

Employee Training

Patient Release Criteria per 10 CFR 35.75

Who Does “Patient Release” Affect?

In regulatory terms, every patient administered byproduct material in either sealed or unsealed form is affected by this section of the regulations.

The NRC notes the following regarding “Patient Release”:

A licensee may 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).

From a practical standpoint and as a gross generalization, this section of the regulations has an affect on patients administered Sodium ¹³¹Iodide in therapeutic quantities.

The overwhelming majority of radiopharmaceuticals administered to patients would not under normal circumstances be capable of delivering an effective dose potential of 500 mrem to others.

What Methods of Release are Acceptable?

A. Based on Administered Activity

Table A notes the calculated administered activity of various radionuclides that would result in a total effective dose equivalent (TEDE) of 5 mSv (0.5 rem). These calculations are based on the following conservative assumptions:

- Administered Activity (vs. Activity Retained by the Patient)
- Physical Half-life Only (No biological elimination)
- No Shielding Attributed to the Patient’s Own Tissue
- No Internal Exposure Considered
- Patient Behavior or Radiation Safety Instructions are Provided
- Occupancy Factor of 0.25 at 1 meter for Half-lives > than 1 day
- Occupancy Factor of 1 at 1 meter for Half-lives < or equal to 1 day

NOTE: What is “Occupancy Factor”?

This can be equated to the “contact time at one (1) meter” that a patient has with other individuals. The NRC assumes an initial period of contact to be based on the first eight (8) hours after administration.

Occupancy Factor of 0.25 means 75% of the first 8 hours (6 hrs.) is at 1 meter.

NOTE: **Minimal Suggested Patient Behavior Instructions for Radiopharmaceuticals**

Patient can maintain prudent distance from others for at least the first two(2) days
Patient can sleep alone in a room for at least the first night
Patient will not travel by mass transit or airplane for first day
Patient will not travel with others for prolonged car trip for two (2) days
Patient will have sole use of a bathroom for two (2) days
Patient will drink plenty of fluids for two (2) days

NRC does not enforce patient compliance. Additionally it is NOT the licensee's responsibility.

If you choose to use administered activity as your release criteria you are accepting the assumptions noted above and may use the values noted in Table A.

Criteria for Release: The administered activity is not greater than the activity listed in Table A, therefore, given the noted assumptions the patient is assumed to not potentially expose others to 5 mSv (0.5 rem) TEDE.

Records of Release: No specific record of release is required. However for the purposes of proof of compliance in an audit, documentation is crucial.

B. Based on Exposure Rate at One (1) Meter

Table B notes the exposure rates by radionuclide at one (1) meter from a patient. Measured exposure rates below these values indicate the patient may be released.

The measured exposure rate from an individual patient automatically assumes by design that shielding by the patient's own tissue is considered. Therefore the administered activity could be greater than the values noted in Table A and/or a time delay is in effect.

All of the other assumptions noted above to include patient instructions are in effect

Criteria for Release: The measured exposure rate is not greater than that listed in Table B, therefore, given the noted assumptions the patient is assumed to not potentially expose others to 5 mSv (0.5 rem) TEDE.

Records of Release: A specific record of release is required. It should contain a patient identifier, radioactive material, administered activity, date of administration, results of the measurement, specific notation of the ion chamber used and the name of the surveyor

C. Based on Retained Activity

This method of release assumes that there is a delay between the time of administration and the assessment of the retained activity value.

The calculated residual activity obviously assumes biological elimination of effective half-life is considered. By the method noted below shielding by the patient's own tissue is also considered.

All of the other assumptions noted under section A above are in effect to include patient instructions.

It is suggested that the following calculation scheme and documentation be maintained to support your case for specific release of this patient. Once the calculated residual activity is not greater than the activity listed in Table A, the patient may be released.

Measurements should be made with a suitably calibrated ion chamber at one (1) meter in a reproducible patient geometry.

