PATIENT RELEASE AFTER RADIOIODINE THERAPY

A REVIEW OF THE TECHNCIAL LITERATURE, DOSE CALCULATIONS, AND RECOMMENDATIONS

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1. INTRODUCTION

This report presents the results of an extensive review of the technical literature pertaining to the release of patients from hospitals or outpatient clinics following administration of therapeutic dosages of radioactive iodine-131 (^{131}I), commonly referred to in the literature as RAI (RadioActive Iodine). Such administrations are usually given as part of treatments for thyroid cancer and other thyroid conditions such as thyrotoxicosis or hyperthyroidism. The purpose of the review is to get a reasonably accurate assessment of the radiological impacts of released patients on members of the public, including family members, as determined by measurements of both internal and external exposures. The report also describes the results of calculations performed at Oak Ridge National Laboratory to supplement the data found in the literature (ADAMS accession No. ML17255A080).

Although many radioactive materials are used in the treatment of a variety of medical conditions, the emphasis of this review is on RAI because it poses the greatest potential for radiation exposure to the public for several reasons: (a) it emits several relatively high energy gamma rays, which easily leave the patient's body and can penetrate another person's body, (b) RIA therapy is used extensively, and (c) RAI used for therapeutic purposes is often administered in relatively large activities. Other radioactive materials used in medical therapy or diagnostic procedures are used less frequently than RAI, are usually administered in much smaller activities, usually emit lower energy gamma rays or no gamma rays at all, or are very short-lived, as is the case for many of the radionuclides used in PET (Positron Emission Tomography). PET procedures are diagnostic and therefore also tend to use low activities. Therefore, they pose a much lower radiation exposure potential to the general public than RAI.

The activity administered in treating thyrotoxicosis is generally much lower than that used with thyroid cancer, the former normally being in the range of 0.185 – 0.925 GBq (5 – 25 mCi) (HA74), the latter of the order of up to ten GBq or more, (several hundred mCi) (NO10). However, from the point of view of exposure of the general public, and especially of family members, thyrotoxicosis treatments usually have the potential for delivering significantly higher total doses than cancer treatments. The reason is that in thyrotoxicosis, a large fraction of the administered iodine is taken up by the intact and often overactive thyroid gland, which retains the activity with an effective half-life of the order of 5-6 days, whereas in the case of cancer patients, most of the thyroid gland is generally removed before treatment, and most or all of the iodine is distributed in the whole body and is excreted in the urine with an effective half-life often of the order of hours. Therefore, for thyrotoxicosis, low activity stays in the patient for long periods of time whereas in cancer patients there is a relatively high activity that is eliminated very rapidly. This difference often means that exposure to cancer patients soon after release, as in public spaces, would normally pose the highest exposure potential, whereas long-term exposure to thyrotoxicosis patients, as in a family setting, would normally pose the highest exposure potential.

Patient release refers to the release of the patient from radiological control of the licensee, either in a hospital setting or on an outpatient basis, after administering the iodine therapy activity. The interest, or concern, regarding this practice is that the released patient contains radioactive material, and therefore constitutes a source of radiation and radioactive material. This may cause radiation exposures to members of the general public who may come in close proximity to the patient in public spaces such as public transportation facilities, restaurants, and similar places, as well as to family members such as in private cars or at home. Once released, there is no further licensee control on what the patient may do or where the patient might go,

other than the hope that the patient will follow behavior patterns designed to minimize the dose to others, as explained in instructions provided by the licensee before release.

This review is prompted by direction from Staff Requirements Memorandum (SRM)-COMAMM-14-0001/COMWDM-14-0001 to review the published technical literature and identify any data that are relevant to patient release practices and particularly to measurements of doses received by members of the public as a result of exposure to released patients. SRM-COMAMM-14-0001/COMWDM-14-0001 also directed that, should the published data be found inadequate to provide a reasonably clear indication of doses received, then work should be undertaken to conduct measurements of a scope adequate to address the gaps in the dose information in the literature.

The ultimate objective of this project is to assess the degree of success of the current patient release regulations, which came into effect in 1997, in protecting the public by keeping the dose received by any member of the public below the specified regulatory limit, while minimizing any negative impacts of keeping patients in the hospital for extended periods of time.
These goals constitute, in essence, the successful application of the principal of As Low As Reasonably Achievable (ALARA), taking all factors such as efficacy of the therapy, patient comfort, public safety, and cost into account, but constrained by a permissible dose limit.

An important consideration in discussions of patient release after iodine treatment is that the practice represents a dose transfer activity. Keeping patients in the hospital does not avoid exposures altogether, but only exposes a different set of people. Patients staying in the hospital following iodine treatment will cause exposures to the hospital staff that care for them during their stay. On the other hand, releasing the patients will cause exposures to members of the public (including family members and care givers) who come in close proximity to them. However, the total dose received by any person during a period of time such as a year will likely be much higher for hospital staff than for any member of the general public. This is because, if patients are not released, hospital staff will be exposed repeatedly to all patients who are treated at that hospital during the year, and will be repeatedly exposed each year that they practice at the hospital. If patients are released, members of the general public are unlikely to be exposed for a significant duration of time to multiple patients and therefore are expected to receive a low dose. This is also most likely to be true for members of the patient's family, who are likely to be exposed for longer durations than other members of the general public but usually only once, or a few times if the patient requires repeat treatments, in a lifetime. This is in addition to the other benefits of releasing patients, such as reduced medical costs, possibly increased patient comfort, potential availability of constant family support, and maybe improved patient psychological well-being during the therapy for those patients who prefer a home environment rather than a hospital setting.

2. BACKGROUND

The release of patients in the United States is subject to regulatory control by the US Nuclear Regulatory Commission (NRC), as stated in the Code of Federal Regulations (CFR), Title 10, Part 35, Section 35.75, Release of individuals containing unsealed byproduct material or implants containing byproduct material:

> *A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem).*

The regulation also requires that the patient be provided with instructions if dose to any member of the public is likely to exceed 0.1mSv (0.1 rem) on ways to minimize the exposure of others. This regulation has been in effect since 1997, and differs from the rule it superseded in that it is dose-based. The requirement prior to 1997 was based on retained activity in the patient, as well as dose rate measured at one meter from the patient, at the time of release:

> *A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either: (1) The measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter; or (2) The activity in the patient or the human research subject is less than 30 millicuries.*

One of the main disadvantages of the old rule was that it was generic, applying equally to all patients regardless of their specific circumstances. This disadvantage arises from the fact that the dose rate measured at one meter from the patient at the time of release is not a good indicator of the total dose that may be received by a member of the public. For a given measured dose rate at the time of release, the total dose to a member of the public can vary considerably depending on the details of the case, such as the underlying disease condition, the distribution of the iodine in the patient's body, the rate at which the iodine is eliminated from the body and the behavior of the patient after release. For example, cancer patients whose thyroids have been removed will eliminate the iodine rapidly, thus shortening the duration of exposure of members of the public, especially the family. Different cancer patients also have different metabolisms, and so elimination even within that subgroup will vary considerably. On the other hand, thyrotoxicosis patients eliminate the iodine more slowly, and can expose others for much longer periods after release. The revised rule addresses these issues by making the release condition dependent on total dose expected to be delivered to any member of the public. This allows the licensee to take into consideration each patient's particular circumstances when considering release.

However, a significant disadvantage of the dose-based rule is that it does not provide an easily used operational quantity, such as a measured dose rate, that licensees may use to determine if they may release a specific patient. A model is needed to convert the dose limit in the rule to a quantity that can be used as a basis for releasing the patient, and NRC has published guidance in the form of a regulatory guide describing several acceptable models of varying complexity. The recommended approach in the guide is graded, with the simplest model serving as a screening step.

This screening model is quite conservative and is generic in that it does not require the licensee to provide much, if any, patient specific data. Licensees who are able to release patients using this model are considered to be in compliance with the primary dose release criterion. The model calculates the dose at a distance of 1 meter from the patient, assumed to be the mean distance at which a member of the public will be exposed during the entire exposure duration. The calculations take no credit for attenuation of the radiation in leaving the patient's body, nor attenuation in entering the exposed person's body, and no credit for biological elimination of the iodine in the urine during the entire exposure period. It also assumes that the exposed person will be at the 1 meter distance during 25% of the time following release until complete decay of the activity, the rest of the time assumed to involve no contact with the patient. Both patient and member of the public in these calculations are assumed to be points, which is an additional layer of conservatism. This approach to estimating dose to a member of the public was

originally recommended by the National Council on Radiation Protection and Measurements in 1970 (NCRP70).

Applying the screening model described above leads to an activity at the time of release of about 1.221 GBq (33 mCi), which is essentially the same retained activity for release of a patient that was in use in the pre-1997 activity-based regulation. There is no connection between the two values, however, and the fact that the two activities are nearly identical is coincidental. Although it may seem that the new regulations lead to the same result as the old, this is true only if the licensee uses the default screening model provided in the guide. However, licensees who cannot release a patient using the screening model can use the more elaborate models also described in the guide that remove some of the conservatisms in the screening approach by allowing for patient- specific parameters rather than the conservative default parameters. The more elaborate models described in the guide provide considerable flexibility to licensees because these models may be tailored to the circumstances of the specific patient. That is the main advantage of the dose-based rule.

One major factor that this flexibility permits is the use of effective half-life rather than radiological half-life in integrating the dose rate function. For a cancer patient for whom nearly all thyroid tissue is removed surgically, the effective half-life for the administered ^{131}I is usually of the order of a day or less, leading to a much smaller integrated dose for the exposed person compared to using the 8-day radiological half-life in the screening calculation. In addition, the default occupancy factor of 0.25 may be changed. The occupancy factor is the fraction of the time that a patient may be assumed to be close to the exposed member of the public, usually a family member at home. As an example, for a cancer patient who drives himself to the hospital to receive the administration and then drives himself back home, and who does not plan to be with others for several days after the treatment, the assigned occupancy factor may be much lower than the default 0.25, and can in fact be close to zero. The result of this flexibility is that the activity at which patients may be released, or the activity that may be administered on an outpatient basis, in the US, may be as high as 9.25 GBq (250 mCi) or higher in some cases, rather than the default 1.11 GBq (30 mCi), while still meeting the primary dose limit of 5 mSv (500 mrem).

