THE UNIVERSITY OF TEXAS

MDAnderson Cancer Center

Release of Radioactive Patients from Restrictions Using NUREG-1556

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NUREG - 1556 Vol. 9, Rev. 2

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

Final Report

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Why do we care?



RAM Licensees

Obligation to protect



Public Dose Limits

- 1 mSv per year
- When releasing radioactive patients, we have more flexibility
- NRC allows the individuals exposed by a released radioactive patient to receive up to 5 mSv for each patient release
 - This person is assumed to derive some benefit from their proximity to the patient (e.g. spouse)
 - "Extra" dose is considered infrequent

The Old "30 mCi Rule"

- Patients with > 30 mCi I-131 onboard had to remain hospitalized until residual activity was ≤ 30 mCi
- Analytical origin not exactly clear
- Old Atomic Energy Commission (AEC) recommendation (1957), then requirement (1963)
- AEC abolished in 1974 (Energy Reorganization Act of 1974)

Siegel JA. Tracking the Origin of the NRC 30-mCi Rule. J Nucl Med 2000;41(#10):10N-16N.

NCRP Report No. 37

- 1970
- Suggests using dose to other individuals as a basis for releasing patients... NOT activity
- Used D(∞) equation from 1956 textbook by Hine & Brownell, Radiation Dosimetry
- No occupancy factor in equation, but suggested accounting for time patient spends with other individuals
- Notes differing exposure rate constants and half-lives as support for dose-based release

NRC Piles On

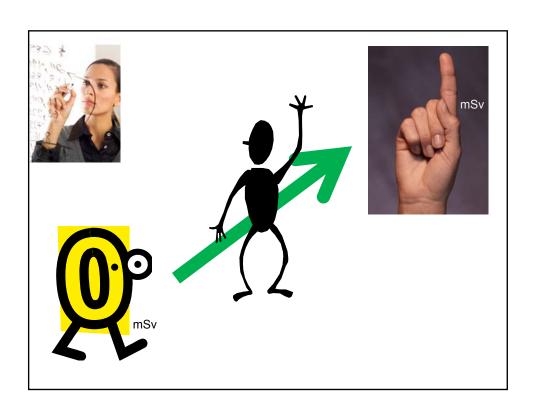
- 30 mCi rule was license condition until 1987
- 1987: 10 CFR 35 modified to include < 30 mCi
 or < 5 mrem/hr
- Presenter aside: I'm not really sure where they got 5 mrem/hr
 - $-\Gamma = 2.2 \text{ R-cm}^2/\text{mCi-hr}, f = 0.963 \text{ rem/R}$
 - -23.5 mCi \rightarrow 5.2 mR/hr & 4.98 mrem/hr
 - Measurement specified at umbilicus... Assumed patient attenuation?

