



## **THE EXTENT OF THE RADIOLOGICAL IMPACTS CAUSED BY THE DIAGNOSTIC AND THERAPEUTIC USE OF NUCLEAR MEDICINE**

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### **1 Introduction**

The topics that will be addressed include the radiation control program in South Africa and in some other countries; the radiological impacts caused by the diagnostic and therapeutic use of nuclear medicine to members of the public, including the family of patients; critical groups exposed to  $^{131}\text{I}$  from patients receiving treatment for thyrotoxicosis, or thyroid cancer; and waste disposal as solids, via the sewage system and decay in storage.

### **2 The radiation control program in South Africa**

The initial steps towards the development of a radiation control program in South Africa were taken in 1948 when legislation was passed to provide for, *inter alia*, the establishment of the Atomic Energy Board. Since then the control over the manufacture and use of radioactive isotopes and the protection against nuclear radiation has been most satisfactory. In 1973 the Regulations concerning the Control of Electronic Products were promulgated in terms of the Hazardous Substances Act, (Act 15 of 1973). This Act provides that the Minister may declare any radioactive material to be a Group IV hazardous substance. It also enables the Minister to make regulations whereby the production, acquisition, disposal, import, export, use or conveyance of a Group IV hazardous substance is a criminal offence unless an authority is obtained with respect to the Group IV hazardous substance. The Minister may by regulation prescribe the requirements to which any Group IV hazardous substance shall conform before such an authority is granted. The Minister may also by regulation prescribe the precautions to be taken for protecting the safety or health of persons concerned with the use of Group IV hazardous substances and of patients.

In 1986 the regulatory control over Group IV hazardous substances was taken over from the Atomic Energy Corporation (AEC) by the Department of Health and in 1993 regulations were promulgated, also in terms of the Hazardous Substances Act, (Act 15 of 1973). In formulating the regulations, both the complexity of the radiation protection problem, and the need to achieve an optimal balance between benefits and risks, were realised. For this reason the legislation is general in character and has been kept to a minimum. Reliance has, to a large extent, been placed on the voluntary co-operation of interested parties willing to participate in a radiation control program designed to protect the general public and radiation workers alike, as well as to ensure that the patient, while not being deprived of the proven benefits of radioactive nuclides, is not unnecessarily exposed either.

In the final analysis, however, the compulsory licensing of radioactive sources and premises, are of no avail unless it can be ensured that the requirements of the regulations are being complied with. The main objective of the Department's very successful radiation control program has been to reduce the exposure to radiation of radiation workers, patients and members of the public as far as is practicably possible.

### 3 Background

In addressing the extent of the radiological impacts caused by the diagnostic and therapeutic use of nuclear medicine, the following risks associated with the application of radiopharmaceuticals need to be considered. Firstly, the radioactivity administered presents a risk to the patient, which should be balanced against the benefit from obtaining a diagnosis or carrying out a treatment. Secondly, contact with radioactive tissue from the patient or exposure to radiation emitted from radioactivity retained by the patient presents a risk to hospital staff and to members of the public. In the latter group, members of the patient's family, particularly young children and breast-fed infants, are of particular concern and their associated risks require careful assessment.

Once the radiopharmaceutical has been administered, the radiation emitted from the patient acts as a potential mobile source of exposure to other individuals. Critical groups within a hospital are nuclear medicine staff, ward staff and visitors. Exposure of these groups is controlled by the designation of controlled areas and internal rules. After the patient has left the hospital, members of the public who could be at risk are fellow travellers, colleagues at work and family members. Their exposure is controlled by keeping the patient in hospital for an appropriate period of time, and after discharge from hospital by issuing instructions to modify their behaviour inside and outside the home for a certain period of time.

In the United Kingdom, the imposition of controlled areas and these periods of time depend on retained activity limits which are specified in the Guidance Notes [1] of the UK Ionising Radiation Regulations of 1985 (IRR) [2] in units of MBq.MeV, a concept introduced by the IRR and is the product of the activity (MBq) and the total gamma ray energy per disintegration. These values are then converted into retained activity for a particular radionuclide according to its total gamma energy per disintegration. The current recommended restrictions for patients leaving hospitals in the UK are shown in Figure 1, together with the corresponding activities of  $^{99m}\text{Tc}$  and  $^{131}\text{I}$ . They are listed according to the method of transport home from hospital, return to work, return to "radiosensitive work", and resuming contact with children.

