

1

NUREG 1556-based Release of Patients from Radiation Safety Restrictions

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The aim of this presentation is to discuss the guidance by Nuclear Regulatory Commission on the release of radioactive patients, to review the calculations that are described in the guidance and to discuss how one might build upon the procedures in the guidance to accomplish an even more effective patient release program. This talk addresses only US regulations. The rules and practices in the rest of the world vary, and some of the references for this talk mention the differences.

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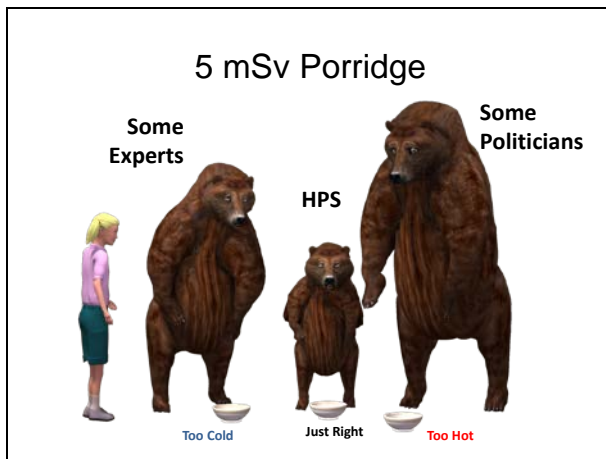
10 CFR 35.75

- A patient who has been administered radioactive materials may be released from controls provided that the total effective dose equivalent to any other individual as a consequence is unlikely to exceed **5 mSv (500 mrem)**.
- NUREG 1556, Volume 9, Appendix U, Revision 2 (née RegGuide 8.39) offers regulatory guidance for compliance.

2

Regulatory compliance is mandatory. The regulatory guidance offers a number of approaches to compliance that we will work through. The regulatory guidance also establishes a framework in which more advanced approaches may be considered by modification of model parameters. The rationale for a higher limit than that to the general public is that the most exposed person is presumed to derive benefit from his or her exposure to the patient.

3



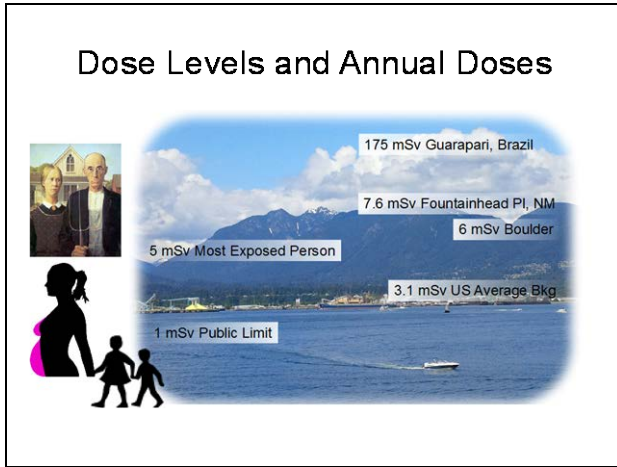
Some influential politicians argue that 5 mSv is too dangerous and that we should return to the old 30 mCi or 5 mR/hr @ 1 m release criteria.

Some influential physicists and physicians argue that the 5 mSv limit is well below the threshold of danger and could safely be relaxed.

The position of the Health Physics Society is that the 5 mSv limit does no discernible harm to the public and balances safety concerns with benefits to patients, their families and society. The Health Physics Society position statement accurately reflects the reality that there is great benefit in releasing patients using the 5 mSv limit.

The computations in the regulatory guidance are arguably quite conservative.

4



We must keep the dose to the most exposed person under 500 mrem (5 mSv). To put this in context, the typical annual background dose is around 300 mrem (3 mSv, but it varies with elevation and the local level of environmental radioactivity). Children and pregnant woman should receive no more than 100 mrem (1 mSv) a year (ICRP 94). Since the dose limit for members of the general public is 100 mrem (1 mSv), it makes sense to keep the doses of disinterested people, including fellow travelers, below 100 mrem (1 mSv) also, as they derive no benefit from exposure to the patient.

American Gothic is in the public domain:

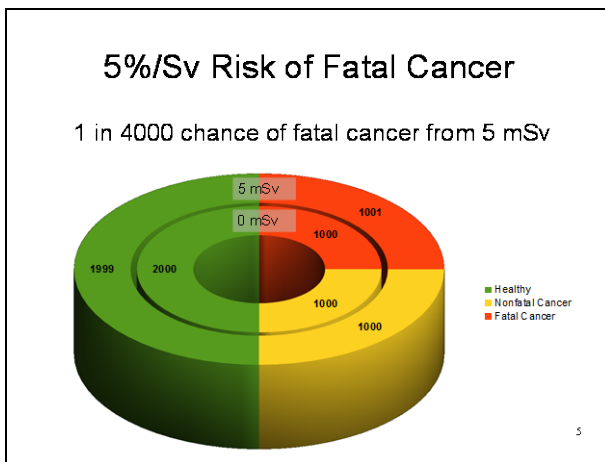
http://en.wikipedia.org/wiki/American_Gothic

The clip art of the pregnant woman and children is from a free clip art Web site

<http://www.openclipart.org/>.

All other illustrations in this presentation are the work of the author, except for a section of a Google map, which is copyright Google, 2012. Many of these were made with the Poser Pro software package.

5



The overall risk of fatal cancer at low doses has been estimated to be 5% per sievert. That predicts one excess fatal cancer in a cohort of 4000 people, each member of which is exposed to 5 mSv.

