Summary of Patient Release after Radioiodine Therapy Research Review

Introduction

This report provides a summary of the Office of Research (RES) staff's efforts to evaluate radiation exposure to members of the public from released patients. The full report, including the recommendations by RES, may be found in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System (ADAMS) using Accession No. ML17262A909.

The Office of Nuclear Material Safety and Safeguards (NMSS) staff requested that RES conduct an analysis to evaluate radiation exposure to members of the public from released patients following Iodine-131 (I-131) therapy. To perform the analysis, RES conducted a review of published peer-reviewed literature (literature review) relevant to patient release practices, with a particular focus on radiation doses received by members of the public as a result of exposure to released patients. In addition, RES contracted with Oak Ridge National Laboratory (ORNL) to model and calculate radiation doses to members of the public from released patients. The results of the literature review and the ORNL dose calculations are summarized below.

Literature Review

Results

Review of Internal Dose Data

The literature review indicates that any surface that comes in contact with excreta (e.g. urine, saliva, sweat) from the released patient treated with I-131 may become contaminated. The reviewed articles validate that the current radionuclide intake fraction assumption used in Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials" of 10^{-5} is conservative. The data further supports that the contributions of internal doses relative to external doses are small, even in the presence of significant levels of contamination. There was no correlation found between radioiodine intake by a family member and the radioiodine activity administered to the patient. These findings indicate that radiation contamination in the home does not easily cause a significant intake of radioiodine, and that for such an intake to occur, it is necessary to engage in close contact activity with the released patient. The cases identified from the literature review included reported thyroid doses of 0.04–13.3 millisievert (mSv) (4–1330 mrem) to members of the public, and all cases involved close contact with the patient, mostly in a child-parent relationship. For example, in a study of family members in proximity to the patient, thyroid uptakes were noted, but these were in the range of 10^{-5} or less of the activity administered to the patient. The highest thyroid dose of 13.3 mSv (1330 mrem) was to a patient's child and the patient was administered a typical hyperthyroid dose of 650 MBq (17.5 mCi). Whereas, family members of a patient administered a typical thyroid carcinoma dose of 5.6 GBq (150 mCi) received a maximum thyroid dose of 0.12 mSv (12 mrem). The higher dose from the lower hyperthyroid administration occurs because of higher radioiodine retention in the thyroid gland, which is typically absent in thyroid carcinoma patients, allowing faster radioiodine body clearance than in the case of hyperthyroid treatment. It was noted that kissing on the mouth was an efficient way of transferring radioiodine, as one study has shown. The literature review results show that the internal dose is small; however, this assumption should only be made if the licensee can ascertain that the patient's behavior at home will be such that it excludes close contact with any other person. The data indicates the spread of

contamination from the patient to other persons can be minimized by following instructions. The results of the literature review affirm that licensees need to consider each patient's specific circumstances to determine the suitable and practical recommendations to give the patient prior to the patient being released.

Review of External Dose Data

The literature review indicates that the external dose to family members, in some cases, doesn't correlate with the activity of I-131 administered to the patient, since some lower activity I-131 administrations (below 50 mCi) resulted in higher external radiation doses to family members as compared to radiation doses received by family members from high activity I-131 administrations (above 200 mCi). In fact, family members of patients receiving the highest activity I-131 administrations often received some of the lowest doses. This points to the importance of behavior patterns and following ALARA (as low as reasonably achievable) guidance and instructions provided by the licensee. Nearly all of the recorded doses to the family members were below the NRC dose limit of 5 mSv (0.5 rem), although in two studies some of the individuals monitored showed doses that exceeded that limit. The reason for the higher doses (7.2–8.5 mSv (720–850 mrem)) in these specific cases were not identified. However, based on the patient behavior patterns described in these studies, the research articles concluded that not following ALARA precautions contributed to the higher doses. The availability of sufficient space for effective patient isolation at home also does not appear to play an important role, as shown by some of the studies

Effective Half Life

The NRC's RG 8.39 default dose rate equation integrates exposure over time to obtain the total dose received by a member of the public. This equation assumes that the activity in a patient decreases as a function of only the radiological half-life, 8.02 days, and does not consider a patient's biological elimination of a significant portion of the activity. Effective half-life, which is not used in RG 8.39, uses a combination of radiological and biological half-lives. Although the literature review contained numerous studies in which the effective half-life in thyroid cancer patients was much less than 8.02 days, there was considerable variability among patients. In thyrotoxicosis (hyperthyroid) patients, the effective half-life was longer than that of thyroid cancer patients, sometimes even equivalent to the radiological half-life, suggesting little to no biological elimination.