<u>Patient Specific Residual Activity Calculation</u>			
Initial Conversion Factor	"F" = (Administered Activity) / (mR/hr @ 1m with Patient Standing)		
INITIAL CONVERSION FACTOR	F =	_____ mCi / _____ mR/hr @ 1m =	_____
Daily Residual Activity = (F) (Daily mR/hr @ 1 m)			
<u>INITIAL SURVEY</u>			
DATE	TIME	EXPOSURE RATE	Administered Act.
_____	_____	_____ mR/hr	_____ mCi
<u>DAILY SURVEYS</u>			
_____	_____	_____ mR/hr	Residual Activity _____ mCi
_____	_____	_____ mR/hr	_____ mCi

Criteria for Release: The calculated residual activity is not greater than the activity listed in Table A, therefore, given the noted assumptions the patient is assumed to not potentially expose others to 5 mSv (0.5 rem) TEDE

Records of Release: A specific record of release is required. It should contain a patient identifier, radioactive material, administered activity, date of administration, time of administration, date & time of release and the results of the decay calculation and specific notation of the ion chamber used and the name of the surveyor

D Based on Patient Specific Calculations

This is an individualized calculation based on the following issues for Iodine-131 therapy patients.

- Specific Gamma Ray Constant (converts mR/hr to mCi) Γ
- Administered Activity Q_o
- Physical Half-lives T_p
- Effective Half-lives
- Distance r^2
- Occupancy Factors for the first eight (8) hours (0.75) E
- Occupancy Factors from eight (8) hours to total decay (0.25)
- Measured Thyroid Uptake Values or
- NRC Assumed Thyroid Uptake Values and
- Extrathyroidal Uptake Values

The following is the base equation for calculation of dose:

$$D(\infty) \text{ mrem} = 34.6 \Gamma Q_o T_p E (1 - e^{-0.693 t / T_p}) / r^2$$

Because of the two phase exponential biological decay of Iodine-131 from thyroidal tissue and the assumed thyroidal and extrathyroidal uptakes of each of the following disease states, the equation noted above must be mathematically expanded to accommodate all of these factors. Additionally due to the fast initial iodine release the occupancy factors must be varied over the time course to total decay.

We have simplified these expanded equations below for hyperthyroid patients with expected high thyroidal uptake and low extrathyroidal uptake values. The first simplified equation allows the use of a patient specific measured thyroid uptake. The second simplified equation uses the NRC assumed thyroid uptake of 80%. Either is acceptable.

HYPERTHYROID – PATIENT RELEASE

- If you are using the patient’s own measured thyroid uptake, i.e. 48% = 0.48, the following equation can be used for patient release

$$D(\infty) \text{ mrem } = \{(9.026)(\text{Thyroid Uptake}) + 1.622\}(\text{_____ mCi})$$

$$= \text{_____ mrem}$$

- If the NRC assumed thyroid uptake value of 80% (0.8) is used:

$$D(\infty) \text{ mrem } = (8.837)(\text{_____ mCi})$$

$$= \text{_____ mrem}$$

We have simplified these expanded equations below for thyroid carcinoma patients with expected low thyroidal uptake and high extrathyroidal uptake values. The following equations assume a near total thyroidectomy has been accomplished on the patient. The first simplified equation allows the use of a patient specific measured thyroid bed uptake value. The second simplified equation uses the NRC assumed thyroid bed uptake of 5%. Either is acceptable.

THYROID CARCINOMA – PATIENT RELEASE

- If you are using the patient’s own measured thyroid bed uptake, i.e. 0.7% = 0.007, the following equation can be used for patient release

$$D(\infty) \text{ mrem } = \{(12.91)(\text{Thyroid Uptake}) + 1.622\}(\text{_____ mCi})$$

$$= \text{_____ mrem}$$

- If NRC assumed thyroid bed uptake value of 5% (0.05) is used:

$$D(\infty) \text{ mrem } = (2.265)(\text{_____ mCi})$$

$$= \text{_____ mrem}$$

What About the Internal Dose / Uptake from a Released Patient?

The NRC estimates that the intake of Iodine-131 from the patient to the most highly exposed individual would be on the order of 1 millionth (10^{-6}) of the administered activity. As a measure of conservatism the NRC assumes the fractional uptake to be 10^{-5} .

The additive internal component as a percentage of the external dose contribution can be ignored if it is likely to be less than 10%. This is due to the inherent uncertainty and assumptions in the external dose calculation.

For hyperthyroid patients this roughly equates to an internal dose that is approximately 3% of the external dose and therefore can be ignored.

For carcinoma patients this roughly equates to an internal dose that is approximately 24% of the external component and must be added to the external calculation. This could have a profound effect on the maximum activity to be administered under "normal" circumstances.

What is the Maximum Activity Allowed to be Administered for Release?

Hyperthyroid Patients:

- Occupancy factor of 0.25 or 6 contact hours of the initial 8 hours at one (1) meter
- Patient behavior instructions as previously noted
- NRC assumed uptake of 80%
- Internal component can be ignored.

