) and the American Congress of Obstetricians and Gynecologists (ACOG) acknowledged their support of the document.

The ATA has carefully reviewed the issues raised by the NRC related to the release of patients after I-131 administration. It strongly endorses the efforts to ensure that patients are informed about exposure issues in a thorough and timely way. However, as described below, the ATA has reservations about possible changes in the threshold-related requirements.

A. Development of an Activity-Based Patient Release Threshold

The NRC is asking the public to comment on whether the NRC should develop an activity-based patient release threshold under which patients would be required to be maintained in a clinic sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met.

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

1. If so, explain why and provide a potential activity-based criterion.

2. If not, explain why the regulations should remain as is.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.

The ATA does not believe that there is a need for the NRC to develop an activity-based patient release threshold.

Although ensuring population safety is clearly essential, patient comfort is also worthy of consideration. Patients admitted for inpatient I-131 therapy are typically confined to a single hospital room for up to several days after treatment. Studies have consistently shown that when patients follow appropriate safety instructions after I-131 treatment, radiation exposures within their homes do not exceed regulatory limits.[2,3,4,5] Although there are no data on long-term outcomes (and such data would be exceedingly difficult to collect), harm from radiation to personal contacts of treated patients under the current system has never been demonstrated.

The costs of inpatient stays following I-131 administration are not trivial, and may substantially burden patients and drive up health care costs. In some instances inpatient radioactive iodine therapy incurs more costs than thyroid surgery. Having any cancer diagnosis has been shown to increase the risk for personal bankruptcy 2.65-fold, while specifically having a thyroid cancer diagnosis increases the risk for bankruptcy 3.46-fold.[6] This has important ramifications for health as well as for personal finance, since financial distress requiring bankruptcy protection after a cancer diagnosis may be a risk factor for mortality.[7] In addition, although inpatient therapy will reduce radiation exposure to family members and the general public, it has the potential to increase occupational exposures to hospital staff.[8]

Inpatient isolation following I-131 administration is appropriate in some instances, such as when patients live with small children or pregnant women in a housing situation which does not allow for patients to keep an adequate distance from others. It is important that insurers and other payors do provide coverage for inpatient isolation when necessary. In most cases, these patients are not acutely ill, and need isolation but not intensive nursing. Lower acuity isolation facilities would be lower-cost and more pleasant for patients than the current practice of providing isolation in acute-care medical beds, but such facilities do not currently exist in most practice settings.

Overall, the ATA believes that current regulations provide a sufficient balance between the twin goals of protection for the general public and healthcare providers and patient comfort and autonomy.

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

Currently, under section 35.75(a) of title 10 of the Code of Federal Regulations (10 CFR), allows a licensee to release a patient if the dose to any other individual is not likely to exceed 5 milliSieverts (mSv) (0.5 rem). The NRC staff determined in the NRC Regulatory Issue Summary 2008–07, "Dose Limit for Patient Release Under 10 CFR 35.75" (ADAMS Accession No. ML063030572) that, as written the regulation is ambiguous and the dose to any other individual from the released individual does not reflect the NRC's intent of a per-year limit and that this limit has been interpreted by others to be per release. The NRC staff explained that a "per release" interpretation does not consider the cumulative dose received in a year from the same

released individual or repeated exposure to different released individuals. The Commission has asked the NRC staff to clarify this issue.
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? In either case, describe the resulting health and safety benefits, or lack of benefit, to the individual being released and to individual members of the public as a result of the proposed clarification.

The ATA believes that the risk of repeated exposure to I-131 treated patients is so low for most members of the general public that there is no need for the NRC to amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals by explicitly stating that the criterion is a per year limit. In addition, the query assumes that there is a difference between multiple exposures over a year compared to multiple exposures over a longer time period, but it is not clear that there are data to support this assumption. It would seem more appropriate to include language about increased risk to close household contacts from repeated I-131 treatment exposure than to include language about annual exposure limits.

There are two categories of individuals who may be exposed to radiation from I-131-treated patients. One category includes those such as relatives, roommates, and home caregivers who are aware that they are in contact with an I-131 treated patient. On occasion thyroid cancer patients need more than one radioactive iodine treatment within a given year. In addition, approximately 10-15% of hyperthyroid patients who receive radioactive iodine treatment require a second treatment (typically within the same year) due to failure of the initial dose to cure their hyperthyroidism.[9,10] Family members and close household contacts of treated patients are more likely to experience repeated exposures than are members of the general public, and they also have the ability to modify their contact. It is primarily in these circumstances that providing guidance regarding repeated exposures might be relevant.

The other category is people who are casual contacts, such as taxi drivers or transit passengers. In most cases contact will occur once and transiently. There are approximately 800,000 people living with a previous thyroid cancer diagnosis in the United States, with 64,300 new patients diagnosed in 2016.[11] The proportion of thyroid cancer patients treated with radioactive iodine increased from 1990 and 2008,[12,13] but has subsequently declined substantially due to changes in clinical guidelines, which no longer recommend routine postoperative radioactive iodine treatment for low-risk thyroid cancer patients.[14] U.S. endocrinologists also report a declining use of radioactive iodine for patients with hyperthyroidism in recent years.[15] The overall number of individuals receiving radioactive iodine treatment in the U.S. is small enough that for members of the general public that the likelihood of ongoing, repeated exposure to radiation specifically from I-131-treated patients is highly improbable.