Determining the correct effective half-life for estimating the total dose received by a member of the public depends on the duration of the exposure. If the duration is short, such as riding a bus for an hour, the dose may be estimated by multiplying the dose rate at the time by the duration to give a total dose. In this case, the use of effective half-life, instead of the radiological half-life, is not relevant. On the other hand, for a member of the patient's family who is continuously around the patient, where exposure continues for a significant duration, from a few days for a cancer patient to possibly weeks for a thyrotoxicosis patient, using the correct effective half-life value will have a significant effect on the expected exposure. Estimating the total dose in such cases will require integrating a time-dependent dose rate over the exposure duration. For a given occupancy factor, a dominant influence on the total dose calculation will be the effective half-life used. Hence, it is important when performing these calculations to use a reasonably good half-life estimate, based on the range of half-lives observed for the patients with a similar medical condition, as well as to consider any patient-specific conditions that might affect the total dose estimate for the particular patient.

Occupancy Factor and Exposure Distance

The occupancy factor (OF) is defined as the fraction of the time a person is close to the patient, with the distance during this time assumed to be an average of 1 meter. The default value for OF recommended in NRC's RG 8.39 is 0.25 and the default distance is 1 meter. The distance of 1 meter is generally regarded as the distance from the surface of the patient to the dose point. The total dose received by a person exposed to the patient is linearly dependent on the OF, so that doubling the factor will also double the dose for a specified dose rate. Dependence of dose rate on distance, however, is more complicated because the relationship is not linear. In many, if not most situations, the dose rate decreases approximately as an inverse exponential function of distance. With this type of dependence, coming closer to the patient has a much greater impact on dose rate than moving farther away. For example, changing the distance from 1 meter to 0.5 meter increases the dose rate by a factor of 4, whereas increasing the distance to 1.5 meters reduces the dose rate by a factor of 2.3.

The literature review indicated that if a patient sleeps alone in a room for 8 hours per day, then the maximum OF will be about 0.7. Assuming that the family member spends about 4 hours per day attending to tasks not related to being with the patient, then the maximum reasonable OF becomes about 0.5. The OF clearly needs careful consideration by the medical institution that treats the patient, since a default of 0.25 may not be appropriate. For example, many published studies have found that a number of patients live in trailers or in otherwise very small apartments where maintaining occupancy of 0.25 at 1 meter is difficult or not feasible. In other situations, particularly those involving children or infirm patients, close contact for extended periods of time may be unavoidable. This is particularly true with children and families with limited means. Whether the patient is the child or the parent, close contact for extended periods may be unavoidable.

Dose Calculations in RG 8.39

The methods suggested in NRC's RG 8.39 for calculating the external dose to a person from the patient assumes that the patient is adequately represented by a point source at a distance of 1 meter from the exposed person, who is also assumed to be adequately represented by a point. The calculation is intended to estimate the dose received by the exposed person located at that distance, rather than the dose rate at that distance, and therefore represents the integration of the time-dependent dose rate function over a specific exposure duration.

The assumption of a point source and a point target means that no credit is taken for either attenuation of radiation while leaving the patient's body, or attenuation while entering the target's body and before reaching the radiologically sensitive internal organs. Calculation of the total dose using the default equation involves integration of the dose rate function using a removal half-life of the iodine equal to its radiological half-life of about 8 days. This means that removal by excretion in urine, a major removal mechanism, is assumed not to occur. This may not be a significant factor for thyrotoxicosis patients, since the removal half-life in such cases is not very different from the radiological half-life. However, it can be a significant factor for cancer patients, since the removal half-life in many such cases may be an order of magnitude smaller than the radiological half-life. The OF is assumed to be 0.25, meaning that the dose is being received during 6 hours each day, the dose received during the rest of the day being zero. As the review of the literature has demonstrated, this assumption may be conservative in some cases, but not conservative in others. Patient-specific data is important in deciding whether changes from the default assumptions are warranted. An average distance of 1 meter from the patient during the 6 hours of exposure is assumed, but again, as in the case of the OF, this may

or may not be an adequate assumption, depending on the details of the patient's living arrangements.