Compare this to the 50% likelihood of developing cancer anyway, and the half of those cases that will be fatal. The inner barrel shows the healthy (green), non-fatal cancer (yellow) and fatal cancer (red) cases in a cohort of 4000 people.

The outer barrel shows the same for a cohort of 4000 people, every one of whom has been exposed to 500 mrem (5 mSv). One green person has turned red.

It is almost impossible to tell the difference by looking at this plot. Furthermore, it is impossible to know which one among the 1001 cancers was caused by exposure to a radioactive patient.

Another way to look at this analysis is that the 1999 healthy people know with certainty that their 5 mSv doses did not cause cancer. The 1001 people who contract a fatal cancer after a 5 mSv dose have a 0.1% probability that their cancer was caused by their 5 mSv dose and a 99.9% probability that they got cancer for some other reason.

6

Radionuclides

- . I-131 sodium iodide for thyroid therapy
- . I-131-labeled radiopharmaceuticals for treating lymphomas or neuroendocrine tumors
- . Sm-153-labeled bone-seeking agents
- . Various brachytherapy sources
- . Numerous research radiopharmaceuticals
- . P-32, Sr-89 and Y-90, which are considered to be pure beta emitters, have no restrictions.

6

I-131 sodium iodide is the principal therapeutic radiopharmaceutical in most nuclear medicine departments. There are other approved therapeutic agents with administered activities for which a calculated release might be needed. Note that P-32, Sr-89 and Y-90 patients are immediately releasable regardless of the administered activity on the basis that these radionuclides are pure beta emitters.

7

Exposed Persons

- . Addressed by regulatory guidance
 - . Most exposed person
 - . Nursing children
- . Additional concerns
 - . Members of the public
 - . Children (other than nursing)
 - . Pregnant women
 - . Fellow travelers

7

The most exposed person is allowed to receive 5 mSv (500 mrem) on the theory that that person derives some benefit from the exposure. This person is often a spouse, a parent, an adult child or friend or someone else who helps to care for the patient. The guidance also addresses nursing children and whether breastfeeding should be discontinued or interrupted for a period of time to keep the dose to the nursing child below 1 mSv (100 mrem). Although the regulatory limit is 5 mSv (500 mrem), in keeping with ICRP 94 and the work of Jeff Siegel and others, in our practice we set the dose limit to those who are especially sensitive or who would derive no benefit from exposure to the patient to 100 mrem. These include members of the general public, children in the patient's household, pregnant women and fellow travelers.

8

Release Bases

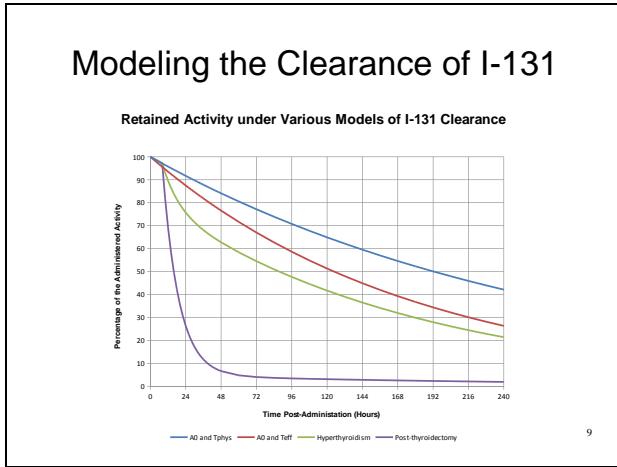
- . Administered Activity and Physical Half-life
- . Measured Exposure Rate and Physical Half-life
- . Administered Activity and Effective Half-life
- . Measured Exposure Rate and Effective Half-life
- . Administered Activity in a Three Compartment Model (geared toward I-131)

- . Internalization

8

The regulatory guidance describes methods of increasing sophistication (and decreasing conservatism) for release calculations. The guidance also addresses internalization by the most exposed person of a portion of the radioactive material that was administered to the patient.

9



The theoretical whole body time-activity curves for these various models demonstrate a wide variation in the cumulated activity within the patient (i.e., the total number of disintegrations and hence the energy radiating from the patient).

The area under these curves represents the number of disintegrations that are presumed to take place within the patient and thus that have the potential to deliver energy to the most exposed person.

10

Occupancy Factors

E	Conditions
1.0 – 0.75 (18-24 hrs/day)	When the half-life is shorter than a day
0.25 (6 hrs/day)	When the half-life is longer than a day and the patient can comply with lifestyle instructions that are consistent with this occupancy factor
0.125 (3 hrs/day)	When the half-life is longer than a day and the patient can comply with lifestyle instructions that are consistent with this occupancy factor
0.75; 0.25 (18 hrs/day; 6 hrs/day)	When a two compartment model has one compartment with a half-life shorter than a day and the other with a half-life longer than a day, one may use as a single occupancy factor whichever one is associated with the compartment that dominates the dose.

The occupancy factor is the fraction of the day that an exposed person is at a specified distance (typically one meter) from the patient.

The regulatory guidance gives some occupancy factors that may be used under the stated conditions.

One can design a custom occupancy factor if specifics of the behavior or the patient and the exposed person are known.

It is important to interview the patient in order to understand his or her living conditions and to assess his or her ability to be an active partner in tempering the dose to the exposed persons. For efficiency, this interview can be conducted by a technologist or physician at the same time that other matters are discussed with the patient.

11

A_0 and T_{phys}

- Occupancy factor of 0.25 @ 1 m if $T_{phys} > 1$ day and 1 @ 1 m if $T_{phys} < 1$ day.
- No shielding by tissue (of the patient or of the exposed person).

It is implicit here that the patient is modeled as a point source and that the exposed person is considered to be a point target. Neither is an accurate approximation. This tends to overestimate the dose to the exposed person.