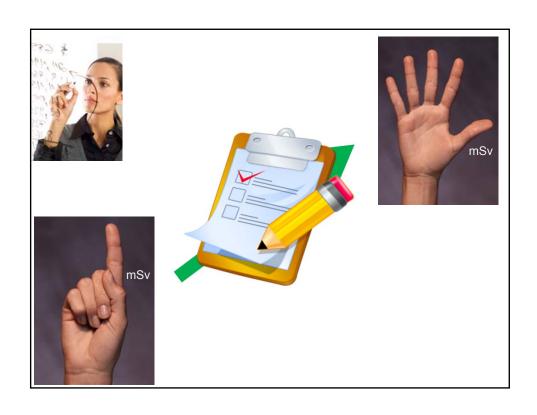
NRC Sees the Light

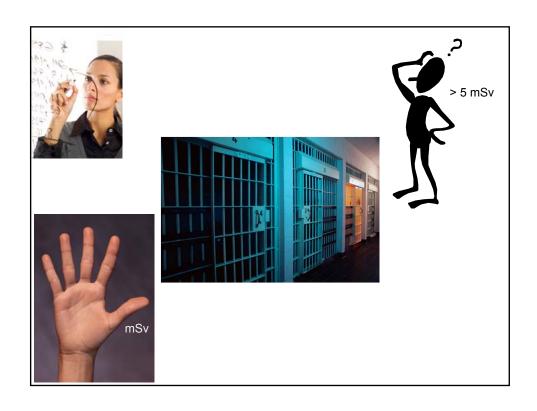
- 1997: 30 mCi rule is [mostly] dropped
- New dose-based criteria
 - Account for differing half-lives and emissions of various radionuclides
- Default activity & dose rate tables given in Regulatory Guide 8.39
- Assume occupancy factor @ 1 m = 0.25, gamma constant (point source) or measured dose rate
- Patient-specific calculations allowed

Dose-Based Criteria 10 CFR 35.75

- Licensees permitted to "authorize the release from its control of any individual... if the total effective dose equivalent (TEDE) to any other individual... is not likely to exceed 5 mSv (0.5 rem)."
- Licensee required to "provide the released individual with instructions... if total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem)."







Instructions Required

- Any time TEDE to an individual is likely to exceed 1 mSv
 - Exceed NUREG tabulated values
- Nursing mothers whose breastfeeding could lead to > 1 mSv to infant

Release Records Required

- Unless administered activity and physical halflife are used as the basis for release, licensee must keep basis of release authorization records for 3 years after date of release
- Or if occupancy factor reduced below 0.25

NCRP 37 (1970)

D (t) =
$$34.6 \Gamma \text{ Ao Tp } (1 - e^{-0.693t/Tp})$$

Release Equation

NCRP 37 (1970)

D (t) =
$$34.6$$
 Γ Ao Tp $(1 - e^{-0.693t/Tp})$

r²

Exposure rate constant for a point source [R/mCi-hr @ 1cm]

NCRP 37 (1970)

D (t) =
$$34.6 \Gamma$$
 Ao Tp $(1 - e^{-0.693t/Tp})$

Initial activity of source at time of release [mCi]

Release Equation

NCRP 37 (1970)

D (t) =
$$34.6 \Gamma$$
 Ao T $(1 - e^{-0.693t}/T)$

NCRP 37 (1970)

D (t) =
$$34.6 \Gamma$$
 Ao T $(1 - e^{-0.693})^{T}$ r²

Release Equation

NCRP 37 (1970)

D (t) =
$$34.6 \Gamma$$
 Ao T $(1 - e^{-0.693 t/T})$

r²

Distance from source [cm]

NCRP 37 (1970)

D (t) =
$$\frac{34.6 \ \Gamma \ Ao \ T \ (1 - e^{-0.693 \ t/T})}{r^2}$$

Conversion of half-life units[24 hrs/day] multiplied by factor of 1.443 from integrating single exponential to infinity.

Release Equation

Most Exposed Person | Total Decay

D (
$$\infty$$
) = 34.6 Γ Ao T (1 - $e^{-0.693 \infty/T}$)

Most Exposed Person | Total Decay | Radionuclide $T_{1/2} > 1$ Day

$$D (\infty) = 34.6 \Gamma \text{ Ao T } (0.25)$$

$$100 \text{ cm}^2$$

Occupancy factor of 0.25 assumed for radionuclides with half life greater than one day.

NOTE: $T_{1/2} < 1 d \rightarrow Occupancy Factor = 1.0$ "...relatively long term averaging of behavior cannot be assumed."

Release Equation

Most Exposed Person | Total Decay | Radionuclide $T_{1/2} > 1$ Day

D (∞) =
$$34.6 \Gamma \text{ Ao T (0.25)}$$

100 cm²

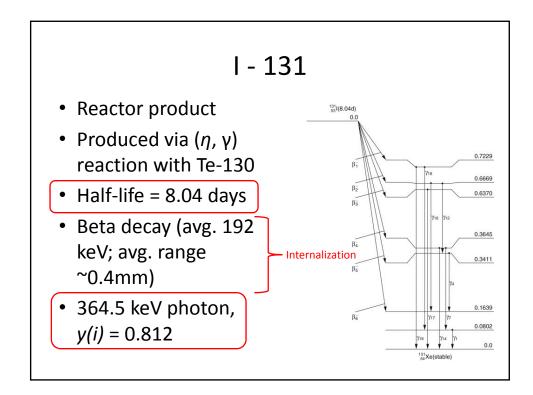
Regulatory analysis indicates 25% of total dose to decay at 1 m is conservative.