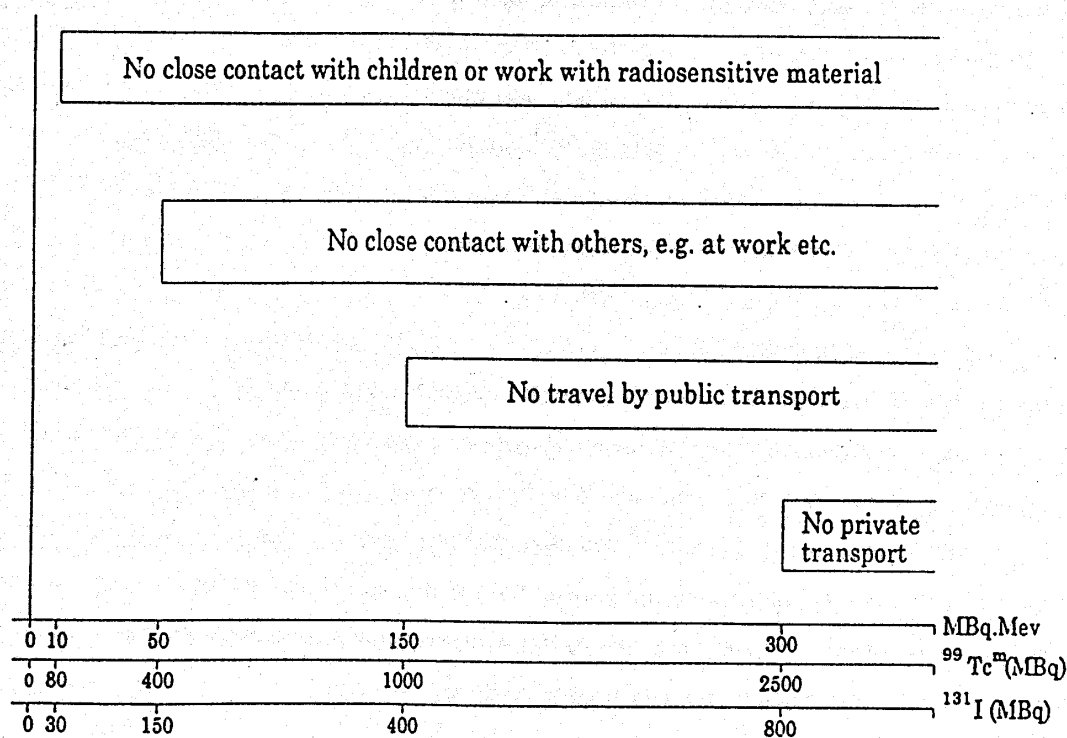


Figure 1: Current restrictions on nuclear medicine out-patients in the UK Guidance Notes

Restrictions are necessary in all these situations for patients who have been treated with  $^{131}\text{I}$  and for patients administered diagnostic radionuclides who will come into contact with children. Essentially, patients need only restrict their behaviour so that they do not come into close contact with young children if the retained activity is greater than 80 MBq of  $^{99\text{m}}\text{Tc}$  or 30 MBq of  $^{131}\text{I}$ . Close contact with other adults should be restricted if they receive greater than 400 MBq  $^{99\text{m}}\text{Tc}$  or 150 MBq  $^{131}\text{I}$ . Also, a therapy patient receiving more than 400 MBq of  $^{131}\text{I}$  should not use public transport, but private transport is allowed as long as the relevant instructions are issued to the driver. For example, if the patient can be assumed to be able to sit at 1 m distance, e.g. in the back seat of the car, an average dose rate at 1 m of 0.06  $\mu\text{Sv/h/MBq}$  means that even with 800 MBq the radiation dose to the driver is 48  $\mu\text{Sv}$  for a 1-h journey [3]. With greater than 800 MBq  $^{131}\text{I}$ , private transport should not be used, so the patient should be admitted to a ward with appropriate facilities. In South Africa we do not have such a complicated system. Also, the UK system has been criticised as being inappropriate for both diagnostic [4] and  $^{131}\text{I}$  therapeutic nuclear medicine procedures [5]. It, e.g., assumes a constant exposure rate throughout the year and it takes no account of physical decay and biological elimination of radioactivity from the patient.

The significant point is to determine the dose to a critical member of the public from their exposure to a radioactive patient. While it is clear that the most straightforward basis for restricting exposure is the activity retained by the patient, this level of activity must be related to a dose value which is just less than the dose limit for the critical group in question. This relation must be established from dosimetry studies of the critical groups. Data gathered from these studies must allow for the decrease in the dose rate from the patient with time. Proper allowance for this decrease may need to include the effect of any anatomical redistribution of radioactivity within the patient.