Furthermore, assuming that the entirety of the administered activity is cleared from the patient only by physical decay is contrary to our clinical experience and might vastly overestimate the dose to the exposed person.

12

A_0 and T_{phys}

- Dose rate @ 1 m = gamma ray dose constant @ 1 cm times the activity divided by $(100 \text{ cm})^2$.
- Cumulative dose is the integral during exposure, which we typically treat as continuing indefinitely to infinity, times the occupancy factor, E.
- The integral to infinity will be the initial dose rate times 1.443 times the physical half-life.

$$D(\infty) = \frac{\Gamma Q_0 1.443 (24) T_p E}{(100 \text{ cm})^2} = \frac{36.4 \Gamma Q_0 T_p E}{(100 \text{ cm})^2}$$

The factor 34.6 is not immediately obvious. It is the 1.443 factor that comes from integrating the single exponential to infinity times 24, which converts the half-life from days to hours.

Table U.5 in the regulatory guidance tabulates physical half-lives in days and exposure rate constants in $\text{R-cm}^2/\text{mCi-hr}$, so assuming that $1 \text{ R} = 1 \text{ rem} (= 10 \text{ mSv})$ we can calculate the dose.

13

A_0 and T_{phys}

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{(100 \text{ cm})^2}$$

Tc-99m: $T_{1/2} = 0.251 \text{ days}$, $E = 1.0$, $\Gamma = 0.756 \text{ R-cm}^2/\text{mCi-hr}$

$Q_0 = 30 \text{ mCi} (1.11 \text{ GBq})$; $D(\infty) = 0.0197 \text{ rem} = 0.197 \text{ mSv}$

$D(\infty) = 0.5 \text{ rem} = 5 \text{ mSv}$; $Q_0 = 762 \text{ mCi} (28.2 \text{ GBq})$

I-131: $T_{1/2} = 8.04 \text{ days}$, $E = 0.25$, $\Gamma = 2.2 \text{ R-cm}^2/\text{mCi-hr}$

$Q_0 = 30 \text{ mCi} (1.11 \text{ GBq})$; $D(\infty) = 0.459 \text{ rem} = 4.59 \text{ mSv}$

$D(\infty) = 0.5 \text{ rem} = 5 \text{ mSv}$; $Q_0 = 32.7 \text{ mCi} (1.21 \text{ GBq})$

- Activity limits for release are tabulated in Column 1 of Table U.1 for common radionuclides

For Tc-99m, the short half-life calls for a high occupancy factor, E. We use $E=0.25$ for I-131 with its 8 day half-life.

We could give a patient as much as 760 mCi of Tc-99m and release. 30 mCi of Tc-99m would impart a very modest dose to the most exposed person.

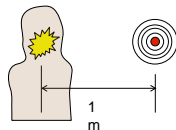
On the other hand, 30 mCi of I-131 is close to the 500 mrem (5 mSv) limit and 32.7 mCi (1.21 GBq) would reach it.

The regulatory guide tabulates the maximum administered activities for many common radionuclides that would give the most exposed person 5 mSv under these assumptions.

14

Measured Exposure Rate and T_{phys}

- Instead of calculating the exposure rate from Γ , measure it, $X_{1\text{m}}$, (with a calibrated exposure rate meter, preferably an ionization meter).
- The measured exposure rate implicitly includes attenuation by the patient.



To adopt a bit more realism, the exposure rate at a meter is measured, but the radioactivity in the patient is still assumed to disappear only by physical decay. While this ignores biological clearance and it treats the exposed person as a point target, it does take into account attenuation by the patient's body.

15

Measured Exposure Rate and T_{phys}

$$D(\infty) = 34.6X_{1\text{m}}T_pE$$

Tc-99m: $T_{1/2} = 0.251\text{days}, E = 1.0$

$$D(\infty) = 0.5\text{rem}(5\text{mSv}): X_{1\text{m}} = 57.6\text{mR/hr}(0.576\text{mSv/hr})$$

I-131: $T_{1/2} = 8.04\text{days}, E = 0.25$

$$D(\infty) = 0.5\text{rem}(5\text{mSv}): X_{1\text{m}} = 7.19\text{mR/hr}(0.0719\text{mSv/hr})$$

- Dose rate limits for release are tabulated in Column 2 of Table U.1 for common radionuclides*

In this calculation, instead of estimating the exposure rate from the administered activity, distance from the patient and gamma ray dose constant, we use the measured exposure rate at 1 meter, $X_{1\text{m}}$.

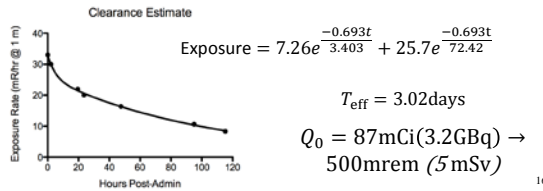
The regulatory guidance tabulates the maximum exposure rate that would deliver 5 mSv to the most exposed person for a variety of common radionuclides assuming physical decay.

16

A_0 and T_{eff}

$$D(\infty) = \frac{34.6\Gamma Q_0 T_{\text{eff}} E}{(100\text{cm})^2}$$

- If we can measure the patient's actual clearance, we can estimate the effective half-life.



If one can measure the effective half-life, then it is possible to estimate the dose to the most exposed person more accurately.

The administered activity that would deliver 5 mSv to the most exposed person is 87 mCi with this effective half-life, not 33 mCi with the physical half-life.

Note that the effective half-life of the rapidly clearing compartment in these actual I-131 patient data is only 3.4 hours, not the 8 hours that the NRC assumes in the three compartment models that we will discuss shortly.