Bases for Release

- Ao and T_{phys}
- Measured Exposure Rate and T_{phys}
- Ao and T_{eff}
- Measured Exposure Rate and T_{eff}
- Ao in a Three Compartment Model

Radionuclides

- I-131 sodium iodide for thyroid therapy
- I-131-labeled radiopharmaceuticals for treating lymphoma or neuroendocrine tumors
- Sm-153-labeled bone-seeking agents
- Various brachytherapy sources
- Numerous research radiopharmaceuticals
- P-32, Sr-89, and Y-90
 - Considered pure beta emitters; no restrictions



I-131 Therapies in Medicine

- Certain types of hyperthyroidism
 - Graves disease, toxic nodular disease, nontoxic nodular goiter
- Differentiated papillary and follicular thyroid cancer
 - Thyroid remnant ablation after thyroidectomy
 - Treatment of residual or recurrent thyroid Cx
- Metastatic disease of thyroid origin

Nursing Mothers

 Following I-131 administration, complete cessation of breastfeeding is required for currently-nursing child(ren)

• Mother may nurse subsequent child(ren)



Simple release calculations

Ao and T_{phys}

D (
$$\infty$$
) = 34.6 Γ Ao T (1 - $e^{-0.693 \infty/T}$)

$$D(\infty) = 34.6 \Gamma Ao T(0.25)$$

Ao and T_{phys}

I-131

$$D (\infty) = 34.6 \Gamma Ao T (0.25)$$

$$\Gamma$$
 (I-131) = 2.2 R-cm² / mCi-hr

$$T = 8.04 \text{ days}$$

$$r = 100$$

$$D (\infty) = 34.6 * 2.2 * 32.5 * 8.04 * 0.25 = 498 \text{ mrem}$$

 100^2

Ao and
$$T_{\rm phys}$$

Tc-99m

$$D (\infty) = 34.6 \Gamma Ao T (0.25)$$

$$\Gamma$$
 (Tc-99m) = 0.756 R-cm² / mCi-hr
T = 0.251 days

r = 100

$$Ao = 760.0 \text{ mCi}$$

$$D (\infty) = 34.6 * 0.756 * 760 * 0.251 * 1 = 499 \text{ mrem}$$

 100^2

Measured Exposure Rate and T_{phys}

$$D(\infty) = 34.6 * X * T * (0.25)$$

Measuring "Γ" @ 1m; Ao and r terms drop out...

→ tissue shielding implicit

T = 8.04 days

$$D(\infty) = 0.5 \text{ rem} = 34.6 * X * 8.04 * 0.25$$

$$X = 7.18 \text{ mR/hr}$$

APPENDIX U

Table U.1 Ac	tivities and Dos	e Rates for Auti	horizing Patient Re	elease'
Radionuclide	COLUMN 1 Activity At or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, At or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
*				,
Ga-67	8.7	240	0.18	18
I-123	6	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
*				
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
T1-201	16	430	0.19	19
Y-90	**	**	**	**

^{**} 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.

Remember instructions!

100 mrem Threshold for Instructions

- Repeat calculations using 0.1 rem threshold
- Or, look at Table U.2

100 mrem Dose Limit

- Children (other than nursing)
- Pregnant women
- Fellow travelers
- Members of the public

Not specifically addressed by regulatory guidance.

