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DEPT. OF HEALTH AND HUMAN SERVICES



Pete Ricketts, Governor

MEMORANDUM

TO: Medical Use Licensees (Nal-131)

FROM: Julia A. Schmitt, Manager
Radiation Control Program *jas*

DATE: June 7, 2017

SUBJECT: Best Practice Concepts for Patient Release

Attached is NRC Information Notice 2017-02 regarding best practice concepts for patient release. We are sending you this notice for informational purposes.

Should you have any questions, please contact our office at 402-471-2168.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL
SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 17, 2017

NRC INFORMATION NOTICE 2017-02: BEST PRACTICE CONCEPTS FOR PATIENT
RELEASE

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to provide addressees with best practices to consider for patients treated with Sodium Iodine-131 (NaI-131) (hereafter referred to as I-131) and released in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." The included best practice concepts are intended to provide information to licensees to consider and individualize for their patients in regards to maximizing radiation safety and minimizing unnecessary radiation exposure. Information contained in this IN does not constitute new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

The NRC staff has anecdotal data from patients and patient advocacy groups which indicate that the quality of instructions that medical licensees provide to patients released under 10 CFR 35.75 varies significantly. The data suggest that some patients are provided with instructions that may not be specific to their needs and are impractical to follow.

BACKGROUND

The NRC regulations in 10 CFR 35.75(a) permit a licensee to "authorize the release from its control 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 millisieverts (mSv) (500 millirem (mrem))." The provisions in 10 CFR 35.75(b) require a licensee to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (100 mrem).

The Commission directed staff to develop, for licensee consideration, best practice release instructions for patients treated with I-131. Toward that goal, the staff published a notice in the *Federal Register* (80 FR 70843) that solicited comments from the medical community and associated stakeholders about their patient release guidance and best practices based on their own experiences. The NRC assessed stakeholder responses to identify best practices with respect to I-131 patient release guidance based on well-established radiation safety concepts.

DISCUSSION

Generally when licensees release patients, it is to the patients' home where family or other caregivers may be present. The NRC believes that the ability of the licensee to provide adequate release instructions under 10 CFR 35.75(b) is related to the licensee's thorough consideration of the destination to which the patient will be released, and on the ability of the patient and/or caregiver to understand and follow the necessary release instructions. By thoroughly ascertaining the patient post-treatment destination, the licensee can best estimate the likely cumulative radiation exposures to other members of the public (e.g., family and caregivers, etc.) and direct appropriate protective measures. Stakeholder comments provided valuable information that helped NRC staff to develop patient release best practice concepts based on sound radiation protection principles. These best practices are shared in this IN for licensee consideration.

BEST PRACTICES CONCEPTS

Patient Preparation Assessment

Engaging the patient early in the treatment process (i.e. during treatment planning) may help licensees better familiarize the patient and caregivers with the treatment procedure, potential complications, side effects, dietary and medication changes, pre- and post-treatment expectations, isolation, and protective measures and precautions to follow before, and immediately after, I-131 administration. Additionally, early engagement with the patient affords both the patient and the licensee an opportunity to ask and answer questions that will help the patient be more compliant with the release instructions. It also provides the licensee with an opportunity to determine if the patient will be able to follow instructions. Sharing information on the impact of pregnancy and breastfeeding during the treatment process is vital in educating and preparing the patient for treatment.

As soon as I-131 is considered as a treatment option, the licensee should conduct an interview with the patient and/or caregiver to aid in assessing the patient's specific circumstances. Topics to consider include:

- Type of post-treatment lodging (e.g., group home, apartment, townhome, detached single family home).
- Patient travel plans to their post-treatment recovery location:
 - Will the patient use a private vehicle, taxi service, or public transportation (i.e. bus, train, or airplane)? Not using public transportation should be recommended, if possible.
 - If driving, might the patient be too impaired to drive?
 - If driving, will the patient drive alone (preferred)?

- If the patient is traveling with other individuals, what is the duration of the trip and how does the duration affect instructions for keeping the patient an adequate distance from others?
- Household members, if any (gender, age, nursing infant, pregnant woman).
- Can the patient be appropriately isolated from others in the household post-treatment?
- Is the patient capable of self-care, compliance with release instructions, and sleeping alone? Is the patient incontinent?
- Discuss household and necessary dietary changes prior to treatment.
- Discuss factors that might be the basis for withholding treatment (e.g., breastfeeding, pregnancy) and consequences if release instructions are not followed.
- Can the patient delay returning to work?