17

Measured Exposure Rate and T_{eff}

$$D(\infty) = 34.6X_{1\text{m}}T_{\text{eff}}E$$

- With the same effective half-life as in the previous example, 3.02 days,

$$X_{1\text{m}} = 19.1\text{mR/hr @ 1 m} \rightarrow 500\text{ mrem}(5\text{ mSv})$$

In a similar fashion to an earlier example, we can substitute the measured exposed rate for the exposure rate calculated from the administered activity. Combined with the effective half-life, it would take an initial exposure rate of 19 mR/hr @ 1 m to deliver 5 mSv to the most exposed person, instead of the 7 mR/hr @ 1 m that was estimated by using the physical half-life.

18

Three Compartment Model

- Designed for I-131 thyroid procedures

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

Extra-thyroidal
Circulating
Thyroidal

E ₁ – Occupancy factor for first 8 hours	E ₂ – Occupancy factor from 8 hours onward	
0.8 – initial circulating fraction	F ₁ – Extrathyroidal uptake fraction	F ₂ – Thyroidal uptake fraction

The previous models make sense for permanent implants and for radiopharmaceuticals that have single exponential clearance characteristics.

The regulatory guidance offers a more complicated model for radioiodine used to treat hyperthyroidism or thyroid cancer.

The model consists of a period during which all of the administered activity circulates in the patient's body, decaying only by physical decay. At the end of that interval, the remaining activity is then divided between a rapidly clearing extra-thyroidal compartment and a more slowly clearing thyroidal compartment.

19

Model Parameters

- Tabulated values may be used if one has not made patient-specific measurements.

Uptake Fraction and Effective Half-life for I-131 Treatments				
Medical Condition	Extra-thyroidal		Thyroidal	
	F ₁	T _{1eff} (days)	F ₂	T _{2eff} (days)
Hyperthyroidism	0.20	0.32	0.80	5.2
Post-Thyroidectomy for Thyroid Cancer	0.95	0.32	0.05	7.3

- We use an image-derived 24-hour uptake in the thyroid bed and any visible metastases as the thyroidal fraction, F₂, and set F₁ = 1-F₂.

We generally acquire a whole body scan about 24 hours after administration of a small activity of either I-123 or I-131. This allows us to estimate the uptake of I-131 in the thyroidal bed and also to visualize metastases. If there are visible metastases, we include them in the uptake fraction of the thyroidal component. The extra-thyroidal fraction is 1 minus the thyroidal fraction.

20

A₀ and Three Compartment Model

- Consider 30 mCi to treat hyperthyroidism with the standard parameters.

$$D(\infty) = \frac{34.6 \times 2.2 \times 30}{(100\text{cm})^2} \left\{ 0.75 \times 8.04 \times 0.8 \times \left(1 - e^{-\frac{-0.693+0.33}{8.04}} \right) + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.2 \times 0.32 + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.8 \times 5.2 \right\}$$

D(∞) = 266mrem(2.66mSv)

Q₀ = 56.5mCi(2.09GBq) → 500mrem(5mSv)

In the case of 30 mCi of I-131 administered to treat hyperthyroidism, we enter the appropriate parameters in the three compartment model, using the default uptake fractions and effective half-lives for the extra-thyroidal (0.2 and 0.33 days) and thyroidal compartments (0.8 and 5.2 days) along with the standard occupancy factor of 0.25.

The dose to the most exposed person is 2.66 mSv and we could administer 56.5 mCi to this patient and just reach the 5 mSv limit to the most exposed person.

21

A_0 and Three Compartment Model

- Consider 200 mCi to treat post-surgical thyroid cancer remnants with the standard parameters.

$$D(\infty) = \frac{34.6 \times 2.2 \times 200}{(100\text{cm})^2} \left\{ 0.75 \times 8.04 \times 0.8 \times \left(1 - e^{-\frac{-0.693+0.33}{8.04}} \right) + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.95 \times 0.32 + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.05 \times 7.3 \right\}$$

$$D(\infty) = 453\text{mrem}(4.53\text{mSv})$$

$$Q_0 = 220.5\text{mCi}(2.20\text{GBq}) \rightarrow 500\text{mrem}(5\text{mSv})$$

21

Now look at a thyroid cancer patient treated post-thyroidectomy with 200 mCi, again using the default extrathyroidal (0.95 and 0.32 days) and thyroidal (0.05 and 7.3 days) parameters and an occupancy factor of 0.25.

This administered activity comes fairly close to giving a 5 mSv dose to the most exposed person.

22

A_0 and Three Compartment Model

- Consider 200 mCi to treat post-surgical thyroid cancer remnants with 1% thyroidal uptake.

$$D(\infty) = \frac{34.6 \times 2.2 \times 200}{(100\text{cm})^2} \left\{ 0.75 \times 8.04 \times 0.8 \times \left(1 - e^{-\frac{-0.693+0.33}{8.04}} \right) + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.99 \times 0.32 + e^{-\frac{-0.693+0.33}{8.04}} 0.25 \times 0.01 \times 7.3 \right\}$$

$$D(\infty) = 350\text{mrem}(3.50\text{mSv})$$

$$Q_0 = 285\text{mCi}(2.85\text{GBq}) \rightarrow 500\text{mrem}(5\text{mSv})$$

22

Although the regulatory guidance says that one may assume a 5% thyroidal compartment uptake in the absence of measured data, we find that many of our patients have 1% or lower thyroidal uptake and thus the dose to the most exposed person is much lower for the same administered activity. In this example of 1% thyroidal uptake, an administered activity of 200 mCi would deliver only 3.5 mSv to the most exposed person.