Nursing children addressed by regulatory guidance

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)		
‡			1			
I-131	0.24	7	0.02	2		
<u></u>						
Tc-99m	5.6	150	0.12	12		

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)		
<i>‡</i>						
P-32	**	**	**	**		
<i>‡</i>				.		
Sr-89	**	**	**	**		
<i>‡</i>						
Y-90	3¢ 3¢	**	3¢ 3¢	**		

^{**} 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.

Radionuclide: I-131 Half-life: 8.0 days Dosage: 157 mCi Date and Time of Administration: Thu, Jan 23, 2014 at 1:00 PM Sample Instructions

Measured Exposure Rate: 21 mR/hr at 1.0 m on Thu, Jan 23, 2014 at 1:05 PM

Date and Time of Actual Release from Radiation Safety Restrictions: Thu, Jan 23, 2014 at 3:00 PM

These instructions are especially for you. They may differ from those given to other patients. They are based upon the information that you have supplied to us about your personal circumstances. By following these instructions, you will reduce the radiation exposure that others will receive from you and it will be possible for you to leave the hospital earlier.

- · Do not start your travel before Thu, Jan 23, 2014 at 3:00 PM.
- Sleep alone (farther than six feet from anyone) until Fri, Jan 24, 2014 at 12:00 PM.
- Avoid children and pregnant women until Fri, Jan 24, 2014 at 3:00 PM.
- Then limit time with children and pregnant women (closer than six feet) until Fri, Jan 24, 2014 at 3:00 PM.
- Stay farther than six feet from others until Thu, Jan 23, 2014 at 8:43 PM.
- Do not return to work before Thu, Jan 23, 2014 at 1:00 PM.

Upon Discharge: After you have been discharged, it is important that you leave the premises immediately and begin your trip home. Please do not make plans to stop into the clinics, pick up prescriptions, eat at a restaurant or go shopping after your release

Once you are at home, it is important that you remember to

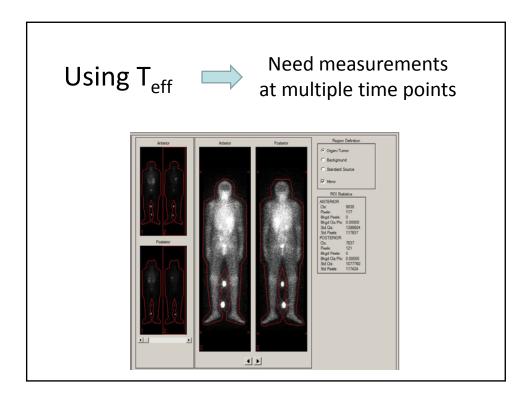
- · Continue to rinse the sink well after use for one week
- · Flush the toilet three times after each use for one week
- · Sit to urinate (both ladies and gentlemen) in order to minimize splashing

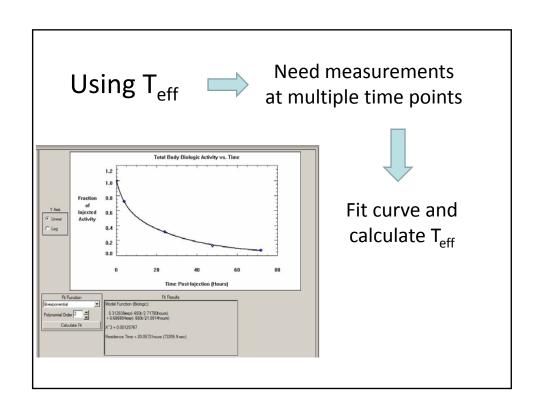
You should carry with you a copy of your specific release instructions for the next few days as the information about your therapy may prove helpful in an emergency situation.

Contact Information: You have been provided with oral and written instructions prior to your release and given an opportunity to ask any questions. If, in the next day or two, you find that you have questions about your instructions, please contact the Department of Nuclear Medicine at 713-563-6160 (Monday-Friday, 6:00 a.m. to 5:30 p.m.) or your home clinic.