By gathering this information prior to the treatment (i.e. during treatment planning), the licensee can provide a patient-specific estimate of the likely cumulative dose to other members of the public, direct appropriate protective measures, and allow the patient time to plan for his/her potential isolation after release. The licensee should provide pre-treatment instructions verbally as well as in writing

Patient Precautions

The following precautions/measures should be adequate for most I-131 patients to keep radiation exposures to others at or below the 5 mSv (500 mrem) limit:

- The licensee may consider discussing the following precautions and measures with the patient (as applicable):
 - Emphasize the importance of keeping an adequate distance from others, especially children and pregnant women. Can arrangements be made for family members (including children and any pregnant household members) to lodge elsewhere temporarily?
 - Encourage the patient not to prepare or share food with others.
 - Encourage the use of a bathroom reserved exclusively for the patient, if possible.
 - Encourage the use of kitchen utensils dedicated to the patient, not shared with other household members and washed separately from other dishes. Alternately, encourage patients to use disposable eating utensils.
 - Encourage the use of disposable gloves, flushable wipes, and frequent hand washing.
 - Encourage the laundering of a patient's clothing separately from other household members' clothing.
 - Emphasize abstention from all forms of intimate contact:
 - Advise the patient on recommended length of time the patient should wait before becoming pregnant to minimize radiation exposures to a developing fetus.
 - Discuss how to clean up an area contaminated with body fluids (e.g., breast milk, vomit).
 - Emphasize disposing of patient-related trash in a separate plastic bag that is not mixed with other household members' trash, and possibly holding the trash to allow for radioactive decay, as well as how to reduce radiation exposure from this trash. Holding trash for decay is important because the landfill may detect the radiation and send the trash back to the patient.

- Discuss how the patient may contact the licensee if needed.
- Provide post-treatment instructions verbally as well as in writing, including how long the release instructions should be followed.

If the patient is mentally and/or physically unable to comply with the instructions provided, and the dose is elevated (i.e., >200 millicuries), licensees may have to consider holding the patient or providing inpatient treatment until the dose to other individuals will not exceed 5 mSv (500 mrem). In this case, the patient should remain hospitalized until he/she can be released without following any instructions. Similarly, if the patient and/or caregiver informs the licensee that the patient plans to use public transportation and/or temporary public lodging at the post-treatment destination, or the patient is unable to meet the release instructions, the licensee should consider holding or hospitalizing the patient until the dose to other individuals will not exceed 5 mSv (500 mrem).

Numerous stakeholders emphasized that the Radiation Safety Officer should be consulted in evaluating the doses to members of the public in both routine and unusual situations (i.e., the patient travels a substantial distance after treatment, or cannot make the trip home without an overnight stay near the treatment medical facility). In addition, licensees may consider documenting the patient's plans to limit radiation exposure to small children.

With regard to female patients of child-bearing age, the NRC recognizes that pregnancy tests have limited ability to detect early pregnancies. The NRC encourages licensees to advise their patients to contact the licensee immediately in instances where a female patient discovers she was pregnant at the time the medical treatment was administered.

Patients receiving I-131 treatment need to be aware that they might trigger the alarms of radiation detectors at national borders, airports, within cities, or at their place of employment for 3 months or more following radioiodine treatment. Consequently, the licensee may consider issuing the patient a letter or card containing appropriate information about the treatment in case law enforcement agents need to verify that information.

CONCLUSIONS

Operating experience has demonstrated that radiation exposure from released patients can be safely controlled through the provision of appropriate instructions by the licensee as required by 10 CFR 35.75, and adherence to those instructions by the patient and/or caregiver. The NRC believes that the current patient release criteria appropriately balance public safety with patient access to medical treatment. This notice provides best practices to consider in order to maintain exposures as low as is reasonably achievable from patients released in accordance with 10 CFR 35.75, and may be used to augment the guidance in NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses." NUREG-1556, Volume 9 provides a variety of suggested protective measures that may be considered for minimizing exposures to others. It is located at the NRC's Web page entitled "Medical Uses Licensee Toolkit" at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>.