After about 15 years of experience with this method of releasing patients, the NRC decided to examine available data on dose to members of the public from released patients to determine the doses people are actually receiving from exposure to released patients, and thus determine whether the rule and guidance now in effect serve their intended purpose or are in need of modification. The first step in the process was to review the literature to determine what work had been done in this area, and whether the data that came out of that work is sufficient to provide assurance, or otherwise, on the effectiveness of current practices. The next step, if the available data proved inadequate, was to commission a set of measurements to provide data where it was lacking in the technical literature. This report describes the results of the work that was done to achieve this goal, and also the methods used to supplement the data found in the technical literature.

3. PATIENT RELEASE PRACTICES OUTSIDE THE UNITED STATES

The 2011 edition of the Basic Safety Standards (BSS) issued by the International Atomic Energy Agency (IAEA11) defines carers and comforters as “people who willingly and voluntarily help in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis and treatment.” The radiation exposures of such carers and comforters are classified as medical exposures and are thus not subject to dose limits, although the principles of ALARA

do apply. IAEA instead recommends that they be subject to dose constraints established by the regulatory agency in cooperation with the licensee. Other members of the public that are outside this classification of carers and comforters are subject to the 1 mSv (100 mrem) annual public dose limit. In an earlier publication (IAEA02) IAEA recommended a dose constraint for carers and comforters of 5 mSv (500 mrem). The International Commission on Radiological Protection (ICRP) holds a similar position (ICRP04), stating that "A dose constraint of a few mSv/episode (few hundred mrem) (not a dose limit) apply to relatives, visitors, and caregivers at home." In addition, "Young children and infants, as well as visitors who are not engaged in direct care or comforting, should be treated as members of the public (i.e. subject to the public dose limit)." Note that the term "caregivers" rather than "carers" is generally used in the United States.

Specific values for dose constraints were proposed by the European Commission (EU97). The Commission explains that "*dose constraints are ceiling levels for optimization purposes. These are guideline forecasts which are not expected to be exceeded; they are not legal dose limits…Because family and close friends may benefit from the presence of the treated patient in the family circle, the pre-set dose constraint can be higher than the public dose limit. Third persons…do not benefit from the exposure at all and are therefore regarded as members of the public*." The report proposes that children be subject to a dose limit of 1 mSv (100 mrem), adults to age 60 be subject to a constraint of 3 mSv (300 mrem), and adults over 60 be subject to a constraint of 15 mSv (1500 mrem). As of 2014, there are no uniform patient release criteria within the European Union, these being set by national regulatory bodies. They vary quite widely, as indicated by a few examples listed below and quoted from IAEA Safety Report No. 63 (IAEA09) and other sources (MU06), (JE11):

Germany	75 MBq (2.0 mCi)
Sweden	600 MBq (16.2 mCi)
Finland	800 MBq (21.6 mCi)
Japan	500 MBq (13.5 mCi)
Australia	600 MBq (16.2 mCi)
Iran	430 MBq (11.6 mCi)
Pakistan	1100 MBq (29.7 mCi)
USA	500 mrem (or 1221 MBq (33.0 mCi) default)

In general, the release criteria in most countries are an activity release criteria in the range of 75 – 1100 MBq (2.0 – 29.7 mCi) (HE10). Using very conservative default parameters, NRC licensees are able to use 1221 MBq (33 mCi) as a default value for the USA dose criterion of 500 mCi. This activity is calculated using very conservative default parameters.

The recommendation by IAEA and ICRP considers radiation exposure to carergivers and comforters as medical exposures and therefore exempt from the dose limit for members of the public. It should be noted that in limited situations, the NRC has instituted a policy similar to this by allowing certain individuals the ability to exceed the public dose limit for visitors of patients that could not be released under 10 CFR 35.75. This policy was established for cases involving patients confined to the hospital, and is explained in Regulatory Issue Summary 2006-18 (RIS06). The RIS treats establishing a constraint on caregivers in the hospital as a special case of a request for exemption from certain parts of the regulations, in this case from the limit on dose to members of the public in 10 CFR 20.1301(c). The exemption is, in a sense, pre-approved, and the licensee need only to notify the appropriate regional office of the need for such an exemption. The default initial constraint is set at 20 mSv (2 rem), but may be raised if the licensee demonstrates a need to do so. A caregiver is defined in the RIS as a member of the patient's family or someone close

to the family or the patient, but does not include hospital staff. Controls are put in place once the exemption goes into effect, such as informing the caregiver of the radiation risks involved as well as providing the caregivers with appropriate dosimetry to monitor their exposure. The caregiver is also instructed on ALARA measures. This policy was initiated following a case involving the daughter of a very ill hospitalized patient who insisted on participating in her mother's care. The mother had been administered a therapeutic dose of ^{131}I but had died after one week in the hospital. An assessment of the exposure received by the daughter during that period indicated a dose in excess of the occupational dose limit of 5 rem/yr. Also prompting this policy were repeated complaints from medical professionals, especially from pediatric departments, that it was very difficult to comply with the dose limits for members of the public while at the same time allowing parents to comfort and participate in the care of their gravely ill children during treatments involving radiation or the administration of radioactive materials.

4. METHODS USED IN THE STUDY

Review of the literature was designed to identify work that was carried out to measure the doses received by members of the public as a result of contact with released patients. The review consisted mainly of using search engines to identify articles published in reputable, peer reviewed technical journals devoted to radiation-related topics. The initial results of the survey revealed what staff had anticipated based on their familiarity with the field: there was considerable work done and described in the literature on measurement of dose, both external and internal, received by members of the released patient's family members. The amount of work done proved sufficient to permit staff to draw reliable conclusions.

On the other hand, there was no work found on doses to members of the public outside the patient's family and close friends. Dose measurement requires that the person to be monitored wear some type of dose measuring device during the exposure period, and to do that, it is necessary to know beforehand who that person will be, and to secure the person's agreement to be exposed to radiation during the measurement period. Family members are identified beforehand and are informed, and agree that they will be exposed by the patient, and so it is easy to prearrange for such measurements. This is not the case outside the family setting. For example, consider public transportation, such as a bus. It is not known beforehand which bus the patient will take, nor is it known beforehand who will be on the bus or next to whom the patient will sit or stand. It is also highly doubtful that a complete stranger will agree to be exposed to radiation from a released patient for the sake of collecting data. The situation is similar for hotels as the patient may not tell the hospital staff they are going to a hotel rather than go directly to their private residence. Even if this information is obtained, it is still not known which members of the hotel staff will need to be monitored, nor which guests will be staying in rooms adjacent to the patient's room, nor is it anticipated that staff or guests will agree to participate in the experiment. Thus, monitoring members of the public outside the immediate family for radiation exposure poses considerable logistical, ethical and legal issues that in most situations would be prohibitively difficult, expensive, and potentially unethical. Staff concluded that this approach therefore may not be a viable option for this project, and that an alternative approach must be sought. The situation in nursing homes is more akin to a hospital setting in that the identities of the residents are known beforehand, and the staff who will care for them are also known. The situation is therefore amenable to performing measurements or at least reviewing the methods used to handle patients who had undergone RAI therapy, the contamination control measures they take, and any ALARA precautions that are in place.

In view of the above, staff decided that, in order to fill the data gap on doses to members of the public outside the family, such as during transportation and in hotels, calculations would be used as an alternative method for measurements. Staff therefore initiated calculations at the Oak Ridge National Laboratory) concurrently with the ongoing literature search. The calculations are described in more detail in a later section of this report and also in the ORNL report (DE15-1,DE15-2,DE17), and this section outlines the basic approach. The calculations included estimating dose to members of the public in a variety of situations that may be expected to occur as the released patient moves about following release. Such situations included public transportation, such as a bus or plane, and hotel stays, as well as some calculations at nursing homes. The calculations were based on the use of a virtual anthropomorphic model of the human body, otherwise known in radiation dosimetry as a phantom, to represent both the patient and the member of the public. The phantom was designed for NRC to conform to a standard human as defined by the ICRP, complete with all relevant internal organs and tissues, with the proper dimensions, compositions and densities as specified by ICRP.

Such phantoms are used as the basis for developing internal and external dose conversion coefficients for use in radiation protection work and in regulations, including NRC's regulations. The phantom used in this work has the unique capability of being able to bend its arms and legs in any realistic configuration, and thereby making it capable of modeling cases such as a sitting patient or member of the public. In the current work, two phantoms were used together, one representing the patient and the other the member of the public, with the iodine placed in the patient. To ensure accurate dose calculations, the distribution of the iodine in the patient's body as a function of time post activity administration was modeled using an iodine biokinetics model developed at ORNL (LE10). The model provides data on how much iodine is in the thyroid, the liver, the urinary bladder, the blood, and any other organ or tissue, at any time after the patient was administered the iodine. This model was used to determine the location and concentration of iodine in the patient's body at various times after treatment, and the data was then used when calculating the dose to the member of the public. Such detailed modeling was important because the dose to the member of the public is affected significantly by the distribution of the iodine in the patient's body.

The dose calculations were carried out using radiation transport calculations, and the code used to implement these calculations was the Monte Carlo N-Particle (MCNP) version 6 code (PE13). This code is a radiation transport code developed at Los Alamos National Laboratory, and is the code used at NRC to perform complex radiation calculations, such as shielding, dosimetry, criticality, and so on. The results of these calculations are presented in a later section of this report, and are viewed by staff as providing highly reliable and realistic estimates of doses to be expected as a result of the presence of the patient in the public arena. They supplement the measurement data in the family setting in areas of public exposure where measurement is not an option.

5. REVIEW OF INTERNAL DOSE DATA

One of the assumptions made in NRC's calculation of dose to a member of the public is that any internal dose that may result from contamination produced by the patient is sufficiently small to be negligible compared with the external dose, and hence may be neglected in the dose calculations used as a basis to release a patient. To arrive at this conclusion, NRC's Regulatory Guide RG 8.39 (RG 97) uses the industry rule of thumb that the fractional intake of unsealed radioactive material being handling is 10^{-6}. This fraction was increased by a factor of

10, to 10^{-5}, for conservatism in RG 8.39. Using the factor of 10^{-5}, a patient administered 1.110 GBq (30 mCi) ^{131}I would lead to an intake by a member of the family of about 11.1 kBq (0.3 μCi) and an effective dose of 0.3 mSv (30 mrem), which is a small dose and only about 6% of the external dose limit of 5 mSv (500 mrem).