Bases for Release

- Ao and T_{phys}
- Measured Exposure Rate and T_{phys}
- Ao and T_{eff}
- Measured Exposure Rate and T_{eff}
- Ao in a Three Compartment Model





Using $T_{\rm eff}$

Fit Results

Model Function (Biologic):

0.312838exp(-.693t/2.71780hours) $T_{bio} = \frac{2.72 * 21.09}{2.72 + 21.09} = 2.41 \text{ hours}$

 $T_{\rm eff} = 2.38 \text{ hours}$

Ao UL for release: 2650 mCi

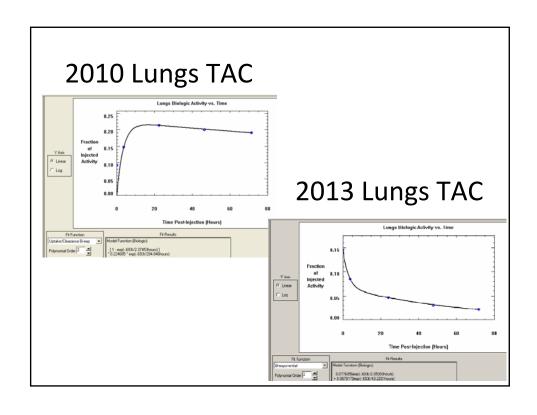
Ao UL for release: 2650 mCi

Other important considerations!

Previous treatment?

Dose to marrow?

Dose to lungs?



Three Compartment Model

Three Compartments

- 1. Circulating
- 2. Extrathyroidal
- 3. Thyroidal

Designed for I-131 Tx

Circulating Compartment

Accounts for:

- a) time for I-131 to be absorbed from stomach to blood
- b) Accumulation of I-131 in bladder

Circulating Compartment

$$t = 0 \rightarrow t = 8 \text{ hrs}$$
 80% * Ao @ T_{phys}

Extrathyroidal Compartment

$$t = 8 \text{ hrs} \rightarrow t = \infty$$

$$F_{ext} * Ao @ T_{eff,ext}$$

Thyroidal Compartment

$$t = 8 \text{ hrs} \rightarrow t = \infty$$



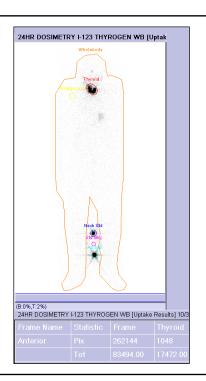
 $\mathbf{F}_{\mathrm{thy}}$ * Ao @ $\mathbf{T}_{\mathrm{eff,thy}}$

New Terms



 F_{thy} is measured

$$\mathbf{F}_{\text{ext}} = \mathbf{1} - \mathbf{F}_{\text{thy}}$$





Equation B-5:

$$D(\infty) = \frac{34.6 \,\Gamma \, Q_0}{(100 \, cm)^2} \left\{ E_1 \, T_p \, (0.8) (1 - e^{-0.693(0.33)/T_p}) \right\}$$

$$+ \quad e^{\,-0.693(0.33)/T_p}\,E_2\,\,F_1\,\,T_{1e\!f\!f}\,+\,e^{\,-0.693(0.33)/T_p}\,\,E_2\,\,F_2\,\,T_{2e\!f\!f} \bigg\}$$

where: $F_1 = Extrathyroidal uptake fraction;$

 F_2 = Thyroidal uptake fraction;

 E_1 = Occupancy factor for the first 8 hours; and

 E_2 = Occupancy factor from 8 hours to total decay.