RG 8.39 provides equations in addition to the default equation that provide an opportunity to take into account some patient-specific data. These equations assume that removal of I-131 from the body can be described by the sum of three exponential terms, with the time period for the first term lasting 8 hours post-administration, during which there is no urine voiding, and therefore the only significant removal mechanism is by physical decay with a half-life of 8.04 days. The OF during this period is 0.8. The time period for the second term extends to total decay, with an OF of 0.25, and consists of two components: an extra-thyroidal component and a thyroidal component. For cancer patients, the thyroidal fraction is 0.05, and for hyperthyroid patients the fraction is 0.8. The effective half-life of the thyroidal fraction is 7.3 days in cancer patients and 5.2 days in hyperthyroid patients. The half-life of the extra-thyroidal component is 0.32 days in both cases. Applying these equations shows that the maximum releasable activity is 8.2 GBq (221 mCi) for cancer patients, and 2.1 GBq (57 mCi) for hyperthyroid patients. It should be noted that these equations, even though more specific than the general default equation, are still generic in the sense that they are applicable to classes of patients rather than individual patients.

There is a wide diversity of views on which parameters should be used to calculate total doses to members of the public. However, it should be noted that the considered application of calculation parameters to improve the accuracy of the dose estimates can be negated when the idealized exposure scenario that is assumed to be followed by the patient and family members, is in fact not realized. The calculations do not predict what will happen in any particular case. For example, according to the equations, the calculated dose should be directly proportional to the iodine activity administered to the patient. However, the data shows that this direct proportionality is either quite different from predictions or in many cases is non-existent. Family members of patients that received high-activity I-131 administrations have shown zero to low measured doses, and families of patients with low iodine levels have shown unexpectedly high measured doses. Behavior seems to be the determining factor, and the calculations serve mainly to provide a basis for a decision on whether or not the patient meets Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75 release criteria. It is clear, however, that performing the calculations is not adequate by itself: it does not determine the dose that will actually be received. The use of RG 8.39 must be accompanied by due diligence in determining the conditions that are likely to exist after release, as well as clear instructions on how to behave in order to protect the family against unnecessary exposure.

Models and Calculations

Methods of this Study

The NRC contracted with ORNL to perform calculations of dose to members of the public exposed to a released patient, specifically, in situations where the exposed member of the public was not known to the patient (i.e., hotel, nursing home, and bus transportation scenarios). The calculations involved use of an anthropomorphic mathematical phantom that had previously been developed by ORNL for the NRC. The phantom, known as PIMAL (Phantom with Moving Arms and Legs), contains all of the relevant organs and tissues with dimensions, masses, and densities that conform to the recommendations in International Commission on Radiation Protection (ICRP) Publication 89. The phantom, along with the corresponding organ tissue densities, mimics the human body. The patient and the member of the public are the same size because the phantom is used for both. The phantom has the capability of bending the arms at

the shoulders and elbows, and the legs at the hips and knees. This permits realistic modeling situations such as the patient or the member of the public sitting on a chair, sitting on a bed, or lying in a bed. In order to model the dose received by a member of the public accurately, it is necessary to know the distribution of the radioiodine in the body as a function of time following administration of the radioiodine. This was accomplished by using a model for the biokinetics of iodine that was developed at ORNL. Preliminary studies using the phantom and the biokinetic model showed that the dominant sources of exposure from the cancer patient were the thyroid and the bladder. This allowed calculations to be performed using PIMAL with the iodine distributed in three regions of the body: the thyroid, the bladder, and the remaining tissues. Two thyroid conditions were examined: thyroid cancer patients and thyrotoxicosis patients.

The specific scenarios and assumptions analyzed in the calculations included the following:

Public Transportation:
- Patient standing face to face with member of the public
- Patient sitting in front of a seated member of the public
- Patient sitting behind a seated member of the public
- Patient sitting next to a seated member of the public
- Patient standing next to a seated member of the public
- Patient sitting next to a standing member of the public

Hotel:
- Patient sitting in bed and member of the public sitting in adjoining room
- Patient and member of the public asleep in adjoining rooms
- Housekeeper cleaning a room after use by a patient

Nursing Home:
- Person sitting next to the patient's bed
- Patient and another resident sleeping in adjoining beds

Calculation of dose to a member of the public involved determining the dose rates at different times following iodine administration, and then integrating the dose rates to obtain a total dose delivered over specified time periods. Voiding of urine, which removed some of the iodine activity from the body, was considered in these calculations. The effective doses were calculated using the recommendations provided in ICRP Publication 103. The full report from ORNL regarding these calculations may be found in ADAMS using Accession No. ML17255A080.

Results

Public Transportation Scenarios

Tables (1a) and (1b) below show the amount of time it would take to exceed a 10 CFR 35.75 patient release dose limit of 500 mrem, as well as the Part 35 dose limit of 100 mrem for providing patient instructions. The data in the tables were based on an I-131 dosage of 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer. Both are typical dosages for their respective uses. In the calculations summarized in Table (1a), it was assumed that the patient had one urine void within 2 hours of I-131 administration. In the calculations summarized in Table 1b, it was assumed that the patient did not void and boarded the bus immediately post-administration.