The 10^{-6} rule of thumb has been demonstrated to be valid for most situations involving released patients and their families at home. Jacobson et al. (JA 78) measured thyroid activity in 17 family members of 7 families of released thyroid cancer patients, as well as ^{131}I levels in the patient's saliva and breath and contamination levels on surfaces. The activities in patients at the time of discharge were all below about 3.0 GBq (81 mCi). All families had been instructed on ways to minimize exposures. The patterns of thyroid activity in the family members showed periodic peaks, suggesting that intakes were due to repeated contamination events rather than a continuous intake. All family members who were in proximity to the patient showed thyroid uptakes, but these were in the range of 10^{-5} or less of the activity in the patient at the time of release. The results showed thyroid doses in the range of 0.04 – 13.3 mSv (4 -1330 mrem), but the study found no correlation between administered patient ^{131}I activity and thyroid dose to family members. For example, the highest thyroid dose of 13.3 mSv (1330 mrem) was to a patient's child, the patient having been administered 650 MBq (17.5 mCi), whereas family members of the patient administered 5.6 GBq (150 mCi) received a maximum thyroid dose of 0.12 mSv (12 mrem). It should be noted that the contribution of the thyroid doses to the effective doses received by the family members is much smaller than the thyroid dose itself because of the small tissue weighting factor for the thyroid. However, in one case the internal thyroid dose was significantly higher than the measured external dose.

Investigation of the reasons for the variability in internal dose and the lack of correlation between administered ^{131}I activity and thyroid dose revealed that it was due mainly to differences in observing the precautions concerning contact with the patient at home. For example, in the case of the child who received a thyroid dose of 13.3 mSv (1330 mrem), the mother, who was the patient, took care of the child during periods when her husband was away. The other case of high thyroid dose of 6.12 mSv (612 mrem), also involving a young child who was cared for by the mother, who was a patient who did not observe any of the precautions that were discussed during the release interview.

In a separate study, Buchan et al (BU70) measured the activity of ^{131}I deposited in the thyroids of 39 members of households of released patients. Their measurements showed ratios of the measured thyroid burdens to administered activities to be 10^{-5} or smaller in all cases, again supporting the general rule of thumb for intake. Again, as found in the Jacobson study, there was no clear correlation between the administered activity and the activity deposited in the thyroids of family members as a result of contamination. The administered activities to patients in this study varied from 148 – 740 MBq (4 - 20 mCi), and the measured thyroid activity in family members was in the range of 0 - 630 Bq (0 -17 nCi). The measured thyroid burden is therefore less than about a factor of 10^{-6} of the administered activity. According to current dosimetry models, a thyroid burden of that magnitude will result in an effective dose of about 10 mrem. Among the findings was that the lowest thyroid burden in a family member was associated with the patient receiving the highest RAI activity. In addition, a subgroup of family members was asked not to observe any contamination prevention precautions, and that subgroup did not show thyroid burdens that were higher than those who did observe precautions. It is also significant that one of the patients lived in close quarters in a trailer with his wife, but the wife did not show any thyroid uptake. Another family member who fell sick during the testing period was cared for by the patient, but again, that family member did not show a thyroid burden that was higher than that shown by the rest of the tested family members.

Pant et al (PA05) monitored doses to family members of patients following RAI treatments for thyroid cancer and for Grave's disease. The doses monitored included external doses, monitored using whole body personal dosimetry, and thyroid uptakes using a thyroid probe. At the hospital where the study was done, patients with retained activities greater than 600 MBq (16 mCi) are held in the hospital in an isolation ward until the retained activity reached that level. The study included a total of 342 family members, 45 family members of patients treated for thyrotoxicosis and 297 family members of patients treated for thyroid cancer. Administered RAI activities to thyroid cancer patients were in the range of 0.925 – 7.4 GBq (25 – 200 mCi). An interesting feature of the isolation ward is that the hospital staff is not classified as occupationally exposed workers, and therefore do not participate in patient care except in emergency situations. Instead, the patients treated for thyroid cancer are cared for by their family members during their stay in the ward. A total of 103 of these family members, whose patient stayed in the isolation ward for at least 2 days, were monitored for thyroid doses in addition to external radiation exposure. The results of thyroid monitoring for the 103 family members showed that 56% received no measurable dose, and 85% of the total received thyroid doses that were less than 0.1 mSv (10 mrem). Only three of the 103 family members received thyroid doses in excess of 1 mGy (100 mrad): two between 1 – 2 mGy (100 – 200 mrad) and one between 2 – 3 mGy (200 - 300 mrad). It is significant to note that all three cases involved family members caring for pediatric patients, and who of necessity had close and constant contact with the patients. It should be noted that these doses to the thyroid contributed to the effective doses to family members was very small, of the order of about 0 – 10 mrem.

Another study demonstrated that concentrations of airborne ^{131}I were measured in the rooms of hospitalized patients, and it was found that although the airborne activity concentrations increased with administered activity, it did not increase proportionately, but at a much slower rate (JI12). For example, when the administered activity increased by a factor of 10, the airborne measured concentration was found to increase by a factor of about 4. For patients administered 7.4 GBq (200 mCi), the average mean airborne activity in the patient's room was found to be about 498 mBq m^{-3} (13.5 pCi m^{-3}). Using a breathing rate of 1.5 m^3 hr^{-1} (ICRP02), and an effective dose conversion factor of 2.2×10^{-8} Sv Bq^{-1} (ICRP96), the dose rate from inhalation of this concentration would be less than 1 μSv hr^{-1}. The inhalation dose received by a visitor under such conditions would therefore be negligible compared with that resulting from external exposures. The same authors estimated inhalation doses to staff while in the patient's room to be of the order of 0.1 μSv (10 μrem) per hour of exposure. A rough comparison was made with the corresponding external doses that the staff received, which averaged 3.8 mSv, or about a factor of 40 higher. The contribution of the internal component of the dose to the total is thus negligible, at least for the conditions prevailing in this study.

In another study of contamination levels produced by RAI patients, Ibis et al. (IB92) measured contamination levels on surfaces of patient treatment rooms occupied by thyroid cancer patients who had received ^{131}I therapeutic activity following thyroidectomy. The administered activities varied from 3.7 – 14.8 GBq (100 – 400 mCi), and the study included eight patients. The patients were hospitalized for about two days before release, and the measurements were made during this hospitalization period. Contamination was measured in saliva, perspiration, breath, toothbrushes, and air in the room, as well as various surfaces in the room, such as door handles, telephones, faucets, and toilet rims. The results showed contamination on all surfaces tested, and the contamination levels were generally found to exceed the level recommended by NRC for removable contamination in licensee restricted areas of 2,200 dpm/100 cm^2 for beta emitters (RG81). This was the case for all surfaces and all patients. The general pattern for contamination on the patients' skin was that levels were approximately proportional to the

administered activities, and the activity in all cases peaked at about 24 hours post administration then declined rapidly. Contamination on surfaces showed roughly the same pattern. The mean concentration in the air in the room during the first 24 hours post administration was measured at 0.44 mBq/mL (0.012 pCi/mL) for the highest administered activity of 14.8 GBq (400 mCi). The study thus shows that even when occupying the same room as the patient for a period of 24 hours, the dose resulting from inhalation of contaminated air is very small. It should be noted, however, that the data were obtained from hospital rooms and that conditions at the patient's home may be different. For example, the room at home may have fewer air exchanges per unit time that that typically found in the hospital, leading to higher air concentrations at home. Precautions against contamination and the handling of contaminated spills in the hospital are under professional supervision by trained hospital staff, whereas this is not likely to be the case at home, again leading to a higher potential for exposure to family members. Nevertheless, the differences are not likely to be very great, and the data obtained in a hospital setting may be viewed as order of magnitude indicators.

The results found in Ibis et al. study are confirmed by several other similar studies of contamination levels in patient rooms. For example, the study by Achey et al (AC01) involved 50 thyroid cancer patients administered 3 – 28 GBq (80 -750 mCi) of ^{131}I and hospitalized after activity administration. The study also involved measurements of thyroid burdens, or thyroid bioassay, for all staff members involved in activity administration and any person substantially involved in patient care during hospitalization. The bioassay results were negative for all persons tested in all 50 cases. As in previous studies, contamination was found on all surfaces handled by the patient or that came in contact with the patient. Specifically, the highest levels of contamination were generally those areas that came in contact with the patient's urine (such as toilet rims, bathroom floor and shower), saliva (sinks, pillow, telephone) or touch (doorknobs, TV controls, etc.).

In a separate study performed by Nishizawa et al (NI80), two cancer patients were monitored for periods of about one week post treatment for production of contamination through breath, saliva, sweat, and contamination of items used by the patients. Also, exhalation of six hyperthyroidism patients was sampled 1 hour after treated with 2-5 mCi of Iodine-131. The results of breath monitoring showed that the average excretion of Iodine-131 into air of both thyroid carcinoma and hyperthyroidism patients for the first day was 3.2×10^{-6} of the administered activity per hour. For a patient treated with 7.4 GBq (200 mCi), the exhalation rate would therefore be about 6.4×10^{-4} mCi/hr. Assuming an average size patient room, the inhalation dose resulting from inhalation of the contaminated air for 24 hours would be about 10 mrem effective and 220 mrad thyroid dose. This is a conservative assumption because typical ventilation rates would lower the concentration of iodine in the air significantly, and if precautions are observed, family members would not be present in the patient's room 24 hours during the first day post treatment. The measured perspiration rate was found to be of the order of 1×10^{-6} – 1.6×10^{-6} of the administered RAI activity per ml of perspiration. The average contamination of sheets as a result was found to be about 4.6×10^{-6} of the administered activity per day per sheet, and decreased with an effective half-life of 1.4 days. For an administered activity of 7.4 GBq (200 mCi), the contamination level on the sheet would therefore be about 1 µCi (3.7E4 Bq). Using the rule of thumb of 10^{-5} of the handled unsealed activity inhaled, handling such a sheet would result in inhalation of 10^{-5} µCi and dose of about 1 µrem.