Two methods can be used to assess the dose to a critical group from the radiation emitted by a patient. Firstly, direct measurements can be made of the integral dose received by an individual in the critical group by securing a thermoluminescent dosimeter or an electronic personal dosimeter to the individual. Although this method obviously satisfies the criteria of being sensitive to the decrease in dose rate with time, it has a number of potential disadvantages. It, for example, relies on the compliance of an individual, rather than the patient, who is not benefiting directly from the nuclear medicine procedure, to wear the dosimeter and to follow instructions for an extended period of time. It also assumes that the measured dose represents the actual dose received.

In the second method, the dose to an individual in a critical group is estimated by multiplying the dose rates measured at different distances from the patient by the times spent at each distance by that individual. These times can be obtained either by observations of the behaviour of the critical groups, or by postulating an appropriate behavioural model which for ease of calculation, is constructed so as to provide a repetitive sequence of exposures. Although this method has the advantage of requiring only the patient's co-operation and of being a simple procedure by which to infer the dose for any pattern of behaviour, it too has a number of potential disadvantages. It, for example, assumes that the total dose to a critical group can be based on repetitive sequences of exposure. It also depends on the validity of the times and distances used to describe the pattern of behaviour.

The use of radioactive materials in the controlled areas of a nuclear medicine department ultimately result in the release of some radioactivity to the environment, the unrestricted area outside of the nuclear medicine department that is not under control of the authority holder. To ensure minimal impact of these releases and acceptable associated risks to the general public, regulations and guidelines exist [6], which can be obtained from the Radiation Control Directorate. The most important routes of release of radioactivity are (1) intentional disposal to the sanitary sewage system, (2) accidental releases, (3) transfer to a commercial disposal company, and (4) patient excreta. The majority of the activity used in a clinical setting is from pharmaceuticals labelled with  $^{99m}\text{Tc}$ , and residual  $^{99m}\text{Tc}$  is disposed of by storage for decay within the facility and then released as non-radioactive waste. All  $^{99m}\text{Tc}$  activity eventually decays to  $^{99}\text{Tc}$ , a beta-emitting radionuclide with a half-life of  $2 \times 10^5$  years. All of the  $^{99m}\text{Tc}$  excreted by the patient or stored for decay within the nuclear medicine department eventually reach the environment in the form of  $^{99}\text{Tc}$ . The activity that is deposited in the environment as "non-radioactive"  $^{99}\text{Tc}$  is about  $3.4 \times 10^{-7}\%$  of the original  $^{99m}\text{Tc}$  activity [7]. As an example, for a 500 mCi  $^{99}\text{Mo}/^{99m}\text{Tc}$  generator, the total activity of  $^{99}\text{Tc}$  produced is approximately 19 nCi. If one considers that the average age adult male contains approximately 13 nCi of  $^{40}\text{K}$ , a beta-gamma emitter with a  $1.3 \times 10^9$  year half-life, monitoring the generator for disposal after significant time has elapsed for decay of essentially all of the  $^{99}\text{Mo}$  would demonstrate negligible activity; hence the generator could be treated as "non-radioactive". With a half-life of  $2 \times 10^5$  years, the environmental inventory of  $^{99}\text{Tc}$  will continue to grow and be widely dispersed through sanitary landfills and sewage treatment plants. However, it will take an extremely long time for sizeable quantities of  $^{99}\text{Tc}$  to accumulate in the environment.

In addition to  $^{99}\text{Tc}$ , probably the most significant release to the environment from the standpoint of potential general public radiation dose include  $^{125}\text{I}$ , through the sanitary sewage system from *in vitro* tests, and  $^{131}\text{I}$  from patient excreta following therapy for thyroid cancer and hyperthyroidism.  $^{125}\text{I}$  has a relatively long half-life of 60 days, but is typically used in very low activities for radioassay tests.  $^{131}\text{I}$  has a shorter half-life of 8 days, but can be released in large quantities in the urine of patients treated for hyperthyroidism or thyroid cancer. The impact of these quantities is minimal when the huge dilution factors of sewage systems are considered, together with the transit time from the patient

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through the sanitary sewage plant, to the point where the iodine could be ingested or concentrated in foodstuffs such as shell fish or milk.

Because all the radionuclides used in nuclear medicine diagnosis and therapy have relatively short half-lives, the impact on the environment is minimal. This minimal impact includes waste shipped for burial to low level waste disposal sites since the retention time is so long with respect to the half-life. The Directorate Radiation Control limits the maximum permissible concentration of radionuclides that can leave a hospital via the sanitary sewage system. There are also limits on the maximum activity per year that can be released.

#### **4 Members of the public**

A patient who leaves the hospital to go home after having been administered a diagnostic or therapeutic dose of radiopharmaceutical, has an influence on the other family members. The influence on different categories of family members will now be discussed.