It is important to note that we encounter a small, but appreciable number of post-thyroidectomy patients with thyroidal uptakes higher than 5% or with substantial metastases that combine with the thyroid bed uptake to exceed 5%.

It is thus important to measure the patient's uptake.

23

Internal Dose

$$D_{\text{internal}} = Q_0 \times 10^{-5} \times \text{DCF}$$

- This is conservative by an order of magnitude since 1 ppm is the more likely maximum internalization in most cases.
- The reference for dose conversion factors (DCF) is an EPA document that is hard to find. The URL of a barely legible scanned copy is cited in the references.
- If $D_{\text{internal}} < 10\%$ of the total, it may be ignored.

23

Although the scant empirical evidence suggests that the most exposed person internalizes very little radioactivity from the released patient, the regulatory guidance includes an extremely conservative calculation of the internal dose.

It uses 10 ppm (rather than the more generally accepted 1 ppm) of the administered activity and a dose conversion factor from an EPA document by Keith Eckerman. There is a link to this document among the references in the handout for this talk.

If the internal dose is less than 10% of the total dose to the most exposed person, the regulatory guidance allows us to ignore it.

24

Internal Dose

$$D_{\text{internal}} = Q_0 \times 10^{-5} \times \text{DCF}$$

- DCF_{I-131} is 1.44×10^{-8} Sv/Bq (53.3 rem/mCi)
 $Q_0 = 30 \text{ mCi} \rightarrow D_{\text{internal}} = 15.9 \text{ mrem} (0.159 \text{ mSv})$
- This is less than 10% of 500 mrem (5 mSv) and hence may be ignored.
 $Q_0 = 200 \text{ mCi} \rightarrow D_{\text{internal}} = 106 \text{ mrem} (1.06 \text{ mSv})$
- This is more than 10% of 500 mrem (5 mSv) and hence must be included in the dose to the most exposed person.

24

In the case of a 30 mCi hyperthyroidism treatment, the internal dose is 160 uSv and it can be ignored. However, for a 200 mCi post-thyroidectomy treatment, the internal dose is 1.06 mSv and must be included in the total dose to the most exposed person.

The 10% rule is insidious, for the more accurately the dose to the most exposed person is modeled (and hence likely lower), the more likely it is that the estimate of the internalized dose will exceed 10% of the external dose and thus would need to be included in the total dose.

25

Internal Dose

- North, et al. recently surveyed 22 households (43 people and 7 dogs) of thyroid cancer patients treated with I-131
 - Only 7 read above background, among them a kissing boyfriend and a licking puppy
 - The worst internalization factor was 2×10^{-5}
 - However, note that all patients had been hospitalized overnight, thereby excluding the time with the greatest potential for contamination of the household.

DL North, Uptake of I-131 in Households of Thyroid Cancer Patients, *Health Physics*, **104**(4):434-436, 2013. The authors draw the conclusion that the internalization advice in the regulatory guidance is reasonable, if not conservative, and that internalization is not a major concern.

26

Instructions and Records

- The patient must be instructed in how to minimize the dose to the various exposed persons if she is breast-feeding or whenever the most exposed person would receive more than 1 mSv (100 mrem).
- A record of the release must be kept if the patient is nursing a child, if the release is on any other basis than that of physical decay of the administered activity or if the most exposed person would likely receive more than 1 mSv.

26

It is important to give patients generic instructions regarding radiation safety, such as sitting to urinate and then flushing the toilet three times.

The patient should be given specific instructions that include the durations of behavioral restrictions, including breastfeeding if the patient is nursing a child.

Record keeping is required under any circumstance that involves a dose to the most exposed person that exceeds 1 mSv or where that dose estimate depends on a patient-specific measurement. The record should identify the personnel involved and the specific instruments that were used.

The details are given in Table U.4 of the regulatory guide.

27

The Need for Prediction

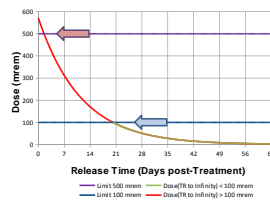
- The regulatory guidance tells how to calculate $D(\infty)$ at the time of administration or exposure measurement, but not how long one ought to delay a release in order to get $D(\infty)$ under 500 mrem (5 mSv) or 100 mrem (1 mSv).
- Some facilities must know prior to treatment that a patient will be an out-patient because of limited suitable in-patient rooms.
- Patients need to make travel, housing and family care plans prospectively.

27

28

Prediction

- We calculate $D(\infty)$ as a function of the start of exposure and work backwards up the cumulative dose curve until the dose limit is reached.
- That is the earliest allowable release time.



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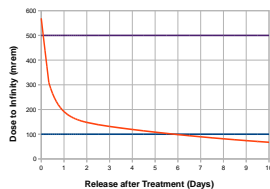
This example is based upon extremely unrealistic values in order to illustrate the point. In this contrived case, we would hold the patient for two days in order to get the dose to the most exposed person down to 5 mSv and would instruct the patient to avoid children and pregnant women entirely for 20 days to get their doses below 1 mSv.

We need to be able to use the measurements from the patient's uptake scan in order to predict these restrictions ahead of time as sometimes patient's plans cannot accommodate the requirements of safety.

29

Prediction

- The rapid clearance of the three compartment model facilitates prompt release.
- This is particularly effective with post-thyroidectomy patients.



29

For thyroid therapy patients, and particularly for post-thyroidectomy patients, the rapid clearance of the extra-thyroidal compartment means that it takes only a few hours for the dose to the most exposed person to fall below 5 mSv.