Nostrand et al (NO10) provides a table of excretion pathways following administration of RAI, the information extracted from a paper by Ibis et al (IB92). According to this table, for thyroid cancer patients, 80% of the administered activity is excreted in urine during the first day post-administration. Saliva showed a high specific activity during the first day post treatment, the

activity averaging about 4 MBq/gm (108 μCi/gm) for a treatment activity of 7.4 GBq (200 mCi). The dose that would result from ingestion of 1 μCi of ^{131}I is about 100 mrem effective dose and 1.8 rem thyroid dose. This would require ingestion of about 10 mg of saliva, an unlikely occurrence except possibly as a result of direct saliva transfer from mouth to mouth, as in intimate kissing. The average air concentration in the patient's room during the first day was 0.17 mBq/ml (0.005 pCi/ml) for a 7.4 GBq (200 mCi) treatment activity. The dose to a person inhaling that air for a 24-hr period, assuming 1.2 m^3 of air inhaled per hour, is about 7 mrem effective and 140 mrem thyroid. Simple contamination avoidance measures would reduce the doses from this pathway to negligible levels compared with dose from external exposures. In another study of internal contamination, North (NO13) studied the thyroid uptakes of 43 family members, ranging in age from 10 months to over 80 years, of 22 thyroid cancer patients. The study group also included seven dogs. The therapeutic activities administered to the patients varied between 3.69 – 7.4 GBq (100 – 200 mCi), with a mean of 5.3 GBq (143 mCi). The remaining patient body burdens at the time of discharge, one day post administration, varied between 0.57 – 3.7 GBq (15.5 – 100 mCi), with a mean of 1.92 GBq (51.9 mCi). Of all the family members who were monitored, three people and four dogs showed an uptake. The estimated thyroid doses based on these results were 0.93 – 1.2 mGy(93 – 120 mrem). The estimate fractional activity transferred from the patient to any family member varied between 8×10^{-6} – 2×10^{-5}, once again supporting the general rule of thumb used by NRC in assessing the impact of iodine uptakes. It is instructive to note that, of the three people showing thyroid uptake, one had taken a 5-day car tour with the patient, sharing car and motel rooms. The second family member (a male) frequently kissed the patient (his girlfriend). The dog showing the highest thyroid burden was a young puppy who constantly licked the patient.

One of the conclusions that may be drawn from the above data is that all surfaces that come in contact with the patient become contaminated which is not an unexpected finding. Measurements show that articles that come into contact with the patient's excreta, such as urine or perspiration, show the highest contamination levels. The data in the cases examined in these publications, also show that the assumption made in RG 8.39 that the intake from handling unsealed radioactive material is less than 10^{-5} of the activity handled is a good one and is conservative, as is the assumption that the contributions of internal doses relative to external doses are very small, even in the presence of significant levels of contamination on patients and the articles they handle. There was also no correlation found between iodine intake by a family member and the iodine activity administered to the patient. These findings indicate that contamination at home does not easily cause significant intakes of iodine, and that for such intakes to occur, it is necessary to engage in activity that results in very close contact with the patient. All the cases identified in these studies that involved relatively high thyroid uptakes in members of the public involved close contact with the patient or with someone in the care of the patient, mostly in a child parent relationship. Kissing on the mouth was also found to be an efficient way of transferring activity, as one study has shown. This suggests that, although assuming that the internal dose is small is generally a good assumption, it should only be made if the licensee can ascertain that the patient's behavior at home will be such that there will not be any close contact with any other person. A specific example might be determination, prior to release, that the patient will be providing most of the care for a small child because of the absence of any other person to take on that responsibility. If that is the case, careful consideration should be given to modifying the timing of the treatment or of the release until more suitable arrangements can be made.

6. REVIEW OF EXTERNAL DOSE DATA

Harbet and Wells (HA74) provided film badges to family members of patients who had undergone RAI treatment for thyroid ablation or cancer. They were instructed to wear the badges at waist level at all times for a period of 8 days following release of the patient. Patients were discharged according to the then applicable criterion of a retained activity not exceeding 30 mCi. The total dose during the 8-day monitoring period was in the range of 0 – 80 mrad, and showed only a weak correlation with the patient's body burden at the time of discharge. In a similar study conducted jointly at eight medical centers in Belgium (MO98) and involving 65 patients, relatives of patients treated with RAI were asked to wear TLD dosimeters on their wrists for a period of 7 to 14 days following patient release. Some of the patients were thyroid cancer patients and others were thyrotoxicosis patients (e.g. Grave's disease, hyperthyroidism). Cancer patients were administered activities in the range of 3.7 – 5.55 GBq (100 -150 mCi), whereas thyrotoxicosis patients received activities in the range of 191 – 851 MBq (5 – 23 mCi). The median dose for the cancer patients' relatives was measured to be about 22 mrem for the first 14 days, with a range of 14 – 94 mrem. The corresponding doses to the family of thyrotoxicosis patients were higher, with a median of about 74 mrem with a range of 0 – 203 mrem. The higher doses in the thyrotoxicosis cases, despite lower administered activity, is due to large differences in the rates of clearance of RAI from the body, with half-lives in the range of less than one day for cancer patients and of the order of a week for thyrotoxicosis patients. The study also showed clearly that the subgroup of families who were issued ALARA guidance showed lower doses than those who were not issued any guidance.

Another study conducted in the United Kingdom (BA99) monitored adult and child family members of hyperthyroid patients using TLD dosimeters mounted on the wrists of the adults and the ankles of the children. There were 35 adults and 87 children in the study, and the patients were treated as outpatients. They were administered RAI in the range of 200 – 800 MBq (5.4 – 21.6 mCi). The TLD monitoring period varied from 9 – 47 days. All family members were given instructions on implementing ALARA measures. The monitoring results were adjusted to account for exposure extending to complete elimination of the RAI from the patients' bodies. The results showed that 97% of adults showed doses below 300 mrem, with one result showing a dose above 300 mrem. For the children, 89% showed doses below 100 mrem, with 7 of the remaining children showing doses below 200 mrem, one under 300 mrem, and one at 720 mrem. The study also measured the doses to persons accompanying the patient during travel from the hospital, and the results showed doses in the range of 0.2 – 52 mrem, with a median of 3 mrem, for one hour of travel time.

Rutar et al (RU01) compared the dose to family members measured using personnel dosimetry and extended until complete decay. The doses were also estimated using the default dose equation given in NRC's Regulatory Guide 8.39 (RG97). There were 22 patients in the study and 26 family members. The patients were being treated for non-Hodgkin's lymphoma and were administered RAI activities in the range of 0.94 – 4.77 GBq (25 -129 mCi). The results showed radiation doses in the range of 17 – 409 mrem, and the average dose was found to be about 32% of the dose predicted by the Regulatory Guide 8.39 default equation. One of the excessively conservative assumptions in the default equation was found to be the assumption of an initial 8-hour non-voiding period, which in this study was found to average only about 3 hours. All measured doses to family members, extended to complete decay of the RAI, were below 500 mrem, with a mean of 168 mrem and a median of 151 mrem. Another conservative assumption is that RAI is removed from the body only by radioactive decay. For example, measurements performed on 17 thyroid ablation patients in 2007 have shown that the effective

removal half-life averaged 12 hours, with a range of 7 – 31 hours compared to the half-life of ^{131}I (8.03 days) (PI12).

Pant et al (PA05) monitored external doses to family members of cancer and thyrotoxicosis patients administered RAI activities in the range of 0.925 – 7.4 GBq (25 – 200 mCi). The doses were monitored using personnel dosimetry issued to the family members, an these members were subdivided into three groups: Group A (25 patients) travelled by private vehicle and had home arrangements that permitted separate sleeping and toilet arrangements for the patient; Group B (96 patients) travelled by public transportation (bus or train) and had reasonable arrangements for isolation of the patient; and Group C (176 patients) had no living arrangements that permitted avoidance of close proximity with the patient. The results of the external dose monitoring showed the following: the minimum doses in all three groups were zero (i.e. not measurable), the average dose for Group A (0.4 mSv, 40 mrem) was about one half that for Groups B and C, which showed equal averages (0.8 mSv, 80 mrem), and the maximum dose was highest for Group B (8.5 mSv, 850 mrem), intermediate for Group C (5 mSv, 500 mrem), and lowest for Group A (0.9 mSv, 90 mrem). The results clearly show that having good patient isolation arrangements are effective in maintaining low family member doses, but that partial and no isolation arrangements are equally effective (or ineffective) at maintaining low doses. The study also showed that there was only a weak correlation between the doses to family members and the activity of RAI administered to the 342 patients. For example, the mean doses to family members were 0.6 mSv (60 mrem) for RAI activities less than 1.85 GBq (50 mCi), 0.7 mSv (70 mrem) for RAI in the range of 1.85 – 3.7 GBq (50 – 100 mCi), 0.9 mSv (90 mrem) for RAI in the range of 3.7 – 5.55 GBq (100 -150 mCi), and 1.2 mSv (120 mrem) for RAI range of 5.55 – 7.4 GBq (150 – 200 mCi). Changing the upper RAI dosage administered by a factor of 4 increases the mean dose to the family member by a factor of 2. The data also show considerable overlap between the dose ranges for each administered RAI range, with all ranges having a lower limit of zero dose (the highest range showed a lower limit of 0.07 mSv, 7 mrem).