##### **4.1 Children exposed to diagnostic patients**

The critical group will be the infant young enough to be held for prolonged periods in close contact with the patient regardless of the sex of the parent, and if the parent is a mother, regardless of whether or not she is breastfeeding. Close contact doses to young infants in these circumstances have been estimated by multiplying the dose rate measured on or near the surface of the patient by an effective exposure time  $T_{\text{eff}}$  which accounts for the intermittency of close contact and for dose rate decay.  $T_{\text{eff}}$  is calculated by assuming that the duration  $\theta$  of each exposure and the time  $t$  between each exposure remains constant:

$$T_{\text{eff}} = \frac{1 - e^{-\lambda\theta}}{\lambda(1 - e^{-\lambda t})},$$

where  $\lambda$  is the dose rate decay constant. Values of  $T_{\text{eff}}$  have been reported in the literature [8], corresponding to the maximum time of 9 hours in every 24-hour period, which has been reported to be spent by an infant in close contact with a parent [9]. These values of  $T_{\text{eff}}$  assume that the total time of 9 hours was spread over a 24 hour period, such as 35 min at the start of each hour for the first 8 h after radiopharmaceutical administration, 35 min at the start of each fourth hour for the next 12 h, i.e. feeding times overnight, and 35 min at the start of each hour for the remaining 4 h. Estimates of close contact doses have been based on either surface dose rates measured directly by an ionisation chamber at a distance of 0.1 m from the anterior mid-trunk of the patient, or inferred from integral dose measurements by a TLD secured to the mid-line of the anterior chest wall.

It has been estimated that the close contact dose to a young infant from a parent who has undergone a diagnostic nuclear medicine procedure will be less than 1 mSv [8], the annual public dose limit, as long as the administered activity does not exceed the activities recommended by the Administration of Radioactive Substances Advisory Committee (ARSAC) [10]. The only exception is  $^{111}\text{In}$  leukocytes where the maximum close contact period observed between a parent and a fretful infant will result in a dose of 1 mSv if the administered activity exceeds 8 MBq. The dose can be minimised by reducing the administered activity or by restricting close contact. For example, restricting close contact to 35 min every fourth hour over the first 3 days after administration will reduce the dose to the infant by about 30%.

It is important to note that even for a particular radiopharmaceutical and activity, there are wide variations in measured dose rates from patients [8,11,12,13]. This is to be expected due to the variations in radiopharmaceutical distribution and patient size. It has been reported that the range of dose rates measured at 0.1 m from the anterior mid-trunk for bone scan patients on departure from a department varied between 16 and 95  $\mu\text{Sv/h}$  for a sample of 37 patients [8].

##### **4.2 Critical groups exposed to $^{131}\text{I}$**

###### **4.2.1 Thyrotoxicosis patients**

The dose rates from patients receiving  $^{131}\text{I}$  for thyrotoxicosis have previously been measured and used to derive radiation doses to relatives or members of the general public. Again, variations in dose rate were observed at short distances. For example, measured dose rates have been reported at 0.1 m from the anterior mid-trunk of a total of 50 patients on departure from the department and a range of 0.8-3.2

$\mu\text{Sv}\cdot\text{h}^{-1}\text{MBq}^{-1}$  was observed [3]. They used measured dose rates, together with estimates of distance and time to determine the total dose to others in various situations. This requires, of course, particular assumptions to be made regarding behaviour. At home, they assumed that the patient and partner were together for 6 h at 1 m, and asleep for 8 h at 0.1 m. This assumption led to a total dose of  $6.2 \text{ mSv}_{200}$ , where the 200 index refers to per 200 MBq, of which  $0.5 \text{ mSv}_{200}$  was derived from daytime contact and  $5.7 \text{ mSv}_{200}$  was at night. They also calculated the number of days that a patient and partner would have to sleep separately in order to reduce the radiation dose to 5 mSv and 1 mSv. This is indicated in Table 1.

