Arkansas' Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide

History

At the direction of former Arkansas Department of Health Director, Faye Boozman an Advisory Panel was gathered to address the issue of hospitalization vs. release of patients administered greater than 33 millicuries of I-131 Sodium Iodine. The Panel met on June 17, 2004, and recommended an "intelligent relaxation of the regulations". Following this meeting, various panel members worked to develop standardized forms, which met the criteria established during the initial meeting. The Panel met again on January 13, 2005 to review these standardized forms and finalize release criteria.

In accordance with a Panel recommendation, upon finalization of the release criteria, the Department began issuing exemptions to Arkansas State Board of Health's Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1214.a. All Arkansas Radioactive Materials licensees requesting an exemption to this regulation had to meet the following two criteria: the facility had to be licensed to conduct inpatient Sodium Iodine I-131 therapy treatments with greater than 33 millicuries of I-131 and the licensee had to submit procedures outlining release criteria for patients administered greater than 33 millicuries of I-131 Sodium Iodine. The submitted procedures had to meet the minimum requirements established by the Panel.

During 2004, the Department also began drafting a revision to ASBH's Rules and Regulations for Control of Sources of Ionizing Radiation. This revision included the addition of an entire Section, Section 9. Use of Radionuclides in the Healing Arts. These proposed regulations included provisions for the release of patients administered greater than 33 millicuries of I-131 Sodium Iodide. Therefore, the Panel determined that a licensing guide should be developed which detailed the established release criteria. This guide outlines the release criteria developed by the Panel, and would include a standardized patient evaluation form and a standardized patient instruction form. The guide would also reference U.S. Nuclear Regulatory Commission Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials", which describes methods for calculating doses to other individuals from exposure to the released patient.

This document, Arkansas' Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide, is the final product of the Panel's activities. This licensing guide details the requirements, which must be met in order to release individuals who have a total patient concentration of greater than 33 millicuries of Sodium Iodide I-131.

Regulation

RH-8420 Release of Individuals Containing Radioactive Drugs or Implants states:

a. A licensee may authorized the release from its control of any individual who has been administered Iodine 131 as Sodium Iodide if:
   1. The total patient concentration has been determined to be 1.22 gigabecquerels (33 millicuries) or less; or
   2. If the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem) per year and criteria outlined in **Arkansas' Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide** have been met.

Licensee Requirements

1. The medical facility's Arkansas Radioactive Material License must authorize the use of RH-8550 materials - Unsealed Radioactive Material for which a Written Directive is Required. In addition, the licensee must have adequate facilities, have established procedures and be authorized by the Department for the hospitalization of individuals administered greater than 33 millicuries of I-131 as Sodium Iodide. In essence, a licensee must be able to hospitalize patients who cannot be released in accordance with RH-8420.a.1. or 2.

2. The licensee is responsible for the education of both the patient and patient family. Proper patient education is an essential and critical element of the outpatient treatment process. In order to reasonably assure patient compliance, a patient friendly education program must be developed, implemented, reviewed, and as necessary changed to meet identified areas of weakness. The patient and their family must be informed and understand the potential consequences associated with noncompliance.

   - At a minimum, a standardized patient instruction form must be discussed with both the patient and patient family. The Radionuclide Therapy Patient Instructions form is included as Attachment A. The licensee may use this Panel developed form or develop an equivalent form, which contains the same minimum criteria. If an equivalent form is used, the form must be submitted to the Department for approval.
   - It is highly recommended that each facility develop a more detailed patient/patient family education program. This program could include additional hand-outs, a video presentation, or a one-on-one patient education session. Education is the key to compliance.

3. The patient must be evaluated at least **24-hours prior to the proposed administration** using a standardized patient evaluation. The I-131 Patient Evaluation Form is included as Attachment B. The licensee may use this model form or develop an equivalent form, which contains the same minimum criteria. If an equivalent form is used, the form must be submitted to the Department for approval.

Licensee Requirements Continued

4. The patient evaluation must be conducted by two individuals, an approved authorized user and another approved member of the nuclear medicine department staff. Both individuals must agree that the patient understands and is capable of complying with the established patient instructions.

    - Licensee management must have a written delegation of authority on file for each authorized user approved by licensee management to evaluate patients and perform outpatient treatments utilizing greater than 33 millicuries of I-131 Sodium Iodide.
    - All individuals authorized by the licensee to perform patient evaluations must be properly trained regarding the procedure and be aware of the potential consequences that could arise from patient noncompliance. This training must be documented and available for review by the Department.

5. Following administration of an outpatient I-131 Sodium Iodide dose greater than 33 millicuries, patients must be held for a minimum of one (1) hour post administration. If anti-nausea medication is administered prior to I-131 administration, it is recommended but not required to hold the patient.

6. The licensee must establish a chain of responsibility for radioactive waste generated by the patient. Due to the potential for contaminated materials entering the commercial waste stream, the licensee must establish procedures to minimize this occurrence. Again, patient education regarding the use of non-disposable items and waste reduction is essential. Two methods of meeting this requirement were discussed.

    - The licensee may request that the patient hold all waste generated during a specified time period. This waste may be returned to the administering facility when the patient returns in approximately ten (10) days for the follow up scan.
    - The licensee may provide adhesive labels which the patient is required to apply to all trash bags disposed during a specified time period. These labels should at a minimum indicate that I-131 Sodium Iodide was administered on a specific date at the licensee's facility. The licensee contact information must also be included. In accordance with HIPPA, patient identifiers must not be included on the label.

      Example: I-131 as Sodium Iodine was administered on (date) at (facility).
      Contact (name) at (telephone number).