In a similar study by Grigsby et al (GR00), 30 patients who had undergone total thyroidectomy followed by outpatient administration of ^{131}I were enrolled in a study to monitor dose received by members of their families following administration of the RAI. The therapeutic activities involved in this study were in the range of 2.8 – 5.6 GBq (76 – 150 mCi). The number of family members enrolled was 65. All patients underwent an initial iodine retention study by administering 37 MBq (1 mCi) ^{131}I to determine retention during the following 48 hours. This study determines the fraction of iodine taken up by any remaining thyroid tissue left after the thyroidectomy surgery. Family members as well as spaces in the patients' homes were monitored using optically stimulated luminescence (OSL) dosimetry for 10 days following the administration of the therapeutic activity of ^{131}I. Family members were instructed to observe ALARA precautions for two days, after which they could resume normal activities. The results showed doses to family members during the first 10 days post administration in the range of 0.01 – 1.09 mSv (1 – 109 mrem). The study did not indicate whether there was any correlation between the administered ^{131}I activity and the doses registered for the family members. The doses measured in the rooms during the same period were in the range of 0.01 – 2.89 mSv (1 – 289 mrem) in the patient's bedroom, 0.01 – 1.90 mSv (1 – 190 mrem) in the living room, and lower doses in the other rooms. There was no indication in the study of the locations of the patients during this time period. It is interesting to note that, as a very rough gauge, considering that the mean dose to a family member was 0.24 mSv, and the mean dose in the combined bedroom and living room was about 0.92 mSv, the overall occupancy factor would be about 0.2.

The conclusions that may be drawn from the above data are that the external dose to family members, as in the case of internal dose, shows little correlation with administered patient iodine activity, although the correlation is slightly higher in the case of external compared with internal doses. Nevertheless, family members of patients receiving the highest administered activities often show some of the lowest doses. This again points to the importance of behavior patterns and observation of ALARA guidance provided by the licensee. Nearly all of the recorded doses to the family members were below the NRC dose limit of 5 mSv (500 mrem), although a small percentage showed doses that exceeded that limit. The reasons for the high doses in these specific cases were not identified, but based on the patterns revealed by these studies, it is probable that not observing ALARA precautions must have been at least a major, if not the only, reason for the high 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 (PA05). Although observing ALARA precautions is shown to be an effective way to minimize dose, it should not however be concluded that failure to observe the ALARA instructions provided by the hospital at the time of release would necessarily lead to high doses to family members. Avoidance of close contact with the patient, either in normal family life or during the recovery period, may be a normal behavior pattern for the family and not an ALARA measure. In such cases, a report of a failure to observe instructions would not lead to high doses.

7. EFFECTIVE HALF LIFE

One factor that may lead to excessive conservatism in the dose calculation method described in NRC's Regulatory Guide 8.39 is that the default dose rate equation is integrated to infinite time to obtain the total dose received by the target person, with integration assuming that the activity decreases with an effective half-life equal to the radiological half-life, in this case 8.02 days. However, the effective half-life in actual situations is often far less than that. For example, as measured by Al-Haj et al (AL07), the mean effective half-life in the extra thyroidal component for a group of 311 thyroid cancer patients was in the range of 12 -14 hours, with the upper 95th percentile being 20.63 hours. In a related study of 238 thyroid cancer patients, North et al (NO01) measured the effective half-life using a set of serial measurements of external dose rates, typically four measurements per session, that spanned a time period of up to 14 days from the time of therapy administration. The decrease in measured dose rates over the period under consideration was assumed to follow a single exponential function. The patients included in this study had undergone total or near total thyroidectomy. The results showed considerable variability between patients, with measured half-lives extending from 10 hours up to about 30 hours with a few above and below these values. The shortest observed value was 7.3 hours, and the longest 106 hours, with most patients falling in the range of 10 – 18 hours. It is interesting to note that the NRC recommends, in Regulatory Guide 8.39, a value for extrathyroidal effective half-life of 0.32 day, or 7.7 hours, which is close to the lowest effective half-life measured in the studies cited above and others, and hence is not conservative. The spread of the data also suggests that there is considerable variability among patients, and that therefore the effective half-life in each case should be measured rather than using a default value.

The above results are consistent with another study conducted by Willegaignon et al (WI06). The study included 90 thyroid cancer patients, 73 female and 17 male who had undergone total or near total thyroidectomy. Administered ^{131}I activity varied from 3.7 GBq (100 mCi) to 16.6 GBq (450 mCi). Dose rates were measured at a distance of 2 meters from the patient to minimize geometry effects that may increase measurement uncertainty at shorter distances,

and the measurements were carried out daily over a period of 7 days after administration of the activity, with the first measurement in the series being performed approximately one hour after activity administration. One of the findings of the study was that the decrease in dose rate with time was well represented by a single exponential function. The average effective half-life for the group of 90 patients was found to be 11.41 ± 0.02 hours, with most values falling within the range of 9 – 19 hours. Again, there were very few values observed to be as low as the NRC recommended extra-thyroidal half-life of 7.7 hours. In a variation on effective half-life determination, Samuel at al (SA94) measured the effective half-life in 87 patients who had undergone thyroidectomy and were then administered ^{131}I to ablate any remaining thyroid tissue. The measured effective half-lives were in the range of 10.3 – 192 hours with a mean of 57.9 hours.

In thyroid cancer cases, the patient has typically undergone total or near total thyroidectomy, and the administered iodine will be distributed over the whole body and quickly eliminated mainly through the urine. In hyperthyroid patients, on the other hand, the thyroid is generally intact, and the administered iodine will be taken up preferentially by the thyroid, where it is retained with a relatively long effective half-life. In a study conducted by Mohammadi (MO05) in which 78 hyperthyroid patients participated, the external dose rates were measured at intervals post iodine activity administration for periods extending up to 42 days. The mean effective half-life for all the patients in the study was about 8.4 days. A similar study was conducted by Berg et al (BE96), in which the records of 555 patients were reviewed to determine the effective half-lives. The patients included those with Grave's disease and toxic nodular goiter. Both conditions lead to hyperthyroidism. The effective half-lives measured for these patients showed a range of 2 – 10 days, with a mean of 5 ± 1.3 for Grave's disease, and a range of 3 – 9 days, with a mean of 6 ± 1.2 for toxic goiter. In both cases there was considerable spread in the measured effective half-lives. Effective half-life values reported as being longer than the radiological half-life are due to experimental uncertainties.

Estimating the total dose received by a member of the public will depend to a large extent on the duration of the exposure. If the duration is short, such as for example when riding a bus for a short period of time such as an hour, the dose may be estimated by multiplying the dose rate at the time by the duration to give a total dose. The effective half-life in such a case is not relevant. On the other hand, for a member of the patient's family, exposure continues for a significant duration, from a few days for a cancer patient to possibly weeks for a hyperthyroid patient. The total dose in such cases will require integrating a time-dependent dose rate over the exposure duration. For a given occupancy factor, the dominant influence on total dose will be the effective half-life used. Hence, it is important when performing these calculations to use a reasonably good estimate of that value, based on the range of half-lives observed for the patients with a similar medical condition as well as any patient-specific conditions that might affect that estimate, such as, for example, the presence of urinary incontinence or, in the case of a cancer patient, the existence of substantial remaining thyroid tissue.

8. OCCUPANCY FACTOR AND EXPOSURE DISTANCE

The occupancy factor (OF) is defined as the fraction of the time a person is close to the patient, the distance during this time assumed to be an average of 1 meter. The default value for OF recommended in NRC's Regulatory Guide 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 further 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. As an example where this effect was measured (MU06), the dose rates from patients administered 556 – 851 MBq (15 – 23 mCi) for thyrotoxicosis treatment, were measured at 1 meter from the patient and the mean was found to be 43 μSv/h (4.3 mrem/h) but the mean contact dose rate was 2410 μSv/h (240 mrem/h).

A study of this effect was also published by Han et al (HA13). In this work calculations were performed using the Oak Ridge National Laboratory series of phantoms to represent family members of different ages, and the calculations were performed using a Monte Carlo radiation transport code. The ages considered were 1, 5, 10, 15, and adult. The patient in all cases was an adult male, and three source distributions were considered: in the thyroid, in the abdominal region, and in the whole body. The patient-to-family member distance considered was 0.1, 0.5, 0.75, 1, and 2 meters, and in all cases the patient and family member were standing face-to face.

The results were expressed as maximum releasable activity, assuming a dose limit of 500 mrem and an occupancy factor of 0.25, with the distance varied from 0.1 – 2 meters. The results showed that the maximum releasable activity that met the dose limit was a factor of about 2 higher for ages above 10 years for the three activity distributions considered when calculated using the Monte Carlo approach compared to the default point source method. The results for younger ages showed significant dependence on the activity distribution, and showed higher permissible release activities compared with the other age groups. This conclusion is valid only for the geometry used in the calculations, which assumed that the adult source and child family member were standing on the floor. The conclusion would not, of course, be valid if the child is being carried. The calculations also showed that the releasable activity is a factor of 8 – 10 times lower when the family members were at a distance of 0.1 meter compared to a distance of 1 meter.

A search of the technical literature did not identify any documented studies showing the origin of the OF of 0.25 nor of the use of 1 meter as the default distance, other than that they are assumed to be reasonable average values. If a patient sleeps alone in a room for 8 hours per day, then the maximum occupancy factor 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 occupancy factor 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 possibly 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 where children are involved in families with limited means. Whether the patient is the child or the parent, close contact for extended periods may be unavoidable.

9. DOSE CALCULATION IN REGULATORY GUIDE 8.39

The methods suggested in NRC's Regulatory Guide 8.39 for calculating the external dose rates resulting 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, and therefore represents the integration of the time-dependent dose rate function over a specific exposure duration. Using the default equation in the Regulatory Guide 8.39, the maximum release activity for ^{131}I is 1221 MBq (33 mCi). There is considerable, or some would say excessive, conservatism, in this calculation:

1. 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.
2. Calculation of the total dose by integration of the dose rate function as performed in the default equation uses 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.
3. The occupancy factor 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 may be conservative in some cases, but not sufficiently conservative in others. Patient-specific data is important in deciding whether changes from the default are warranted.
4. 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 occupancy factor, this may or may not be an adequate assumption, depending on the details of the patient's living arrangements.

The Regulatory Guide provides equations in addition to the basic default equation that provide opportunity to take into account some patient-specific data. These equations assume that removal of ^{131}I from the body can be described by the sum of three exponential terms: an initial component 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 occupancy factor during that period is 0.8. The next period extends to total decay, with an occupancy factor of 0.25, and consists of two components: an extra-thyroidal component and a thyroidal component. The partition of the RAI between these two components depends on the patient's condition. 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 (SI07). 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.