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

In the current NRC patient release dose criterion, the NRC does not distinguish between family members, young children, pregnant women, caregivers, hotel workers, and other members of the public. Further, the NRC patient release dose criterion is above the 10 CFR part 20 public dose limit.

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? 1. If so, explain why.

2. If not, what criterion should the NRC use for an individual group or groups? Specify the group (e.g., family members, young children, pregnant women, caregivers, hotel workers, or others) for each criterion.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to individual members of the public.

The thyroid is among the most susceptible organs to radiation carcinogenesis. Current data support a linear effect of thyroidal radiation exposure on thyroid cancer risk, without a clear threshold.[16] Thyroid cancer risks associated with iodizing radiation exposure are strongly age-dependent and are essentially confined to pregnant women and children aged 15 and younger.[16,17,18] Any thyroid cancer risk to non-pregnant adults from low-level I-131 exposure is almost certainly too small to be measureable. For non-pregnant adult contacts of I-131 treated patients, concerning risks would instead be those for blood and solid malignancies.

The ATA believes that, while pregnant women and young children are more susceptible to risk from I-131 exposure than are other groups, the current dose criteria of 5 mSv (0.5 rem) applies adequate protection to all members of the general public, including young children and pregnant women. As discussed below, however, the ATA believes that special verbal and written instructions to treated patients are required to avoid exposure of young children or pregnant women to doses above the public dose limit.

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

The current NRC patient release program requires the licensee to provide the released individual with instructions if the dose to any individual is likely to exceed 1 mSv (0.1 rem). The NRC does not have specific requirements for releasing patients who are likely to expose young children or pregnant women to doses above the public dose limit.

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?

1. If so, explain why and describe what the requirement should include.

2. If not, explain why the requirement is not needed. 3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released and to a young child or to pregnant woman.

The ATA believes that special verbal and written instructions to treated patients are required to avoid exposure of young children or pregnant women to doses above the public dose limit.

The International commission in Radiological Protection (IRCP) has estimated the risk for all cancers in children is 0.1-0.2% from an effective I-131 dose of 1 mSv.[19] Risks to children include those from external radiation exposures as well as potential ingestion of contamination from excreted or secreted I-131 from treated patients.

The ATA currently recommends that "having a treated parent staying in the home with children is often problematic due to children's needs and desires to be near the treated parent. Special arrangements should be made for children to stay with relatives or friends; alternatively, the treated parent may stay with relatives or friends where children and pregnant women are absent."[1] In circumstances where this is not possible, inpatient isolation is an appropriate alternative. Development of lower acuity isolation facilities would help help reduce the cost of inpatient isolation.

E. Requirement for Timely Discussion with the Patient about Patient Isolation to Provide Time for Licensee and Patient Planning

The current NRC patient release program permits the licensee to authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). In some common procedures (e.g., Iodine-131 procedures), the patients must isolate themselves for the licensee to meet this dose release requirement. In other cases, the patient cannot be released and the licensee must make arrangements to isolate the patient. The requirements are silent on when the licensee should discuss patient isolation with the patient. As a result, both patients and licensees may not have time to make appropriate isolation arrangements prior to the planned administration. Some patients reported that they were unaware of a need to isolate themselves from others prior to the administration.

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?

1. If so, explain why and describe what the requirement should include.

2. If not, explain why the requirement is not needed.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to individual being released, the licensee, and to the public.

The ATA fully supports a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to allow the patient to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released. We believe that a patient cannot provide fully informed consent to radioactive iodine treatment procedures without a detailed understanding of the safety precautions which would be entailed. Current ATA recommendations state that "A discussion of patient-specific radiation safety precautions should... be part of the shared decision-making with the patient and the referring and/or treating physicians and should allow the patient to select the best timing for I-131 treatment and to make appropriate preparations at home and at work" and that "It is essential that radiation safety recommendations be discussed with each patient as soon as treatment with I-131 is considered."[1]

Any discussion should encompass information about avoidance of pregnancy or breastfeeding, ensuring safe travel home following the I-131 treatment, and precautions to minimize radiation exposure to others at home. Information should be provided both verbally and in writing. Specific recommendations regarding important elements of this patient discussion, as well as an eligibility assessment checklist for outpatient radioactive iodine treatment, can be found in the 2011 ATA document.[1]

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

The current NRC patient release regulations require the licensee to provide the released individual with instructions if the dose to any individual is likely to exceed 1 mSv (0.1 rem). The requirements are silent on when the required instructions should be given to the patient. Some patients are given instructions along with other medical release paperwork and may not be aware of the instructions.

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)?

1. If so, explain why and provide a recommended time period for the instructions to be provided.

2. If not, explain why the requirement is not needed.

3. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released, the licensee, and to the public.

As noted above, the ATA supports a specific requirement for the licensee to have a patient isolation discussion with patients prior to I-131 administration. However, the exact timing of such discussions needs to be individualized. The appropriate amount of lead time required in order to ensure radiation safety can differ substantially (from days to weeks) depending on specific patient, living situation, and employment characteristics. Fortunately, I-131 treatment can usually be delayed sufficiently to allow for this. Clinical circumstances requiring urgent or emergent I-131 treatment are the exception rather than the rule. However, in those rare cases when urgent administration is required, requiring a fixed amount of lead time could serve as a barrier to optimal patient care.

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