Maximum Administered Activity 56.58 mCi

Thyroid Carcinoma Patients

- Occupancy factor of 0.25 or 6 contact hours of the initial 8 hours at one (1) meter
- Patient behavior instructions as previously noted
- NRC assumed uptake of 5%
- Internal component must be added

Maximum Administered Activity 178 mCi

Maximum administered activity can be adjusted if contact hours within the initial 8 hours are adjusted as follows:

<u>Contact Hours</u>	<u>Max. Administered Activity</u>
6 hours	178 mCi
4 hours	200 mCi
2 hours	235 mCi
1 hour	255 mCi

These data point to the extreme importance of a pre-administration patient interview to ensure that the patient can comply with the assumptions noted previously and the initial contact hours limitation once released.

The most common practical issues that determine if a patient can be released or must be treated as an inpatient are the inability to comply with one or both of the following assumptions:

Patient will have sole use of a bathroom for two (2) days

AND

Limited Initial Contact Hours (as noted above)

Criteria for Release: Through the patient specific dose calculation, it is assumed that the patient will not potentially expose others to 5 mSv (0.5 rem) TEDE, given the attention to the limitations noted above and strict adherence to the patient behavior instructions,

Records of Release: A specific record of release is required and should include a patient identifier, radioactive material, administered activity, date of administration, the equation used, the calculated TEDE, the patient specific factors (i.e. effective half-life & uptake fraction) and occupancy factor.

Patient Instructions

10 CFR 35.75(b) requires that for any administration of unsealed or sealed byproduct material or radiation from byproduct material that results in the dose to others of 1 mSv (0.1 rem) instructions must be provided to the patient to reduce doses to ALARA levels,

PATIENT RELEASE CRITERIA PER 10 CFR 35.75

MPC has prepared two (2) sets of tailored instructions for patients. They are specific for patients treated for hyperthyroidism and those treated for thyroid carcinoma. Each set is tiered by activity levels as follows:

Hyperthyroid	Below 7 mCi (Can be used for Whole Body Scans also)
	7- 15 mCi
	16 – 33 mCi
	34 – 55 mCi
Thyroid Carcinoma:	Below 33 mCi
	33 – 100 mCi
	101 – 150 mCi
	151 – 200 mCi

Because hyperthyroid patients have an over-functioning thyroid gland, the duration of their behavior modification instructions are long when compared to a carcinoma patient who is assumed to not have a thyroid gland and would biologically release Iodine-131 faster, making them less of a hazard over the long term.

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Table A: Activity Threshold For Patient Release

Radionuclide	Activity At or Below Which Patients May Be Released	
	(GBq)	(mCi)
Ag-111	19	520
Au-198	3.5	93
Cr-51	4.8	130
Cu-64	8.4	230
Cu-67	14	390
Ga-67	8.7	240
I-123	6.0	160
I-125	0.25	7
I-125 implant	0.33	9
I-131	1.2	33
In-111	2.4	64
Ir-192 implant	0.074	2
P-32*	370	10000
Pd-103 implant	1.5	40
Re-186	28	770
Re-188	29	790
Sc-47	11	310
Se-75	0.089	2
Sm-153	26	700
Sn-117m	1.1	29
Sr-89*	135	3660
Tc-99m	28	760
Tl-201	16	430
Y-90*	1420	38500
Yb-169	0.37	10

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

*Bremsstrahlung Radiation Exposure from Pure b-Ray Emitters
P.B. Zanzonico, et.al. JNM Vol 40:6 1024-1028 June 1999

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Table B Dose Rates for Authorizing Patient Release

Radionuclide	Dose Rate at 1 Meter, at or below Which Patients May Be released*	
	(mSv/hr)	(mrem/hr)
Ag-111	0.08	8
Au-198	0.21	21
Cr-51	0.02	2
Cu-64	0.27	27
Cu-67	0.22	22
Ga-67	0.18	18
I-123	0.26	26
I-125	0.01	1
I-125 implant	0.01	1
I-131	0.07	7
In-111	0.2	20
Ir-192 implant	0.008	0.8
P-32	**	**
Pd-103 implant	0.03	3
Re-186	0.15	15
Re-188	0.20	20
Sc-47	0.17	17
Se-75	0.005	0.5
Sm-153	0.3	30
Sn-117m	0.04	4
Sr-89	**	**
Tc-99m	0.58	58
Tl-201	0.19	19
Y-90	**	**
Yb-169	0.02	2

*If the release is based on the dose rate at 1 meter, 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.

** 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.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated based on the millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants.

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In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values