Siegel et al (SI07) pointed out that recent biokinetic models of iodine in cancer patients show that there is little justification for the assumed 8 hour non-voiding period and that more current models should replace those in the Regulatory Guide. They note that this is significant because close to half the dose to an exposed person can be attributed to this period, and that data indicate that about half of the administered iodine is voided during this initial 8-hour period. As an alternative to the default values used in the Regulatory Guide, the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) recommend the following defaults that are viewed as more realistic (SI04): an exposure rate constant of 1700 mR cm^2 mCi^{-1} h^{-1} instead of 2200, a non-void period of 1 hour instead of 8 hours, and an occupancy factor during this period of 0.25 instead of 0.75. They estimate that these changes would raise the maximum releasable activity for cancer patients from 8.2 GBq (221 mCi) to 18.2 GBq (493 mCi) and for hyperthyroid patients from 2.1 GBq (57 mCi) to 3 GBq (80 mCi) (SI07).

Several calculations and measurements have been completed to test the validity of some approximations used in the Regulatory Guide. Siegel et al (SI02) compared the calculated doses using the point source approach with a modification using a line source to represent the patient. They found that, at a distance of 1 meter, the ratio of line to point source dose rates for a line of length 174 cm was 0.823. The point source approximation became less valid as the distance was decreased below 1 meter. For example, at 50 cm the line to point ratio was calculated to be 0.603.

Another approach to checking the validity of the default Regulatory Guide equation was followed by Al-Haj et al (HA07). Their approach consisted in taking dose rate measurements at 30 cm and 1 meter from the patients immediately after administration of the RAI activity, and daily for several days thereafter. The dose rates were also calculated using a variation of the default Regulatory Guide approach. A total of 311 cancer patients were included in this study.
The study results showed a dose rate of 0.028 μSv hr^{-1} (2.8 μrem hr^{-1}) per MBq administered activity, with a range of 0.012 – 0.052 μSv hr^{-1} per MBq. Therefore, a patient administered 7.4 GBq (200 mCi) would show a measured dose rate of about 200 μSv hr^{-1} (20 mrem hr^{-1}). The dose rate using the default Regulatory Guide equation would be about 39 mrem/hr, or nearly a factor of 2 higher than the measured dose rate. The study also estimated the shielding factors provided by the patients' body, which was determined by comparing the measured dose rate with the expected dose rate without taking shielding into account. The average value of the shielding factor was found to be 0.46, with a range of 0.20 – 0.87.

In another work on the same subject, Sparks et al (SP98) attempted to improve the accuracy of dose calculations by using an anthropomorphic phantom to represent the patient as a radiation source, together with a Monte Carlo radiation transport code to calculate the dose rate at a distance of 1 meter. The target was also a phantom, and the 1 meter distance is measured from the front face of each phantom, which equates to a distance of 120 cm between phantom centerlines. The ^{131}I source was distributed in the abdomen region of the source phantom because this represents the distribution in the actual cases being simulated, which involve uptake mostly by abdominal organs such as the liver, kidney, and spleen. The dose to the target was not calculated as the effective dose, but was calculated by adding all the energy deposited in the phantom and dividing by the mass of the phantom. The results of these calculations were also compared with measured dose rates at a distance of 1 meter from 49 non-Hodgkin's lymphoma patients who had received ^{131}I anti B1 therapy as reported by Kaminski et al (KA93, KA96). The results showed that using the point source approximation overestimates the dose by

60% when compared with measurements. However, the authors also point out that the measurements overestimate the dose to the target because they do not account for attenuation of the radiation in target before reaching the sensitive internal organs. When this effect is taken into account, using the results of the Monte Carlo calculations, the overestimation of the dose using the point source approximation goes up to about 160% compared to corrected whole body dose equivalent rate. These results are consistent with the findings of Al-Haj noted above.

Another comparison of the effects of source/target geometry was performed by Alberico et al (AL11). Three source geometries were compared: point, line and volume. The volume source was represented by an anthropomorphic, voxel phantom called FAX (Female Adult Voxel) developed by Kramer et al (KA04), and the target was also represented by the same type of phantom. The phantom was used in conjunction with a visual Monte Carlo code developed by Hunt et al (HU00). Three conditions were considered in the Monte Carlo simulations: hyperthyroidism, thyroid cancer, and non-Hodgkin's lymphoma. These three conditions are characterized by different distributions of the administered iodine activity. The distributions assumed when using the phantom calculations were: for hyperthyroidism, 80% of the iodine is assumed to be in the thyroid and 20% in the rest of the body; for thyroid cancer 5% is assumed to be in remaining thyroid tissue and 95% distributed in the rest of the body; and for lymphoma, all of the activity is assumed to be in the abdominal region. The results of the calculations showed the following ratios of effective dose at 1 meter: hyperthyroidism – point/line/voxel 1/0.84/0.68; thyroid cancer: 1/0.84/0.58; and lymphoma: 1/0.84/0.56. In all three conditions, the point source calculation overestimates the dose at 1 meter by a factor that approaches 2 compared to the Monte Carlo simulation using the voxel phantom, which is consistent with the other studies cited above. The differences between the three methods at 0.3 meter are much larger, as would be expected, since the assumption of point and line source become progressively invalid as the source target distance gets smaller.

An extensive set of calculations was described by Han et al (HA13, HAN13) that estimated the dose to family members from patients treated with ^{131}I for hyperthyroidism and thyroid cancer. The phantoms were voxel and represented family members of ages 1, 5, 10, 15 years and adult, and the patients were adult voxel phantoms. The calculations were made using a Monte Carlo radiation transport code, and the results were expressed as dose per unit time integrated activity (mSv/Bq-s). Multiplying these values by the activity in the source region integrated over the exposure duration gives the total dose to the family member. This approach follows the schema developed by the Medical Internal Radiation Dose (MIRD) Committee. The dose rates were calculated in face-to-face geometries for the different ages and at distances of 10, 50, 100 and 200 cm surface-to-surface. Calculations were also made for a mother patient holding a newborn in her arms and for a mother with a 1-year-old child standing on her lap. Two source distributions were used: a hyperthyroid patient, in which the activity was in the thyroid, and a cancer patient, in which the activity was in remnant thyroid tissue as well as in locations where the thyroid cells may have migrated, such as the lungs, stomach small intestine, kidney, bladder, and a few other locations. The activity concentration was assumed to be uniform in all these locations. The results showed that, for a hyperthyroid patient at a distance of 1 meter, the calculated dose rates were lower by a factor of 2 for a 5-year-old to 1.5 for a 15-year-old, and 1.6 for an adult compared with the Regulatory Guide point source calculation. The dose rates increased rapidly with decreasing distance for the 1 year and 15 year old children compared with the rates at 1 meter, being 1.7 times at 50 cm, 3 times at 30 cm, and about 5.7 times at 10 cm. Interestingly, the doses for the 5-year-old decreased with decreasing distance because of the low stature of the child and the location of the activity in the adult thyroid. The trends were similar for the cancer patient except that the dose to the 5-year-old increased with decreasing distance, because in this case the activity was located mostly in the abdominal region of the

patient. The calculations for the mother cuddling a baby showed higher doses for the hyperthyroid patient than the cancer patient (HAN13). The dose rate for the hyperthyroid case was a factor of 10 higher than the dose rate estimated using the default equation in Regulatory Guide 8.39.

As is clear from the above data and opinions expressed in journal articles, 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 remembered that these efforts at improving the accuracy of the dose estimates are in fact attempts to improve the accuracy of estimating dose to a situation in which an idealized exposure scenario is followed by the patient and family members. The calculations do not in fact 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. Families of patients with very high iodine dosages 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 assign a theoretical release category to each specific case on which to base a decision of whether or not the patient meets release criteria. It is clear, however, that doing the calculations is not adequate by itself: it does not determine the dose that will actually be received. It must be accompanied by diligent investigation of 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.

10. NRC DOSE CALCULATIONS

The NRC contracted with Oak Ridge National Laboratory (ORNL) to perform calculations of dose to members of the public exposed to a released patient. The calculations were designed to provide dose estimates in situations for which measurement data were not found in the technical literature. These situations included exposure during use of public transportation, such as a bus, exposure at a hotel, and exposure at a nursing home. The calculations used an anthropomorphic mathematical phantom that had previously been developed by ORNL for the NRC. The phantom, known as PIMAL, contains all of the relevant organs and tissues with dimensions, masses and densities that conform to the recommendations in ICRP Publication 89 (ICRP89). 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 in bed, or lying in bed. In order to model the dose received by a member of the public accurately, it is necessary to know the distribution of the iodine in the body as a function of time following administration of the therapeutic activity. This was done in this study by using a model for the biokinetics of iodine that was developed at ORNL (LE10). 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 urinary 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 biokinetic model was used to predict the iodine distribution in each of these two cases as a function of time.

The specific scenarios analyzed in the calculations included the following:

Public Transportation (Figures 1a and 1b):

- 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 (Figure 2):

- 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 (Figure 3):

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

Some of these exposure geometries are illustrated in the screen shots shown below. The dose calculations were performed using the MCNP6 code, which is a radiation transport code developed at Los Alamos National Laboratory and is the code used at the NRC for complex radiation dosimetry, shielding, and criticality calculations. Calculation of dose to a member of the public was performed by calculating the dose rates at different times following iodine administration, and then integrating the 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 (ICRP 03).

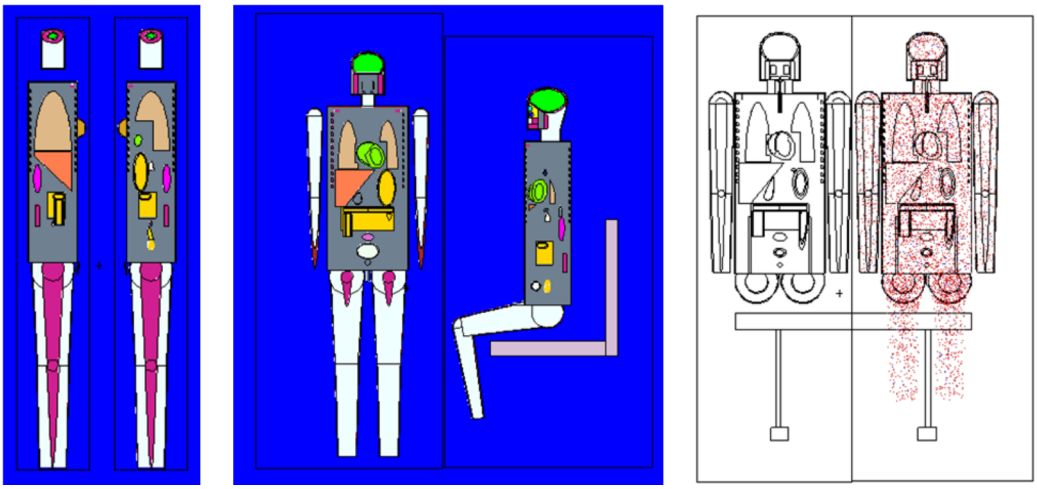

Figure 1a. Diagrams showing exposure scenarios in public transportation. From the left, patient and passenger facing each other, passenger standing and patient seated, and passenger and patient seated.

