

Release 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 radiopharmaceuticals or permanent 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)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Patients who are breast-feeding an infant or child must be considered separately, as discussed in Regulatory Position 1.1, "Release of Patients Based on Administered Activity."

Regulatory Position

1 Release Criteria

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1. 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 in Regulatory Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table U.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table U.1. In this case, a record is required by 10 CFR 35.75(c) 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, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem).

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. In this case, it may be necessary to give instructions as described in Regulatory Positions 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

1.2 Release of Patients Based on Measured Dose Rate

Licensees 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, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

Table U.1 Activities and Dose Rates for Authorizing Patient Release[†]

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

† 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 licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Regulatory Position 3.1, "Records of Release," for information on records.

** 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 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations, the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.⁽¹⁰⁾ Column 1 of Table U.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table U.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Regulatory Position 2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.⁸ The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be

breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table U.3, instructions on discontinuation or on the interruption period for breast-feeding and the consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table U.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table U.3 are commonly used in medical diagnosis and treatment.

2.3 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. 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 2.3.1 and 2.3.2).

Table U.2 Activities and Dose Rates Above Which Instructions Should be Given When Authorizing Patient Release*

Radionuclide	COLUMN 1 Activity above Which Instructions are Required		COLUMN 2 Dose Rate at 1 Meter above Which Instructions are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7

Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** 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.

Table U.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	COLUMN 1		COLUMN 2		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding*
	Activity above Which Instructions are Required (MBq)	(mCi)	Activity above Which a Record is required (MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hr for 370 MBq (10 mCi) 12 hr for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hr for 150 MBq (4 mCi)

Tc-99m Pertechnetate	100	3	600	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq(12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2000	50	6 hr for 740 MBq(20 mCi)
Tc-99m Red Blood Cell In Vitro Labeling	1000	30	6000	150	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hr for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to

a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

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

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.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The pamphlet contains blanks, for the physician to fill in the length of time that each instruction should be followed. While this pamphlet was written for the release of patients to whom less than 1,110 mega becquerels (30 millicuries) of iodine-131 had been administered, the NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

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. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 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

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table U.1. This record 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. In addition, depending on the basis for release, records should include the following information:

For Immediate Release of a Patient Based on Measured Dose Rate: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

For Delayed Release of a Patient Based on Radioactive Decay Calculation: The time of the administration, date and time of release, and the results of the decay calculation.

For Delayed Release of a Patient Based on Measured Dose Rate: The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table U.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

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, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.