Three Compartment Model

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \, cm)^2} \left\{ E_1 T_p (0.8) (1 - e^{-0.693(0.33)/T_p}) \right\}$$

$$+ \quad e^{\,-0.693(0.33)/T_p}\,E_2\,\,F_1\,\,T_{1e\!f\!f}\,+\,e^{\,-0.693(0.33)/T_p}\,\,E_2\,\,F_2\,\,T_{2e\!f\!f}\,\Big\}$$

Three Compartment Model

$$D(\infty) = \frac{34.6 \,\Gamma \, Q_0}{(100 \, cm)^2} \left\{ E_1 \, T_p \, (0.8) (1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 \, F_1 \, T_{1eff} + e^{-0.693(0.33)/T_p} E_2 \, F_2 \, T_{2eff} \right\}$$
Circulating Compartment

Three Compartment Model

$$D(\infty) = \frac{34.6 \,\Gamma \, Q_0}{(100 \, cm)^2} \left\{ E_1 \, T_p \, (0.8) (1 - e^{-0.693(0.33)/T_p}) \right.$$

$$+ e^{-0.693(0.33)/T_p} E_2 \, F_1 \, T_{leff} + e^{-0.693(0.33)/T_p} \, E_2 \, F_2 \, T_{2eff} \right\}$$

Extrathyroidal Compartment

Three Compartment Model

$$D(\infty) = \frac{34.6 \,\Gamma \, Q_0}{(100 \, cm)^2} \left\{ E_1 \, T_p \, (0.8) (1 - e^{-0.693(0.33)/T_p}) \right.$$

$$+ e^{-0.693(0.33)/T_p} E_2 \, F_1 \, T_{leff} + e^{-0.693(0.33)/T_p} \, E_2 \, F_2 \, T_{2eff} \right\}$$
Thyroidal Compartment

Model Parameters

Uptake Fraction and Effective Half-Life for I-131 Treatments						
	Extrat	hyroidal	Thyre	oidal		
Medical Condition	F_1	T _{1eff} [d]	F ₂	T _{2eff} [d]		
Hyperthyroidism	0.20	0.32	0.80	5.2		
Post-Thyroidectomy for Thyroid Cancer	0.95	0.32	0.05	7.3		

If patient-specific uptake measurements are unavailable, one may use tabulated values.

Hyperthyroidism

	Extrat	hyroidal	Thyro	oidal
Medical Condition	F ₁	T _{1eff} [d]	F ₂	T _{2eff} [d]
Hyperthyroidism	0.20	0.32	0.80	5.2

Ao = 30 mCi D (∞) = 266 mrem

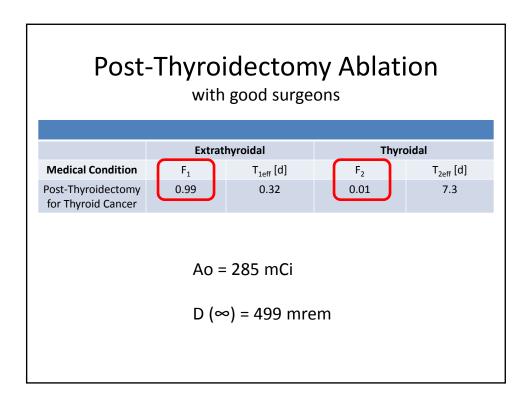
Ao = 56 mCi D (∞) = 496 mrem

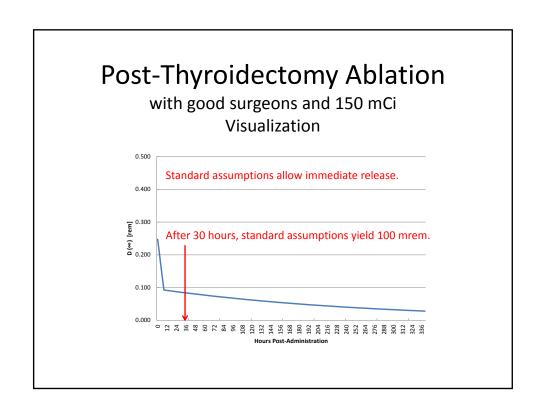
Post-Thyroidectomy Ablation

	Extrathyroidal		Thyroidal	
Medical Condition	F_1	T _{1eff} [d]	F ₂	T _{2eff} [d]
Post-Thyroidectomy for Thyroid Cancer	0.95	0.32	0.05	7.3

Ao = 220 mCi

D (∞) = 499 mrem





If you're bored... A B C D E F G Post-Thyroidectomy for Thyroid Cancer Administered Activity 150 mci E1 0.75 E2 0.25