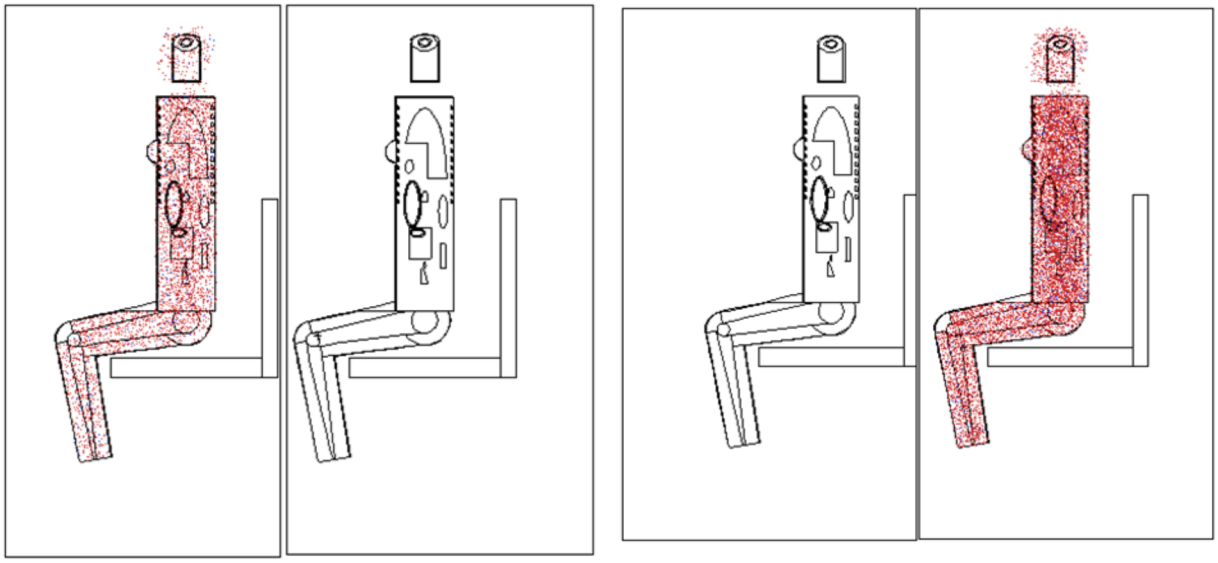

Figure 1b. Diagrams showing exposure scenarios in public transportation. From the left, patient seated in front of passenger and patient seated behind passenger.

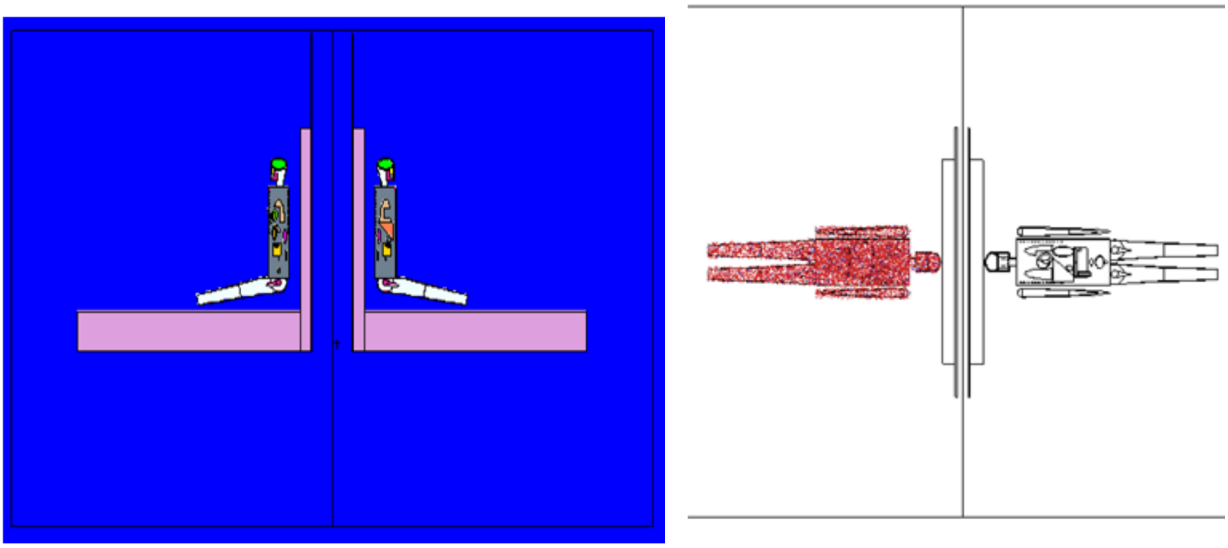

Figure 2. Diagrams showing exposure scenarios in hotel rooms. From the left, patient and guest sitting in bed, back to back, in two adjacent rooms, and sleeping head to head in two adjacent rooms.

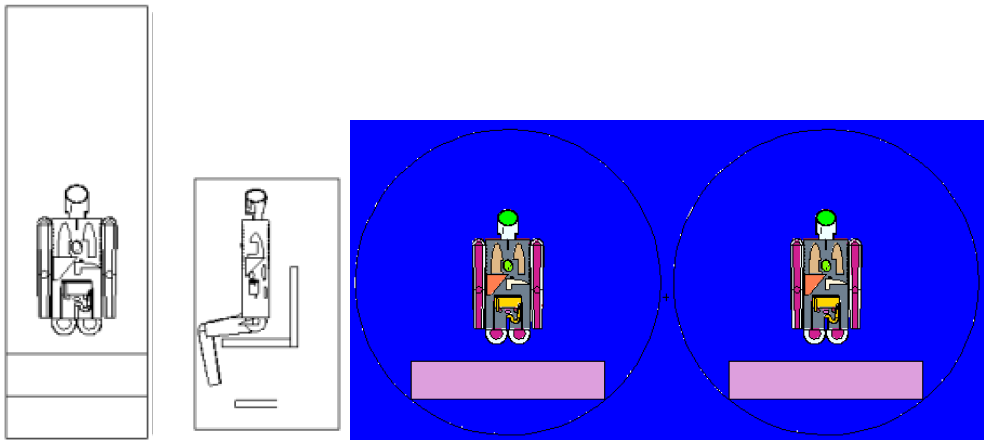

Figure 3. Diagrams showing exposure scenarios in nursing homes. From the left, a caregiver is seated from a patient seated upright in bed, and the patient and a nursing home roommate seated upright in bed.

11. TRANSPORTATION

The results of the transportation calculations are shown in the Table (1a) and (1b) below. They are presented in the form of the time it would take while engaged in the stated activity to exceed the 10 CFR Part 35.75 patient release dose limit of 500 mrem, as well as the Part 35 instruction dose limit of 100 mrem. The data may of course be presented in other forms, but this form is likely to be the most instructive.

In the calculations summarized in Table (1a), it was assumed that the patient has one urine void within 2 hours of RAI administration. This means that before taking public transportation, the patient will have voided the full contents of the bladder once at the licensee's facility. The patient is assumed to board the transportation immediately after voiding. In the calculations summarized in Table 1b, it was assumed that the patient does not void and boards the bus immediately post-administration. This is contrary to guidance currently provided to the licensee, but represents an upper bound (conservative) estimation.

All calculations were normalized to a unit activity of 1 MBq (37 mCi). The data in tables (1a) and (1b), were based on an iodine dosage of 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer.

Table 1a - Time in hours to exceed 100 mrem and 500 mrem effective dose on public transportation. Administered activity is 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer. Data assume one urine void before release (2 h post RAI administration), 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[(1)] (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[(1)] (409.61 mrem)	28.5
Seated/standing patient	57.5	4.5	>238[(1)] (187.38 mrem)	26.7

(1) *Simulations were conducted over a period of 240 hours post-administration (i.e. 238 hours after the patient voids 2 hours post-administration and boards the transportation). All scenarios assume 100% occupancy factor.*

Table 1b - Time in hours to exceed 100 mrem and 500 mrem effective dose on public transportation. Administered activity is 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer. No void assumed 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[(1)]	13.2
Seated in front of patient	20.5	2.7	109.3[(1)]	16.4
Seated next to patient	28.2	4.1	147.6[(1)]	26.1
Standing facing patient	4.6	0.7	22.1	3.6
Standing/seated patient	23.0	4.4	120.1[(1)]	22.8
Seated/standing patient	47.1	3.6	215.4[(1)]	20.7

(1) *Simulations for no-void assumption were conducted over a period of 72 hours post-administration. Values beyond 72 hours were extrapolated via a least-squares fit with R^2>0.98. All scenarios assume 100% occupancy factor.*

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 facing each other and at very close distances (10 cm). For cancer patients, on the other hand, all exposure scenarios indicate that transportation situations need consideration.

12. HOTELS

Three scenarios were used in calculating dose to hotel staff and guests in adjacent rooms. These scenarios, and the calculated times to exceed 100 mrem and 500 mrem, are shown in Table (2) below. 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 the 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-RAI 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-RAI administration.

Table 2 - Time in hours to exceed 100 and 500 mrem effective dose in hotels. Administered activity is 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer. Data assume one urine void before release (4 h post RAI administration), and voids every 4 h thereafter.

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(1)	>10 days(1)
Sleeping	>10 days(1)	>10 days(1)	>10 days(1)	>10 days(1)

(1) The calculations did not extend beyond 10 days post RAI administration. All scenarios assume 100% occupancy factor.