We keep our I-131 out-patients for at least two hours as a matter of course, so they typically have no restrictions with respect to the most exposed person immediately upon release. However, they will have restrictions with respect to other aspects of their lives, as evident in the additional time that is required for the dose out to infinity to fall below 1 mSv.

30

Prediction

- Sometimes searching for the answer is easiest.

The spreadsheet displays columns for 'Release Time', 'Dose', and 'Total Dose (mSv)'. A callout at the top right shows the formula $D(T_R \rightarrow \infty)$. A yellow callout on the left points to a row with a release time of '2 hours' and a dose of '5.04 mSv'. Another yellow callout on the left points to a row with a release time of '5.5 days' and a dose of '1.03 mSv'.

One cannot easily calculate the release time analytically for the more complicated models. A straightforward approach is to develop a spreadsheet that tabulates the cumulative doses for various release times. One then simply searches through the table to find the release time at which the cumulative dose has fallen to the desired level.

Another approach is to use the calculators on the RADAR Web site and adjust the release time until the dose is below the desired level.

31

Modeling Behavior

- The regulatory guidance does not address how to handle any exposed person other than the most exposed.
- We have adapted the models for members of the public, fellow travelers, children and pregnant women, and sleeping partners that Jeff Siegel developed for the I-131-labeled radiopharmaceutical Bexxar.

32

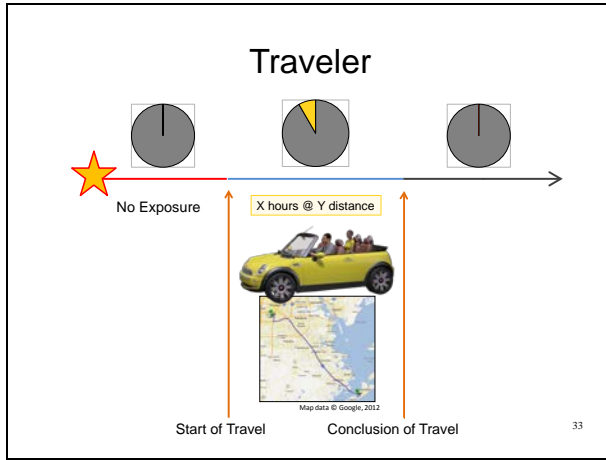
Most Exposed Person

The diagram illustrates exposure scenarios. A star points to a pie chart labeled 'No Exposure'. A green arrow points to another pie chart labeled '6 hours a day @ 1 m'. Below this, a graph plots 'Dose to Infinity (rem)' on the y-axis (0 to 600) against 'Release after Treatment (Days)' on the x-axis (0 to 10). The curve shows a rapid initial drop in dose, leveling off around 100 rem after 5 days. A photo of a man and a woman is shown at the bottom right.

Supposing that Mom has had radioiodine treatment of her thyroid gland, Dad is likely the most exposed person. He clearly derives benefit from caring for his wife in their home and thus the 5 mSv limit makes sense.

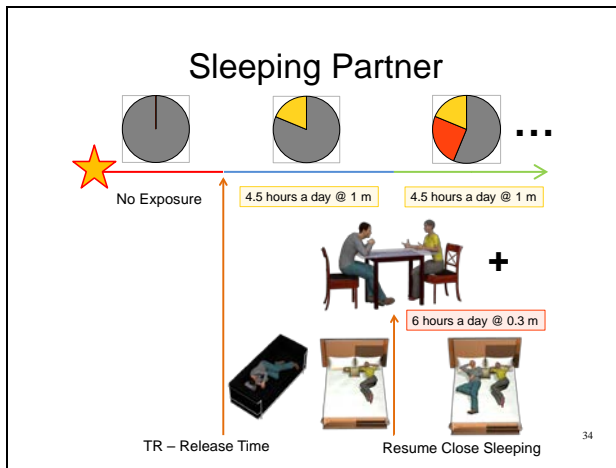
Dad's occupancy factor is based upon no exposure between Mom's treatment and release and then six hours a day at a distance of one meter.

33



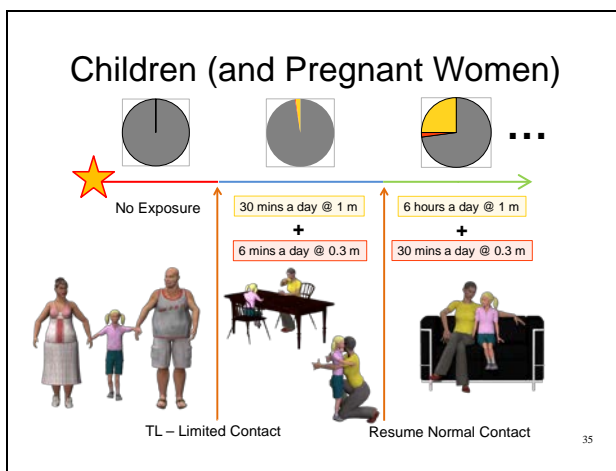
If Mom will be flying home to rejoin her family, the most exposed traveler is likely to be a stranger. It is hard to justify a dose to the stranger in excess of 1 mSv, although the regulatory guidance does not technically forbid it. One can calculate the dose from an exposure for the duration of the trip at typical traveling distances (such as sitting cheek-to-jowl on most commercial airliners). We sometimes have to tell patients not to travel for a day or two after their release (especially if they plan a long trip). If Dad will be driving Mom home, the travel time typically comes out of his 6 hours at a meter for that day unless there is an extraordinary circumstance.