0.25 E2 F1 0.99 0.32 Teff2 7.3 index distance [cm] 100 10 34.6*Gamma*Ao/r^2 1.142856 11 12 Post-Admin **Compartmental Contributions** 13 14 days Circulating Extrathyroidal Thyroidal 15 0.00 0.155 0.088 0.020 16 0.08 0.116 0.088 0.020 0.224 0.17 0.077 0.088 0.020 0.185 18 0.038 0.146 0.25 0.088 0.020 19 0.33 0.088 0.020 0.108 0.087 0.020 0.107 0.087 0.020 0.107 0.58 0.086 0.020 0.106 0.67 0.085 0.020 0.105 0.75 0.085 0.020 0.104 0.084 0.019 0.104

Advanced Behavior Modeling

Regulatory guidance does not address how to handle any person other than the most exposed.

http://jnm.snmjournals.org/content/43/3/354.full.pdf

Siegel et al developed models for public, fellow travelers, children & pregnant women, and sleeping partners, for I-131-labeled radiopharmaceutical Bexxar.

Most Exposed Person

- 500 mrem
- 6 hours per day @ 1 m after release
 - Fellow traveler?
 - Sleeping partner?

Fellow Traveler

- 100 mrem (depending)
- X hours @ Y distance
 - Caretaker?
 - Sleeping partner?

Sleeping Partner

- Probably 500 mrem
 - But from multiple sources
- 4.5 hrs/day @ 1 m
 - During period of sleeping apart
- Then add 6 hrs/day @ 0.3 m
 - Caretaker?
 - Fellow traveler?

Children & Pregnant Women

Period of no exposure

Limited Contact:

• 30 mins/day @ 1 m + 6 mins/day @ 0.3 m

Normal Contact:

• 6 hrs/day @ 1 m + 30 mins/day @ 0.3 m

Public (Co-Workers)

• 6 hrs/day @ 1 m

Internal Dose

$$D_{internal} = Ao * 10^{-5} * DCF$$

- DCF are tabulated in old EPA document DCF = $1.44 \times 10^{-8} \text{ Sv/Bq} = 53.3 \text{ rem/mCi}$
- 10 ppm (10⁻⁵) assumed fraction of ingestion
- Two 1970's papers suggest 1 ppm

Internal Dose

$$D_{internal} = Ao * 10^{-5} * DCF$$

- 2013 paper by North et al in *Health Physics*
- Conclusion: Regulatory guidance is reasonable, if not conservative wrt internalization
 - Note: All patients were hospitalized overnight

Internal Dose

$$D_{internal} = Ao * 10^{-5} * DCF$$

If $D_{internal} < 0.10 * D_{external}$

D_{internal} may be ignored

"Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose."

Critical Details

- Not every patient is fit for release
- Accelerated release has strings attached
- One size does NOT fit all
- Ability to follow instructions

Why bother?

- Reduction of personnel exposure
- Cost of care
- Patient welfare
- Room availability

Case Study #1

0.2% Thyroidal Uptake

99.8% Extrathyroidal Uptake

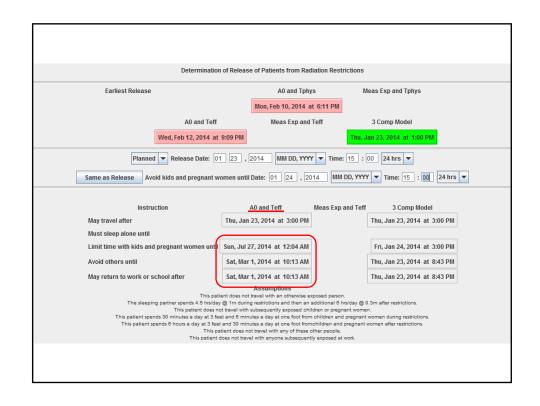


Son was traveling companion...