Table 1a – Time in hours to exceed 100 mrem and 500 mrem effective dose on public transportation, assuming one void before release and no voids thereafter.

Geometry	Time after boarding transit, hours			
	Thyrotoxicosis	Thyroid Cancer	Thyrotoxicosis	Thyroid Cancer
	100 mrem	100 mrem	500 mrem	500 mrem
Dosage Administered	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**
Seated behind patient	18.4	3.5	133.1	16.4
Seated in front of patient	22.3	3.4	>238 (448.91 mrem)	21.1
Seated next to patient	30.3	5.1	92.2	33.8
Standing facing patient	5.00	0.9	25.1	4.4
Standing/seated patient	24.6	5.5	>238 (409.61 mrem)	28.5
Seated/standing patient	57.5	4.5	>238 (187.38 mrem)	26.7

Table 1b – Time in hours to exceed 100 mrem and 500 mrem effective dose on public transportation, assuming no void prior or after release.

Geometry	Time after boarding transit, hours			
	Thyrotoxicosis	Thyroid Cancer	Thyrotoxicosis	Thyroid Cancer
	100 mrem	100 mrem	500 mrem	500 mrem
Dosage Administered	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**
Seated behind patient	16.6	2.8	87.4	13.2
Seated in front of patient	20.5	2.7	109.3	16.4
Seated next to patient	28.2	4.1	147.6	26.1
Standing facing patient	4.6	0.7	22.1	3.6
Standing/seated patient	23.0	4.4	120.1	22.8
Seated/standing patient	47.1	3.6	215.4	20.7

The tables above show that thyrotoxicosis patients pose a transportation concern in only one scenario, namely that in which the patient and member of the public are standing face to face at very close distances (10 cm). For cancer patients, on the other hand, all exposure scenarios indicate that transportation situations pose a radiation concern for members of the public.

External Exposure at Hotel

Hotel Scenarios

Table 2 shows the calculated time to exceed 100 mrem and 500 mrem in specific hotel scenarios. The sitting in bed scenario assumes that the patient is sitting in bed and leaning against the headboard, and the member of the public is doing the same on the other side of the wall. The sleeping scenario assumes that the patient and member of the public are sleeping in

beds on opposite sides of the wall, with their heads up against the headboards. The check-in staff is assumed to stand about 1 meter facing the patient. For all hotel cases, the patient was assumed to void the full contents of the bladder 4 hours post-administration and checking into the hotel immediately after the first void. Voiding was assumed to occur periodically in 4-hour increments for simulations up to 10 days (240 hours) post-administration. The calculations did not extend beyond 10 days post-administration and assumed 100 percent occupancy factor. The data shows that neither the 1 mSv (0.1 rem) nor the 5 mSv (0.5 rem) are exceeded in any credible hotel scenario.

Table 2 – Time in hours to exceed 100 and 500 mrem effective dose in hotels.

Geometry	**Time post check-in, hours**			
	Thyrotoxicosis	**Thyroid Cancer**	**Thyrotoxicosis**	**Thyroid Cancer**
	100 mrem	**100 mrem**	**500 mrem**	**500 mrem**
Dosage Administered	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**	**1 GBq (27 mCi)**	**7.4 GBq (200 mCi)**
Facing the check-in staff	33	5.1	93.5	27.6
Sitting in bed	189.1	172.2	>10 days	>10 days
Sleeping	>10 days	>10 days	>10 days	>10 days

In addition to the calculations above, which pertained to external exposures, ORNL also conducted a study to estimate the magnitude and resulting dose from any intake by hotel cleaning staff. The staff person was assumed to spend about 10 minutes cleaning the patient's bathroom and 20 minutes cleaning the room. The calculations were based on measurement data published in the technical literature for contamination levels on various surfaces such as toilets and bedding as well as airborne contamination levels. From the calculations, ORNL estimated the total dose for cleaning the patient's room would be about 0.15 mrem. Therefore, a person would need to clean approximately 670 patient rooms to accumulate a dose of 100 mrem, and 3300 rooms to obtain a total dose of 500 mrem. These doses are based on cancer patients who had been administered 7.4 GBq (200 mCi) of I-131. The dose from thyrotoxicosis patients would be significantly less. In the case of a cancer patient staying at the hotel for a number of days, the dose to the cleaning staff after the first day would diminish substantially on consecutive days because of the rapid excretion rate of the iodine. Consequently, the number of rooms that would need to be cleaned to obtain a dose of 100 mrem and 500 mrem (670 and 3300 rooms, respectively) is based on the assumption that a newly released patient has been staying at the hotel each time before the room is cleaned. However, it should be noted that this evaluation did not include exposure from a hotel worker cleaning vomit from a released patient. While no assumption can be made about the respiratory uptake, it can be assumed that hotel cleaning staff would wear gloves while cleaning vomit and therefore internal radiation exposure via skin absorption should be minimal.