**Table 1:** Number of nights of separate sleeping arrangements required following  $^{131}\text{I}$  therapy for thyrotoxicosis to ensure less than 1 and 5 mSv to the patient's partner

| Administered activity (MBq)             | 200                              |    | 400 |    | 600 |    | 800 |    |
|---|----------------------------------|----|-----|----|-----|----|-----|----|
|   | Time after administration (days) |    |     |    |     |    |     |    |
| Dose to patient's partner (mSv)         | <1                               | <5 | <1  | <5 | <1  | <5 | <1  | <5 |
| Thomson <i>et al</i> [15]               | 8                                | -  | 16  | -  | 24  | 4  | 30  | 8  |
| Hilditch <i>et al</i> [16]              | 2                                | -  | 9   | -  | -   | -  | 15  | 2  |
| O'Doherty <i>et al</i> [3] <sup>a</sup> | 15                               | 1  | 20  | 7  | 24  | 11 | 26  | 13 |
| O'Doherty <i>et al</i> [3] <sup>b</sup> |                                  | 2  |     | 9  |     | 14 |     |    |

a Assumes complete separation day and night

b Assumes separation at night only

O'Doherty *et al* [3] noted that if a patient and partner wish to maintain contact during the day, then they should sleep apart for a longer period of time, as indicated in Table 1. If one looks at the dose results of other workers in this field as well, on the average  $5.6 \mu\text{Sv}\cdot\text{MBq}^{-1}$  is received by the spouse and  $1.5 \mu\text{Sv}\cdot\text{MBq}^{-1}$  by other family members.

The times for different administered activities of  $^{131}\text{I}$  to decay to the retained activity limits recommended in the IRR Guidance Notes [1] for the different situations after the patient has been discharged from hospital are given in Table 2.

**Table 2:** The duration of restrictions for patients administered <sup>131</sup>I for thyrotoxicosis

| Administered activity (MBq)  | Time after administration (days) |     |     |     |
|--|----------------------------------|-----|-----|-----|
|  | 200                              | 400 | 600 | 800 |
| Travel by private transport  | 0                                | 0   | 0   | 0   |
| Travel by public transport, and return to work not involving close contact with other people | 0                                | 0   | 1   | 2   |
| Contact with children and return to radiosensitive work                                      | 14                               | 21  | 24  | 27  |

However, recent studies have indicated that these time restrictions are inappropriate in limiting the dose to the critical group [14-17], e.g. the guidance for travelling home is too restrictive; and there is no need to stay off work. Also, the most important guideline without any doubt, a restriction which is not mentioned in the IRR85 Guidance Notes, is for partners to sleep apart. Where the patient's partner is concerned, the Department of Health supports the ICRP concept within the definition of medical exposure that voluntary "helpers" who "knowingly and willingly" support patients treated with radionuclides should not be subject to strict dose limits, but rather to non-rigid dose constraints while following the ALARA principle. This would encompass the irradiation of the patient's relatives or friends caring for the patient in the home as long as they consented. This raises the issue of what is the level of acceptable dose in each circumstance. The NRPB have suggested that a reference dose level of 5 mSv is appropriate for this circumstance, but also recommended that the dose to infants should not in general exceed 1 mSv. A number of authors have calculated restrictions on the basis of limiting doses to 1 mSv, since this is the dose limit for members of the public recommended by ICRP 60. Within the USA, recent proposals have reflected the change in emphasis of ICRP 60. The Nuclear Regulatory Commission has proposed new regulations which set a limit of 5 mSv per year for an individual exposed to a patient [18].

It is important to note that ALARA is governed by the phrase "social and economic factors taken into account". Both these types of factors should be taken into consideration, but social factors may be particularly important in relation to patients. Since family members benefit from the non-hospitalisation of the patient, it may be argued that limits recommended for the general public should not be applied to them. Nevertheless, in view of the ALARA principle, the Department of Health supports the recommendations of a recent study [19] that couples should sleep in separate beds spaced at least 1 m apart for at least 14 days after the administration. This simple measure will reduce the average radiation dose to the spouse to below the 5 year limit of 5 mSv in practically all but the small percentage of cases requiring up to 1600 MBq cumulatively for control of the disease [19]. Even with these administrations, the doses to other family members will be well below this limit, provided close contact such as cuddling of infants are avoided. The period of 14 nights seems to be a reasonable compromise between the radiation protection of the partner and the social isolation of the patient. The guideline of advising parents to let children under 7 years old stay with family or friends is also strongly recommended.

Avoidance of physical contact with the patient and advising the patient to follow simple hygiene rules such as flushing the toilet twice and regularly washing of hands are also in keeping with the ALARA principle and will certainly help to limit both irradiation and contamination of relatives.

#### 4.2.2 *Thyroid cancer patients*

Another situation that needs to be considered involves the potential radiation hazard encountered in the practice of nuclear medicine arising from the administration of radioiodine to ablate thyroid remnants or to treat metastases in patients with thyroid cancer. Precautions should be taken to limit the radiation exposure of members of the public and staff with whom a treated patient may come into contact. These precautions vary between countries, but recommendations are usually based on the measurement of iodine retention or instantaneous dose rates. Treatment at home has also been advocated, but the majority of patients who receive high doses of radioiodine are isolated in hospital for a period of time for radiation protection purposes.