The data in Table (2) shows that neither the 1 mSv (100 mrem) nor the 5 mSv (500 mrem) are exceeded in any credible hotel scenario.

In addition to the calculations above, which were concerned with 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 of ^{131}I on various surfaces such as sinks, toilets, bedding, and other surfaces as well as airborne contamination levels. The calculations estimated the total dose for cleaning the patient's room to be about 0.15 mrem. It would thus take cleaning over 660 patient rooms to accumulate a dose of 100 mrem, and over 3300 rooms for a total dose of 500 mrem. Although cleaning this many contaminated rooms would generally be very unlikely, this may not be the case for hotels that are routinely used by patients treated in a nearby medical center. These doses are based on cancer patients who had been administered 7.4 GBq (200 mCi). 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 on days after the first will diminish substantially on consecutive days because of the rapid excretion rate of the iodine. The above estimated above therefore apply only if one assumes a newly released patient staying at the hotel each time the room is cleaned. Two scenarios were

not analyzed in the hotel situation: one in which the patient vomits in the hotel or urinates in the linens and the external dose to the housekeeper from contaminated items in the room. These scenarios would be very difficult to quantify because the number of assumptions that would have to be made are such as to render the results of the calculations virtually meaningless, even as an order-of-magnitude estimate. Such situations would need to be considered in discussions on the advisability of using hotels after iodine treatment, especially since clean-up of highly contaminated vomit is a specialized activity and poses the potential of delivering very high doses if not performed professionally. This implies, of course, that the hotel personnel are aware that vomitus is radioactive.

13. NURSING HOMES

NRC has performed some calculations for the nursing home situation to estimate the dose levels that may be expected under certain conditions. Two scenarios were used in these calculations: a resident and the patient share a room and sleep in adjacent beds 2.5 m apart, and a person seated about 30 cm from the edge of the patient's bed. The results of these calculations are shown in Table (3) below. The data in this table are presented in terms of the occupancy factor because of the manner in which the dose to the member of the public was calculated. 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, the remaining time assumed not to involve any radiation exposure.

Table 3 – Occupancy factors, F, to exceed 100 and 500 mrem effective dose in nursing home for continuous exposure over a 90-day period. Administered activity is 1 GBq (27 mCi) for thyrotoxicosis and 7.4 GBq (200 mCi) for thyroid cancer.

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[1]	F = continuous	F = continuous	F = continuous	F = continuous

[1] "Continuous" in the table means that the dose of 100 mrem or 500 mrem is never exceeded even if the exposure is continuous.

The occupancy factors were used in this case because the doses in most cases were such that the 100 and 500 mrem limits could not be exceeded except in the case of sitting at the edge of the bed.

14. GENERAL DISCUSSION

The data and calculations described above lead to several conclusions. It is clear that the dominant factor in determining both internal and external doses to members of the public is the behavior of the person after release. This factor is much more important than the amount of radioactive iodine in the patient at the time of release, which shows little correlation with the doses the family members actually receive. An exception is when using public transportation,

where calculations show a direct proportionality to iodine activity in the patient. This is expected because on public transportation, there is not much leeway for wide variations in behavior, whereas at home, there is ample opportunity to behave in ways that make it likely that significant intakes of iodine by family members as well as high external exposures will occur.

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, an occupancy factor of 0.25, etc. Significant deviations from one or more of these values in actual behaviors can result in substantially different doses to family members than the calculated values. It should therefore be understood that release calculations are designed to answer the question: if a hypothetical family behaves in the standardized way, can the patient be released? This is appropriate and is probably the best that can be done in that respect. However, it should also point to the central importance of instructions to the family before release. These instructions, in essence, tell the family how to behave in ways that closely approximate the theoretical behaviors on which the calculations are based, and also how to go beyond that to behaviors that reduce dose further, that is, behaviors that implement ALARA. Lacking such clear and well understood guidance, calculations would serve little purpose other than show compliance, in theory, but do not, in themselves, help to protect the public against unnecessary radiation exposures.

It may be desirable to improve the accuracy of the dose calculations by improving the models and the parameters used in them, but the disconnect between the models and actual behavior will not thereby be diminished. An important consideration to note is that the normal behavior pattern of specific families may be such that it naturally reduces radiation exposures, even though ALARA instructions might have been ignored. For example, the habit within the family might be not to share any personal items such as eating implements, towels, cups, etc. and to wash hands frequently, all of which will help reduce the transfer of contaminants. Some families may also not be in the habit of extensive hugging or other similar close contact, which will minimize external doses. These considerations help explain some findings reported in the literature that showed that in some cases, the doses received by family members were comparable whether or not ALARA precautions were observed. Following ALARA instructions clearly is a good way to minimize dose to persons coming in contact with the patient, but failure to follow ALARA instructions explicitly does not, by itself, mean that the doses will thereby be high: some people's natural behavior patterns are such as to be consistent with ALARA precautions, even though these people might not be aware of the formal ALARA instructions.

Recommendations

The following are recommendations provided by the Office of Research in 2014 at the conclusion of the research described above. These recommendations were considered in the complete NRC staff evaluation, which included public comments and the licensee survey information which was received after the completion of the efforts described in this paper.

1. The default general equations given in Regulatory Guide 8.39 should not be used as an unjustified default in any particular case but, if the licensee chooses to use them, then they must be justified based on the licensee's assessment of the patient's likely behavior after release. This means that the tables of retained activity and dose rates at 1 meter given in the guide should also be justified before being used. In this context, "justified" means an assessment which will provide a reasonable probability that the assumptions that are inherent in the calculations will be reflected in the patient's expected behavior

after release. Current guidance is not explicit on this issue, and may be interpreted to imply that these equations may be used in the absence of any specific information about the patient. This change, or strengthening of existing requirements, would not impose any significant additional burdens on licensees, partly because most licensees already follow this approach, and also because justifying the use of the default will be, in most cases, an easy matter.

2. The decision to release the patient should be reviewed prior to starting treatment to determine the conditions under which the patient is expected to be released, and whether the living arrangements, modes of transportation, staying at a hotel, and so on are such that releasing the patient is unlikely to result in doses above 5 mSv (500 mrem) and that at least some ALARA measures can be implemented. This practice would allow time for making special arrangements if necessary, before starting the treatment. Most licensees already follow this practice, but some may not, and it is not required by regulation or advised in guidance.

3. The means of transportation to be used by the patient should be determined to ensure that using such public transportation is not likely to result in excessive dose to any member of the public. As in Recommendation 2 above, this must be considered prior to treatment to allow time to make alternate arrangements if necessary. Current guidance is largely silent regarding doses during transportation, nor does the guidance provide methods that may be used to estimate dose under typical transportation situations.

4. The guidance in Regulatory Guide 8.39, as well as the equations and parameters used in the guide, should be reviewed, updated, and possibly simplified. The purpose of making these calculations should be made clearer, and the conditions under which the results of these calculations and guidance have any meaningful validity should be made more explicit.

5. Patients who are known to be going to nursing homes after release 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.

6. The release of patients known to be going to hotels should be re-examined. An explicit statement of policy would then be 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. This is unsurprising, since the dose estimates depend very heavily, or more to the point, entirely, on the many assumptions that must be made regarding the magnitude of the intake of radioactive materials that may be expected to occur with hotel workers. Different assumptions can lead to internal dose estimates that differ by an order of magnitude or more. For example, a subcommittee of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) provided estimates of dose to a hotel housekeeper that varied from 91 mrem, referred to as “unrealistic” to 0.9 mrem, called “realistic,” the difference being the types of assumptions made in the calculations. A consensus set of assumptions and calculations, followed by a decision,

may be a reasonable approach to this issue, with participation from all interested parties, possibly in the form of an NRC-sponsored working group.

In addition, the NRC Office of Research staff provided two additional recommendations for consideration in the complete staff evaluation. These recommendations were opinions of NRC Office of Research staff, but not included in the evaluation above, which were evaluated during the entire NRC staff evaluation.

1. The Rule in 10 CFR 35.75 states that the licensee is to provide ALARA instructions to patients if the effective dose to any member of the public is likely to exceed 1 mSv (0.1 rem). This is contrary to the basic idea of ALARA and should be revised. A dose of 1 mSv (100 mrem) should not be considered acceptable if it can be lowered by reasonable means. In addition, without ALARA instructions, the dose to a member of the public, which the licensee estimates to be less than 1 mSv (100 mrem) using approximate equations containing multiple assumptions, may in fact turn out to be much higher because the patient was not instructed on ways to make sure that it stays low. For example, if the patient is not told to keep others at a distance, then family members may be permitted to sit very close, to kiss, and to share eating utensils, all of which could easily cause the actual dose to exceed the limit. Patient instruction should be required regardless of dose estimates because, as all the findings in this report indicate, the determining factor in the success of this activity is patient behavior, not dose calculations.

2. The doses to adult family members and caregivers who participate in caring for the patient, either during hospitalization or after release, should be reclassified as medical exposures subject to a constraint of 5 mSv (500 mrem), to be raised by the licensee if there is adequate justification, such as a parent taking primary responsibility for a pediatric or a very sick patient. Such exposed family members or caregivers would not be subject to a regulatory dose limit. This approach is supported by national and international organizations. Hospital staff would not be subject to the policy because their radiation exposures would be considered occupational exposures, which is currently subject to an annual dose limit of 50 mSv (5 rem). The use of constraints provides considerable flexibility in patient care, and permits tailoring that care on the basis of patient needs rather than on compliance with a dose limit. This policy would also be consistent with a similar policy approved by the Commission and described in RIS-2006-18 (RIS06), in which family members and other non-hospital staff who participate in caring for the patient are exempted from the dose limit to members of the public and assigned an initial constraint of 20 mSv (2 rem), which may be increased if there are justifications to do so based on the needs of the patient. Although this policy is approved for application only in a hospital setting, it can be extended to home care, provided certain conditions are met. The main advantage of using a constraint is that it may be readily exceeded if adequate justification is provided, and exceeding a constraint does not constitute a violation of regulatory requirements. Under such a policy, children and all adult members of the public who do not participate in patient care would be subject to the public dose limit of 1 mSv (100 mrem).

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