Nursing home

Table 3 shows the minimum occupancy factor necessary to exceed 100 mrem and 500 mrem in two specific nursing home scenarios. The first scenario is where a resident and the patient share a room and sleep in adjacent beds, and the second scenario is where a person is seated about 30 cm from the edge of the patient's bed. The total dose was obtained by integrating the dose rate function to total decay of the iodine assuming continuous presence of the member of the public over a 90-day period. To allow for non-continuous exposure, an occupancy factor is

used. The occupancy factor shown in the table is the fraction of the time that a member of the public is exposed to the patient, for the remaining time, it is assumed that no radiation exposure is involved.

Table 3 – Occupancy Factor necessary to exceed 100 and 500 mrem effective dose in nursing homes.

Geometry	Thyrotoxicosis	Thyroid Cancer	Thyrotoxicosis	Thyroid Cancer
	100 mrem	100 mrem	500 mrem	500 mrem
Dosage Administered	1 GBq (27 mCi)	7.4 GBq (200 mCi)	1 GBq (27 mCi)	7.4 GBq (200 mCi)
Person at edge of bed	F > 0.2	F = 0.25	F > 0.97	F = continuous
Person & patient in beds	F = continuous	F = continuous	F = continuous	F =continuous

Note: Continuous in the table means that the dose of 100 mrem or 500 mrem is never exceeded even if the exposure is continuous.

The data shows that patients sharing a room would not exceed the 100 and 500 mrem dose limit. However, a person sitting on the edge of the bed could exceed the 100 mrem limit if they had an occupancy factor of greater than 0.2 (4.8 hours a day) following a thyrotoxicosis administration, or 0.25 (6 hours a day) following thyroid cancer administration, and could exceed 500 mrem if they had an occupancy factor of 0.97 (23.3 hours a day) following a thyrotoxicosis administration.

Recommendations

At the conclusion of the research described above, the Office of Research summarized for NMSS staff consideration in determining whether changes to 10 CFR 35.75 are warranted, a number of issues regarding the patient release program. These were:

- The equations in RG 8.39 should not be used as an unjustified default in any particular case, but if the licensee chooses to use them, then the default assumptions need to be justified based on the licensee's assessment of the patient's likely behavior after release.
- The decision to release the patient should be reviewed before starting treatment to determine the conditions under which the patient is expected to be released, and whether the living arrangements, modes of transportation, and staying at a hotel are such that releasing the patient is unlikely to result in doses above 5 mSv (500 mrem).
- The means of transportation to be used by the patient after treatment should be determined by the licensee to ensure that using such public transportation is not likely to result in excessive dose to any member of the public.
- The guidance in RG 8.39, as well as the equations and parameters referenced in the guide, should be reviewed, updated, simplified, and made more clear and explicit.
- Patients who are known to be going to nursing homes after treatment should not be released unless the nursing home provides the facilities and trained staff necessary to care for a radioactive patient. The same considerations should apply to patients who may not be in good health and may cause considerable contamination as a result of incontinence, vomiting, or similar events.

- The release of patients known to be going to hotels should be re-examined and a statement of policy made. The calculations described in the second part of this paper show clearly that external doses are highly unlikely to be a concern. However, controversy surrounds the issue of internal dose to hotel workers, particularly those who clean contaminated rooms.

Conclusions

Based on the results of the literature review, it is clearly evident that the dominant factor in determining both internal and external doses to members of the public from exposure to a patient that has been administered I-131, is the behavior of the patient after release. This factor is more important than the amount of I-131 administered to the patient. In addition, the calculations performed by licensees to determine whether the patient meets regulatory release criteria are attempts to estimate dose under a set of standardized hypothetical behavior conditions, such as a distance of 1 meter and an occupancy factor of 0.25. Significant deviations from one or more of these assumptions can result in substantially different doses to family members than the calculated values. This highlights the central importance of instructions. The ability of a licensee to provide adequate release instructions under 10 CFR 35.75(b) is directly related to the licensee's thorough consideration of the destination to which the patient will be released, and on the ability of the patient and/or caregiver to understand and follow the necessary release instructions. By thoroughly ascertaining the patient's post-treatment destination, the licensee can accurately estimate the likely cumulative radiation exposures to other members of the public, including family members and caregivers, and direct appropriate protective measures and instructions.