34



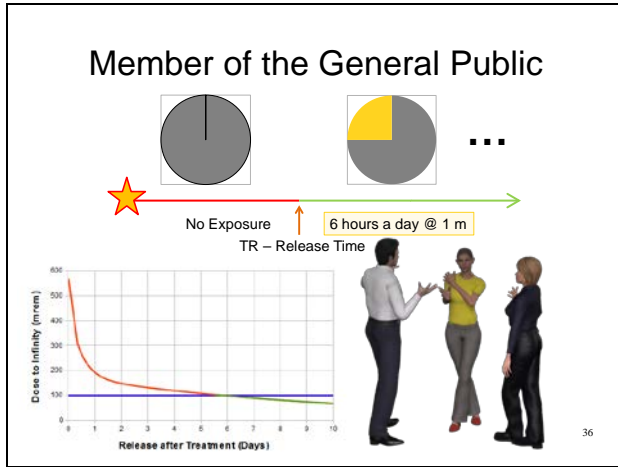
The model of exposure to a sleeping partner is curious. It assumes only 4.5 hours a day at a distance of one meter after a period of no exposure. Following a period of sleeping apart, an exposure of six hours a day at 0.3 meters is added to the 4.5 hours a day at a meter. Another reason to interview patients regarding their lifestyles is that some patients routinely sleep in close proximity to their children. In such a scenario, the use of a 1 mSv total dose rather than a 5 mSv total dose might be warranted.

35



Mom and Dad have a daughter, a member of a sensitive population, whose dose we would like to limit to 1 mSv. The model has three phases like the sleeping partner model. If little Suzy can be sent to Grandma's and Grandpa's for a few days, she could then resume limited contact with Mom, which we model as 30 minutes a day at 1 m and 6 minutes a day at 0.3 m. After a period of limited contact, Mom and Suzy can resume regular activities, which we model as 6 hours a day at 1 m and 30 minutes a day at 0.3 m.

36



Finally, members of the general public, such as regular customers, co-workers, or others who encounter the patient regularly, should be limited to a dose below 1 mSv. We model the patient's contact with these people as a period of no exposure followed by six hours a day at 1 m.

37

Instructions – 200 mCi, 5% Uptake

Release of a Patient from Radiation Safety Restrictions

Patient: Thyroid Patient MDA #: 2299099999
 Radioisotope: I-131 (Half-life: 8.0 days) (Doseage: 200 mCi)
 Date and Time of Administration: Mon, Aug 5, 2013 at 8:00 AM
 Measured Exposure Rate: 1.108 µR/hr at 1.0 m (at Mon, Aug 5, 2013 at 8:10 AM by GA using instrument 251B #1)
 Date and Time of Planned Release: Mon, Aug 5, 2013 at 10:30 AM

Determination of Release from Radiation Safety Restrictions: Based upon the three compartment model parameters below, this patient may be released after Mon, Aug 5, 2013 at 10:30 AM. Under the conditions of this release, the most exposed person is unlikely to receive a total dose of more than 500 µSv.

Compartment	Uptake	Effective Half-life	Start	Stop
Circulating	0.8	8.89 days	0.75	0.9 days
Extracellular	0.25	0.25 days	0.25	0.33 days
Threshold	0.05	7.3 days	0.25	0.33 days

Instructions for the Patient: This patient has been given the following instructions orally and in writing.

These instructions are especially for you. They may differ from those given to other patients. They are based upon the indications 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, Aug 8, 2013 at 8:18 AM.
- Stop alone (other than on that same date) until Sat, Aug 10, 2013 at 7:47 AM.
- Avoid children and pregnant women until Wed, Aug 7, 2013 at 10:31 AM.
- Do not have sex with children and pregnant women (other than sex that will end Sat, Aug 17, 2013 at 8:18 AM).
- Stop further than six feet from others until Thu, Aug 8, 2013 at 8:18 AM.
- Do not return to work before Thu, Aug 8, 2013 at 8:07 AM.

You may contact the Nuclear Medicine Department at 353-4332 if you have any questions about these instructions.

A hypothetical post-thyroidectomy patient with a 5% uptake who received 200 mCi just a few minutes ago could be released after 2-1/2 hours. He should not start his four hour plane flight until mid-morning tomorrow. He should sleep alone for about a month. He should avoid his kids entirely for two days and then limit time with them for another ten days. He should not go back to work or spend time around strangers until Friday morning. Under the A0 and Teff model, this patient would have been hospitalized for almost three weeks.

38

RADAR Approach

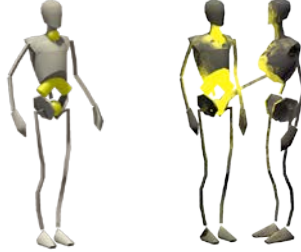
- Incorporates a factor of 0.6 to account for patient self-shielding.
- Eliminates the circulating (“pre-voiding”) component of the three-compartment model.
- RADAR-based dose estimates are roughly half those made by the method in the regulatory guidance.
- This is acceptable, provided that one documents the details of the calculation.

Although this approach is usually quite effective, the RADAR experts argue that the regulatory guidance is still too conservative. They advocate including a factor of 0.6 to reflect the attenuation by the patient and the elimination of the circulating component of the three-compartment model. These refinements are incorporated into their online calculators mentioned earlier. The regulatory guidance is just that – guidance – and other methods of release calculation, such as the RADAR approach, are valid as long as the basis of the release is correctly calculated and thoroughly documented.

39

Better Physical Models

- Representing the patient and the exposed person by points is very conservative.



Yi, et al., have reported that a shielded line source is a good model for post-thyroidectomy I-131 therapy patients.

De Carvalho, et al., used voxelized phantoms for the patient and the exposed person and calculated the effective dose from three types of treatments. They compared these to doses from point and line sources. In general, the dose from the more realistic, 3D source was about 50-70% of that from the point source at a distance of one meter. At a distance of 0.3 m, the 3D source doses were more like 25% of those from a point source.

