

# University of Alabama at Birmingham Release Criteria of Patients or Human Research Subjects Administered Radioactive Materials

Section (41) (a), "**Release of Individuals Containing Radioactive Drugs or Implants**" of Chapter 420-3-26 of the Rules published by the Alabama Department of Public Health, Office of Radiation Control, permits licensees to "authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)." The following procedure largely follows the Program-Specific Guidance About Medical Use Licenses (NUREG-1556, Vol. 9), published by the United States Nuclear Regulatory Commission, which is available for use by Agreement States such as Alabama.

## 1 Patient Release Criteria

Release of the patient must be approved by an individual listed as an authorized physician user on a UAB radioactive materials medical license (Radiation Oncology Administration, License Number 314, Nuclear Medicine Division, License Number 313, or Oncology Nuclear Medicine, License Number 237), and who is approved for the type of radioactive material use for which the patient being released has received.

### 1.1 Release of Patients Based on Administered Activity

An authorized physician user may release a patient from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1 below, and if the patient is not breast-feeding an infant or child. The activities in Table U.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual.

In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed below. The authorized physician user may demonstrate compliance by using the records of activity that are already required by the State of Alabama.

If the activity administered exceeds the activity in Column 1 of Table U.1, the authorized physician user may release the patient when the activity has decayed to the activity in Column 1 of Table U.1. In this case, **a patient survey by the UAB Health Physicist on-call (Pager: 7746) is required** because the patient's release is based on the retained activity rather than the administered activity.

If a radionuclide not listed in Table U.1 is administered, contact the UAB Radiation Safety Officer or the UAB Assistant Radiation Safety Officer (Robert J. Heath, Jr., Work: 934-2487, Pager: 8125, Home: 205-520-9568.)

The release activities in Column 1 of Table U.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table U.1 are not applicable to the infant or child.

## 1.2 Release of Patients Based on Measured Dose Rate

An authorized physician user may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, **a patient survey by the UAB Health Physicist on-call (Pager: 7746) is required** because the release is based on considering shielding by tissue.

## 1.3 Patient Release Consent Form

If a patient survey by the UAB Health Physicist on-call (Pager: 7746) is required, an authorized physician user must sign the **PATIENT RELEASE CONSENT FORM**, which contains the following statement:

“I consent to the release of the above patient upon meeting the following criteria:

The total activity remaining in the patient’s body has decayed to the activity listed in Column 1 of Table U.1 for that radionuclide, or the exposure rate at a distance of one meter away from the patient is no greater than the value in Column 2 of Table U.1 for that radionuclide, as determined by the UAB Health Physicist on-call. A copy of Table U.1 is printed on the other side of this form.”

As described below, this **PATIENT RELEASE CONSENT FORM** does not apply to patients who are breast-feeding an infant or child.

**Table U.1 Activities and Dose Rates for Authorizing Patient Release<sup>†</sup>**

Radionuclide	COLUMN 1		COLUMN 2	
	Activity at or below Which Patients May Be released		Dose Rate at 1 Meter, at or below Which Patients May Be released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

<sup>†</sup> The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

\* If the release is based on the dose rate at 1 meter in Column 2, the UAB Health Physicist on-call must perform a patient survey, because the measurement includes shielding by tissue.

\*\* Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

## 2 Instructions

### 2.1 Patients Requiring Instructions

An authorized physician user shall provide the released individual, or the individual's parent or guardian, with **both oral and written instructions** on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA) after the patient is released. If the patient is breast-feeding an infant or child, additional instructions may be necessary as described below.

### 2.2 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. Forms commonly used at UAB for written patient instructions can be found at the following web address:  
[http://www.healthsafe.uab.edu/pages/radiationsafety/patient\\_release\\_criteria.html](http://www.healthsafe.uab.edu/pages/radiationsafety/patient_release_criteria.html).

The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to 2.2.1 and 2.2.2).

#### 2.2.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

<p>Maintaining distance from other persons, including separate sleeping arrangements. Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events). Precautions to reduce the spread of radioactive contamination. The length of time each of the precautions should be in effect.</p>
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## 2.2.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for \_\_\_\_ days.

Stay at a distance of \_\_\_\_\_ feet from \_\_\_\_\_.

Maintain separate sleeping arrangements.

Minimize time with children and pregnant women.

Do not hold or cuddle children.

Avoid public transportation.

Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If you find a seed or pellet that falls out:

Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.

Place the container with the seed or pellet in a location away from people.

Notify \_\_\_\_\_ at telephone number \_\_\_\_\_.

## 3 Records of Release

There is no requirement for recordkeeping on the release of a patient who is released in accordance with the activity listed in Column 1 of Table U.1 for that radionuclide, and if the patient is not breast-feeding an infant or child, as described in Section 1.1. **The UAB Health Physicist on-call (Pager: 7746) performs patient surveys and generates records of release in all other cases.** A record of release should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration.

## 4 Patients Who Are Breast-Feeding an Infant or Child

It is assumed that the authorized physician user will inquire, as appropriate, regarding the breast-feeding status of the patient.

### 4.1 Release of Patients Who Are Breast-Feeding an Infant or Child

**If a patient is breast-feeding an infant or child, contact the UAB Radiation Safety Officer or the UAB Assistant Radiation Safety Officer (Robert J. Heath, Jr., Work: 934-2487, Pager: 8125, Home: 205-520-9568.)** The criteria for releasing patients who are breast-feeding an infant or child are much stricter than the criteria for releasing other patients.

#### **4.1.2 Patient Release Consent Form for Patients Who Are Breast-Feeding an Infant or Child**

An authorized physician user must contact the UAB Radiation Safety Officer or the UAB Assistant Radiation Safety Officer to obtain and sign a special **PATIENT RELEASE CONSENT FORM** for patients who are breast-feeding an infant or child.

#### **4.2 Instructions for Patients Who Are Breast-Feeding an Infant or Child**

Instructions for patients who are breast-feeding an infant or child follow the guidelines given in Sections 2.1—2.2.2 above, as well as the additional instructions given in the next section.

##### **4.2.1 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release**

If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions provided by the authorized physician user shall also include:

- 1) Guidance on the interruption or discontinuation of breast-feeding; and
- 2) Information on the potential consequences, if any, of failure to follow the guidance.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid.

Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. The requirements regarding both oral and written instructions to patients who could be breast-feeding an infant or child do not in any way interfere with the discretion and judgment of the authorized physician user in specifying the detailed instructions and recommendations.

#### **4.3 Records of Instructions for Breast-Feeding Patients**

The authorized physician user must maintain a record of the instructions provided to breast-feeding women. The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, and the date of the administration.

## **5 Additional Notification Requirements**

An authorized physician user must notify the UAB Radiation Safety or the UAB Assistant Radiation Safety Officer (Robert J. Heath, Jr., Work: 934-2487, Pager: 8125, Home: 205-520-9568) immediately if an incident occurs involving a patient, such as a patient departing prior to an authorized release.

## **6 Special Procedures for Authorizing Patient Release**

Patients who ordinarily cannot be released from licensee control by an authorized physician user may be released under an approved special procedure, such as the GliaSite patient release procedure. A special release procedure must be approved by the Alabama Department of Public Health, Office of Radiation Control, before patients can be released under the procedure.