ATTACHMENT A

I-131 Therapy Patient Instructions

I-131 Therapy Patient Instructions

Patient Name: _____ Administration Date: _____

Radionuclide _____ Administered Activity _____ mCi

Measured Dose Rate _____ mRem/h at 1 meter

For you to leave the hospital as an outpatient you must follow these instructions:

1 Sleep in a separate bed (at least 6 feet from anyone else).

2. Do not take a long trip (4 hours or more) sitting near others (eg, car, train, airplane, bus).
3. Avoid any direct or indirect contact with infants and children less than 12 year of age for a specified amount of time as determined by your doctor (recommended time is 2-7 days).
4. Stay at least 6 feet away from children over the age of 12 and pregnant women.
5. Minimize time spent near others and delay return to work.

In addition to the above instructions you must also:

- Keep at least 6 feet from others. When taking shorter trips, sit as far as possible from others.
- Do not let others use your bathroom.
  - Sit while urinating and flush the toilet 3 times with the lid down.
  - Avoid using disposable items that cannot be flushed down the toilet.
  - Menstruating women should use tampons that can be flushed down the toilet.
- Wash hands often, including after each toilet use, and shower daily.
- Drink plenty of liquids.
- Use separate towels, washcloths, and toothbrush from rest of household members.
- Use separate dishes and utensils for 1 week and wash separately.
- Hold clothing and linen (sheets and towels) for 1 week before laundering and launder separately from rest of household's laundry
- Inform your physician, emergency medical personnel or other healthcare provider of your treatment.
- Do not breast-feed.

I understand the above mentioned safety instructions and guidelines explained to me and I am willing and able to follow them in order to minimize exposure to others:

Instruction Duration _____ (days). Follow these instructions until _____.

Instruction Duration for homes with infants and children less than 12 year of age_____(days). Follow these instructions until_____.

Patient may return to work on _____.

Authorized physician: _____ Date _____

Patient signature: _____ Date _____

Treatment facility: _____

Contact at treatment facility: _____ Phone: _____

ATTACHMENT B

I-131 Patient Evaluation Form

I-131 Patient Evaluation Form

NOTE: ***To be completed at least 24 hours before planned administration time.***

Patient Information

Patient: _____ Date: _____

Male _____ Female _____ Is patient breast-feeding? Yes _____ No _____
NOTE*: Patients should discontinue breast-feeding before treatment*.

Persons Interviewed: Patient _____ Spouse _____ Guardian _____ Other _____

Dwelling Information

Type of dwelling: Single-family _____ Multifamily_____ Apartment _____ Dormitory _____ Other _____

Does the patient have sole access to bathroom facilities? Yes _____ No _____ # of bathrooms _____
Note: Instructions must be given to the patient if there is a shared bathroom.

If not single-family, possible proximity to neighbors: _____feet

Household members:

Name _____ Gender ____ Age _____ Name _____ Gender ____ Age _____

Name _____ Gender ____ Age _____ Name _____ Gender ____ Age _____

Name _____ Gender ____ Age _____ Name _____ Gender ____ Age _____

Are any household members or regular visitors pregnant? Yes _____ No _____

General Information

Is the patient willing and able to follow the instructions? Yes _____ No _____

Is the patient continent? Yes _____ No _____

Is everyone living in the house at low risk for radiation exposure (no small children or others that depend on the patient for care)? Yes _____ No_____

If the answer to any of the above 3 general information questions is No, the patient must be treated as an inpatient.

Are there any regular visitors to the house? Yes _____ No _____

If yes, can these visiting arrangements be modified to reduce contact? Yes _____ No _____

Does the patient visit anyone regularly? Yes _____ No _____

If yes, can these visiting arrangements be modified to reduce contact? Yes _____ No _____

Can patient be isolated (stay at least 6 feet from other people)? Yes _____ No _____

Does patient understand the importance of the isolation? Yes _____ No _____

Is the patient capable of self-care? Yes _____ No _____

Is the trip home less than 4 hours? Yes _____ No _____

Can the patient delay return to work? Yes _____ No _____
NOTE: *Special considerations for school teachers or individuals working in food preparation, child care, and healthcare.*

While a No response to one or more of the above questions does not preclude the patient from being treated as an outpatient, the response must be factored into the patient release calculations.

Items Discussed With Patient
____Patient instructions (*Patient instructions are required for **all** radionuclide therapy.)*
____Importance of limiting contact with individuals (distance and time)
____Sleeping arrangements
____Added precautions for children and pregnant women
____Personal care
____How long to wait before becoming pregnant
____Procedures for notification of healthcare workers if hospitalized or receive medical care
____ Handling of waste
____Other

Patient Release Criteria
Note: *Records of release criteria and all related calculations must be maintained for department review.*

____Administered activity does not exceed the value listed in Column 1 of Table 1 of NRC Regulatory Guide 8.39 for that radionuclide.
____ Retained activity at time of release does not exceed the value listed in Column 1 of Table 1of NRC Regulatory Guide 8.39 for that radionuclide.
____ Measured dose rate at one meter from the patient (from the surface of the patient) does not exceed the value listed in Column 2 of Table 1of NRC Regulatory Guide 8.39 for that radionuclide.
____ The patient was released based on patient-specific calculations according to the procedures NRC Regulatory Guide 8.39. The maximum likely dose to an individual exposed to the patient must not exceed 500 mRem per year. The maximum likely dose to an individual exposed to this patient is _____ mRem per year.

Determination

Based on the above, can the patient be released? Yes_____ No_____

Occupancy factor used (0.25 is the default value) _____ 0.25 _____ 0.125 _____ 0.5
_____ Other (please specify:_____)

Justification for modified occupancy factor:

_____ Date _____
Authorized user-physician

_____ Date _____
Radiation Safety Officer/Technologist