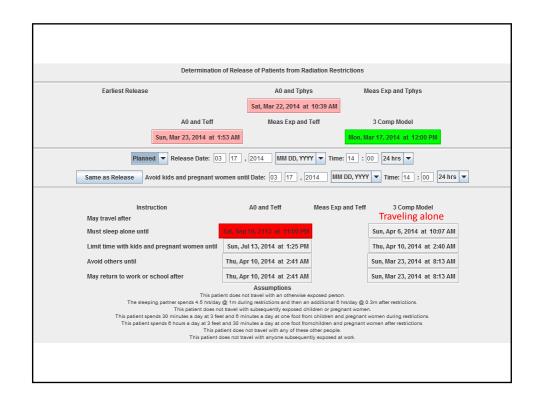
Young [grand]child at home

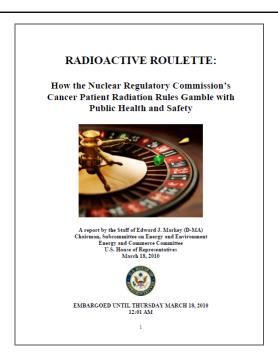
2 hour drive home

157 mCi



Case Study #2 Houston resident Two young kids at home ~50 mCi Not from USA Three prior thyroid removal surgeries





Rebuttal: http://pbadupws.nrc.gov/docs/ML1034/ML103481099.pdf

Q1: An individual administered radioactive material can be released by the licensee if the TEDE to the most exposed individual is not likely to exceed:

30% 1. 1 mSv

13% 2. 2 mSv

20% 3. 5 mSv

17% 4. 50 mSv

20% 5. 500 mSv

- 3. 5 mSv
- Ref: 10 CFR Part 35, §35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material."

Q2: What model for patient release described in NUREG-1556 (Vol.9, Rev.2, App.U) is most realistic (and yields the least onerous restrictions on the patient) for I-131 sodium iodide treatments of hyperthyroidism? 1. Administered activity and physical half-life 20% 2. Administered activity and 3-compartment 13% model 3. Administered activity and effective half-life 20% 4. Measured exposure rate and physical half-23% life 5. Measured exposure rate and effective half-23%

- 2. Administered activity and 3-compartment model
- Ref: NUREG-1556, Volume 9, Revision 2, Appendix U

Q3: A female patient who is nursing a child and receives I-131 sodium iodide should discontinue breastfeeding:

- 1. Until her exposure rate is less than 2 mR/hr at 1 meter
- 2. Until her exposure rate is less than 7 mR/hr at 1 meter
- 3. Only if she becomes nauseous after I-131 administration
- 4. Completely for that child and all future children
- 5. Completely for that child, but may nurse a subsequent child

- 5. Completely for that child, but may nurse a subsequent child
- Ref: Silberstein EB, et al. The SNM Practice Guideline for Therapy of Thyroid Disease with ¹³¹I 3.0. J Nucl Med 2012;53:1633-1651.

Q4: The 7 mrem/hr criteria for patient release is based on which assumptions? 1. Measured dose rate, physical half-life, 0.25 7% occupancy factor, tissue shielding 2. A₀, physical half-life, 0.25 occupancy 17% factor, no tissue shielding 3. A₀, biological half-life, 0.25 occupancy 33% factor, tissue shielding 4. A₀, biological half-life, 0.25 occupancy 27% factor, no tissue shielding 5. A₀, three compartment model, 0.25 17% occupancy factor, no tissue shielding

- 1. Measured dose rate, physical half-life, 0.25 occupancy factor, tissue shielding
- Ref: NUREG-1556, Volume 9, Revision 2, Appendix U

Q5: Internal dose to the most exposed person(s) may be ignored in calculations of total dose when they are likely to be less than:

- 1. 1% of external dose
- 2. 5% of external dose
- 30% 3. 10% of external dose
- 4. 20% of external dose
- 5. 50% of external dose

- 3. 10% of external dose
- Ref: NUREG-1556, Volume 9, Revision 2, Appendix U

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