Potential sources of risk include both emitted radiation and excretion of radioactivity in exhaled breath, perspiration, urine and saliva. Apart from urinary iodide excretion, other contamination risks are small compared with emitted radiation. Direct irradiation of the public and health workers is the major concern. The dose received by an individual from a patient will be governed by the iodine distribution, the rate of iodine clearance and the time spent in close proximity with the person. The length of hospital stay, however, is dictated by the excretion pattern of each individual patient.

In South Africa, in order to restrict the exposure of any member of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital until the dose rate at a distance of 1 m is below 25  $\mu\text{Sv/h}$ , which corresponds to approximately 400 MBq  $^{131}\text{I}$ , which is in line with recent IAEA recommendations [20]. It is necessary for the health physics personnel to monitor patients daily to determine the rate at which the  $^{131}\text{I}$  is being excreted from the patient's body and the approximate date of discharge. It is also required that patients who have been administered  $^{131}\text{I}$  for therapeutic purposes be hospitalised in specially designated wards with a toilet and bathroom in the same suite for their exclusive use only. In order to comply with the above-mentioned limit,  $^{131}\text{I}$  patients with an administered activity of greater than 400 MBq will have to be treated as in-patients, and those having been administered less than 400 MBq can be treated as out-patients.

At Tygerberg Hospital, the following procedures are being adhered to in the treatment of  $^{131}\text{I}$  MIBG patients [21]. The patient may not leave the ward without the permission of the medical physicist. No visitors are allowed inside the ward. Only nursing personnel who has received training in the handling of radionuclides, the radiotherapist, and the medical physicist may visit the patient inside the ward. Such visits may not exceed 23 minutes in a period of 24 hours, provided that the personnel member does not come closer than 1 metre to the patient. Babies should preferably be catheterised before administration of the radioactivity. After a few days, when most of the  $^{131}\text{I}$  that have not been taken up in the tumour tissue, have been excreted, the catheter may be removed and put in a double plastic bag. Nappies are stored in a plastic bag inside the ward and monitored on a daily basis. The nappies for each day should be collected in a separate plastic bag. If the bag with nappies exceed 5  $\mu\text{Sv/h}$  at the surface, the nappies should be marked and taken to a "radioactive" store room. These are stored until the reading at the surface is less than 5  $\mu\text{Sv/h}$ , after which it may be disposed of. Personal properties that exceed the limit of 5  $\mu\text{Sv/h}$ , should also be locked away at the hospital, until the radiation levels have dropped below this limit.

The MIBG bottles should be put in a cabinet and marked with the activity and calibration date. Each bottle should be monitored after 10 half-lives, i.e. 83 days. The bottles may only be disposed of when the reading at the surface of the bottle is less than 5  $\mu\text{Sv/h}$ .

#### **4.3 The breast-fed infant**

When a radiopharmaceutical is administered to a breastfeeding mother, radioactivity will be secreted in her milk, and her infant will receive a dose from the ingested radioactivity. Metabolic models and limits of intake for ingested radioactivity recommended by the ICRP apply to occupationally exposed workers. However, because of the absence of an accepted method to calculate the ingested dose to a breast-fed infant, approximate estimates of such doses can be obtained from the ICRP adult values of EDE per unit activity ingested after a simple correction for the weight of the infant [22]. The radioactivity secreted in milk can be minimised by considering the following ALARA points:

- (i) Is there an alternative technique which does not rely on the *in vivo* use of radioactivity?
- (ii) Will a delay in carrying out the procedure reduce or eliminate the radiation hazard without compromising the patient's clinical management?
- (iii) Is there an alternative radiopharmaceutical which yields a lower radiation dose?
- (iv) Can the desired result be obtained with less than the usual administered radioactivity?
- (v) What is the possibility of a repeat investigation in the near future, and will this affect the magnitude of the administered activity?

The ingested dose can be reduced either by the mother interrupting feeding until the secreted activity has reached an acceptable level or by ceasing breast-feeding. The exact form of these latter

instructions will depend on the magnitude and effective half-life in milk of the secreted activity. Both parameters vary according to the radiopharmaceutical administered to the mother. If feeding is to be interrupted, then the mother can be advised to express milk before administration of radioactivity, store the milk in a refrigerator, and feed her infant with it during the period of interruption. A simple method has been proposed of quantifying secretion data and deriving an appropriate period of interruption calculated to reduce the infant's EDE to 1 mSv. An excessive delay in the resumption of breast feeding should be avoided in order not to jeopardise the supply of milk. This is a particularly important consideration in the immediate *post partum* period, when the mother may be experiencing difficulty in establishing her milk supply.