Y Yi, MG Stabin, MH McKaskle, MD Shone and AB Johnson, Comparison of Measured and Calculated Dose Rates Near Nuclear Medicine Patients, *Health Physics*, **105**(2):187-191, 2013.

AB de Carvalho, MG Stabin, JA Siegel and J Hunt, Comparison of Point, Line and Volume Dose Calculations for Exposure to Nuclear Medicine Therapy Patients, *Health Physics*, **100**(2):185-190, 2011.

40

Resources

- RAdiation Dose Assessment Resource Patient Release Criteria: <http://www.doseinfo-radar.com/RADAR-INT-NM-Release.html>
- RADAR Patient Release Calculators: <http://www.doseinfo-radar.com/ExposureCalculator.html>
- SNM Guidelines for I-131 Patients: http://www.snm.org/docs/Guidelines_for_Patients_Receiving_Radioiodine_Treatment.pdf

The RAdiation Dose Assessment Resource at <http://www.doseinfo-radar.com/> has a wealth of information on many aspects of radiation protection and internal dosimetry. In particular, RADAR members have been active in the development of the risk-based approach to patient release.

41

Conclusions

- The patient release calculations in NUREG 1556 are straightforward.
- The simplest ones tend to be very conservative.
- They can be made more realistic by using patient-specific parameters that are based on direct measurements and on modeling of the patient's lifestyle.
- More realistic 3D modeling of sources and targets yields doses that are even more realistic.

41

42

References

- NUREG 1556, Volume 9, Revision 2, Appendix U, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>
- Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion and Ingestion, <http://www.epa.gov/radiation/docs/federal/520-1-88-020.pdf>
- NUREG 1492: Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Materials, US NRC, 1997, <http://www.osti.gov/bridge/servlets/purl/453778-p8OWG6/webviewable/453778.pdf>

42

- DB Howe, M Beardsley and SR Bakhsh, Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials, in *Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses, Final Report*, Nuclear Regulatory Commission, NUREG 1556, Volume 9, Revision 2, Appendix U, January 2008, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final.pdf#app-u>
- KF Eckerman, AB Wolbarst and ACB Richardson, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion and Ingestion*, Federal Guidance Report No. 11, Environmental Protection Agency 520/1-88-020, September 1988, <http://www.epa.gov/radiation/docs/federal/520-1-88-020.pdf>.
- S. Schneider and S.A. McGuire, NUREG 1492: Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, US Nuclear Regulatory Commission, February, 1997, <http://www.osti.gov/bridge/servlets/purl/453778-p8OWG6/webviewable/453778.pdf> .

43

References

- A Practical Methodology for Patient Release after Tositumomab and (I-131)-Tositumomab Therapy, JA Siegel, et al., <http://jnm.snmjournals.org/content/43/3/354.full.pdf>
- Licensee Over-Reliance on Conservatism in NRC Guidance Regarding the Release of Patients Treated with ¹³¹I, JA Siegel, et al., *Health Physics* **93**(6):667-677, 2007.
- NRC ACMUI Patient Release Report, <https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/NRC-release-of-patients.pdf>

43

- JA Siegel, et al., A Practical Methodology for Patient Release after Tositumomab and (I-131)-Tositumomab Therapy, *Journal of Nuclear Medicine* **43**(3):354-363, 2002, <http://jnm.snmjournals.org/content/43/3/354.full.pdf>
- JA Siegel, CA Marcus, and MG Stabin, Licensee Over-Reliance on Conservatism in NRC Guidance Regarding the Release of Patients Treated with ¹³¹I, *Health Physics*, **93**(6):667-677, 2007.
- D Fisher, et al., Patient Release Report, Advisory Committee on the Medical Use of Isotopes, Nuclear Regulatory Commission, 2010, <https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/NRC-release-of-patients.pdf>

44

References

- Release of Patients after Radionuclide Therapy, IAEA, 2009, http://www-pub.iaea.org/MTCD/Publications/PDF/pub1417_web.pdf
- Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources, Health Physics Society, PS027-0, http://hps.org/documents/patientrelease_ps027-0.pdf
- Comparison of Measured and Calculated Dose Rates near Nuclear Medicine Patients, *Health Physics*, **105**(2):187-191, 2013.
- Comparison of Point, Line and Volume Dose Calculations for Exposure to Nuclear Medicine Therapy Patients, *Health Physics*, **100**(2):185-190, 2011.
- Uptake of I-131 in Households of Thyroid Cancer Patients, *Health Physics*, **104**(4):434-436, 2013.

44

- International Atomic Energy Agency, Release of Patients after Radionuclide Therapy, Report 63, Safety Reports Series, Vienna: IAEA, 2009, http://www-pub.iaea.org/MTCD/Publications/PDF/pub1417_web.pdf
- Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources: Position Statement of the Health Physics Society, March 2012, http://hps.org/documents/patientrelease_ps027-0.pdf
- A.B. de Carvalho, MG Stabin, JA Siegel, and J Hunt, Comparison of Point, Line and Volume Dose Calculations for Exposure to Nuclear Medicine Therapy Patients, *Health Physics*, **100**(2):185-190, 2011.
- Y Yi, MG Stabin, MH McKaskle, MD Shone and AB Johnson, Comparison of Measured and Calculated Dose Rates Near Nuclear Medicine Patients, *Health Physics*, **105**(2):187-191, 2013.
- D.L. North, Uptake of I-131 in Households of Thyroid Cancer Patients, *Health Physics*, **104**(4):434-436, 2013.