The activity concentration in secreted milk decreases exponentially with time after administration, and therefore, assuming the volume of milk per feed to be  $V$  and the time between feeds  $\tau$  are constant, the total activity ingested  $I$  by the infant for all feeds is:

$$I = \frac{\sum_{j=1}^m c_j V}{(1 - e^{-\lambda_j \tau})}, \text{ where}$$

$m$  is its number of exponential components for each of which  $c_j$  is its concentration of activity ingested in the first feed, and  $\lambda_j$  is its effective decay constant. The effective dose to the infant is given by:  $D = Ie$ , where  $e$  is the effective dose to the infant per unit activity ingested. For a mono-exponential decrease in activity concentration with time, the period  $P$  after the time of administration for feeding to be interrupted to reduce the infant's effective dose from  $D$  to  $x$  can be calculated from:

$$P = t_{1/2} \frac{\ln(D/x)}{\ln 2} + t_c, \text{ where}$$

$t_{1/2}$  is the effective half-life of the radioactivity in milk, and  $t_c$  is the time after administration when a resumption of feeding would give a dose  $D$  to the infant. This method can be used to estimate the dose if feeding had been resumed when the first sample was expressed and to derive the interruption time to reduce this dose to 1 mSv.

A comprehensive set of recommendations derived to ensure that the effective dose to the infant does not exceed 1 mSv has been reported [23] and is listed in Table 3. These recommendations assume that the infant ingested 850 ml per day in six feeds taken at regular intervals [24].

Table 3: Radiopharmaceuticals in breast milk: dosimetry and recommendations

| Interruption not essential            | Interruption for a defined period                          | Interruption with measurement     | Cease breast-feeding             |
|---------------------------------------|--|-----------------------------------|----------------------------------|
| $^{99m}\text{Tc}$ DISIDA              | $^{99m}\text{Tc}$ MAA (13 h: 100 MBq)                      | $^{99m}\text{Tc}$ erythrocytes    | Sodium $^{32}\text{I}$ phosphate |
| $^{99m}\text{Tc}$ DMSA                | $^{99m}\text{Tc}$ pertechnetate (47h: 800 MBq; 25h:80 MBq) | $^{99m}\text{Tc}$ technegas       | $^{125}\text{I}$ HSA             |
| $^{99m}\text{Tc}$ DTPA                |  | $^{99m}\text{Tc}$ MAG3 (>100 MBq) | $^{131}\text{I}$ iodide          |
| $^{99m}\text{Tc}$ diphosphonates      |  | $^{99m}\text{Tc}$ microspheres    | $^{67}\text{Ga}$ citrate         |
| $^{99m}\text{Tc}$ glucoheptonate      |  | $^{99m}\text{Tc}$ pyrophosphate   |                                  |
| $^{99m}\text{Tc}$ gluconate           |  | $^{123}\text{I}$ iodide           |                                  |
| $^{99m}\text{Tc}$ HMPAO               |  | $^{123}\text{I}$ MIBG             |                                  |
| $^{99m}\text{Tc}$ MAG3 (100 MBq)      |  | $^{123}\text{I}$ hippuran         |                                  |
| $^{99m}\text{Tc}$ MIBI                |  |                                   |                                  |
| $^{99m}\text{Tc}$ sulphur colloid     |  |                                   |                                  |
| $^{111}\text{In}$ leucocytes (20 MBq) |  |                                   |                                  |
| $^{201}\text{Tl}$ chloride (80 MBq)   |  |                                   |                                  |
| $^{51}\text{Cr}$ EDTA                 |  |                                   |                                  |

#### 4.4 Parents

A parent looking after a young child who has undergone a diagnostic nuclear medicine procedure will receive a dose from the radiation emitted from the radioactivity retained by the child's organs. As with radioactive parents, the critical group will be parents of young infants who require extended periods of close contact. Estimates of these doses have been made by several authors from maximum values of the dose rate measured at 0.1 m from paediatric patients multiplied by the effective exposure times [8,13]. In one of these investigations [8] it was assessed that a parent could receive a dose of 1 mSv if the infant had been administered an activity of 500 MBq of  $^{99m}\text{Tc}$ . However, it is most unlikely for a parent to receive such a dose because the estimate was based on the maximum dose rate per unit activity observed at 0.1 m ( $0.5 \mu\text{Sv}\cdot\text{h}^{-1}\cdot\text{Bq}^{-1}$ ), as well as on the maximum reported period of close contact for a fretful patient who needs considerable attention, up to 9 h in a 24-h period. Also, an infant young enough to need such a long period in close contact with a parent should not require an administered activity of  $^{99m}\text{Tc}$  as high as 500 MBq for any nuclear medicine procedure. The ICRP concept within the definition of medical exposure that voluntary "helpers" who "knowingly and willingly" support patients treated with radionuclides should not be subject to strict dose limits, but rather to non-rigid dose constraints while following the ALARA principles, is also applicable in this situation.

### 5 Waste disposal

Because all the radionuclides used in diagnostic and therapeutic nuclear medicine have relatively short half-lives, radioactive waste disposal does not pose a serious problem. There are two practical methods of disposing of these radioactive wastes, i.e. sewer dilution and decay in storage.

#### 5.1 Sewage dilution

The amount of radioactive waste discarded daily in the sewage system depends upon the half-life and the concentration. The quantity of any individual radionuclide that can be disposed of in the sewage system is regulated by the Directorate Radiation Control.

In South Africa, low level radioactive waste for disposal via the sewage system must take place in accordance with certain specific requirements and limits [6], which include, amongst other requirements, that:

- (1) the activity per release and the total activity per month shall not exceed certain limits;
- (2) the release of radioactive waste is confined to one release point for each laboratory; and
- (3) water to dilute the discharge is flushed before and for at least one minute after the discharge.

The total activity of low level liquid waste released into the sewage system may not exceed  $10 \text{ ALI}_{\text{min}}$  per month per laboratory. On each occasion on which a release is made, the activity may not exceed  $1 \text{ ALI}_{\text{min}}$  and must not exceed 100 MBq. The values for  $\text{ALI}_{\text{min}}$  which must be applied are shown in Table 1 of the appendix. If the waste contains more than one radionuclide, the maximum permitted activity must be calculated. Where more than one type of radionuclide is disposed of to the sewage system or sent to an incinerator, the sum of the ratios of the activity of each radionuclide released  $A_k$  to the  $\text{ALI}_{\text{min}}$  for that radionuclide  $\text{ALI}_{\text{min},k}$  must not exceed 10 in any month. In other words, the following shall apply to the total activity released during one month:

$$\sum_k \frac{A_k}{\text{ALI}_{\text{min},k}} < 10$$

For the activity in one individual waste package, or for a single release to the sewage system, the following shall apply:

$$\sum_k \frac{A_k}{\text{ALI}_{\text{min},k}} < 1$$

For example, a waste package containing two radionuclides would be acceptable if it contained half an  $\text{ALI}_{\text{min}}$  of the one radionuclide and half an  $\text{ALI}_{\text{min}}$  of the other, or if it contained  $1/3 \text{ ALI}_{\text{min}}$  of the one radionuclide and  $2/3 \text{ ALI}_{\text{min}}$  of the other, etc.

Urine and faeces from patients who have been administered radionuclides in connection with diagnostic and therapeutic treatments may be released to the sewage system without the activity being included in the maximum permitted activity.

The total activity of low level solid supplied to an incinerator of which the Department of Health has been informed, may not exceed 10 ALI<sub>min</sub> per month per laboratory. The maximum activity per waste package may not exceed 1 ALI<sub>min</sub>. The values for ALI<sub>min</sub> which must be applied are shown in the appendix. If the waste contains more than one radionuclide, the highest permitted activity must again be calculated according to the previously mentioned formula.

## 5.2 *Decay in storage*

This is the more practical method of disposing of radioactive materials in a nuclear medicine department. The radioactive material is allowed to decay for at least 10 half-lives, when it is presumed to be non-radioactive. However, <sup>99</sup>Mo/<sup>99m</sup>Tc generators should be allowed to decay for 25 half-lives of <sup>99</sup>Mo because <sup>99</sup>Mo may contain a large amount of activity. Before disposal, the radioactive waste should be monitored and show less than 0.5 µSv/h exposure rate at the surface. Radionuclides with activities of less than 4 kBq are not being regarded as radioactive.

If an incinerator is used for the disposal of the radioactive waste, it must be approved by the Department of Health. The activity per waste package and the total activity disposed of per month again shall not exceed the limits specified by the Department of Health [6]. Short-lived materials not meeting the activity and/or surface dose rate limits for packages, must be stored until they have decayed to below the specified limits.

## 6 **Conclusions and Recommendations**

In relation to the external dose to others, for diagnostic studies there appears to be little need for restrictions with <sup>99m</sup>Tc radiopharmaceuticals. Even for other longer-lived radionuclides, e.g. <sup>111</sup>In, the radiation dose to others does not exceed 1 mSv, with the exception of a close contact dose to a fretful infant. There would seem to be no need to restrict the movement of <sup>99m</sup>Tc thyrotoxicosis patients with regard to both travelling and work, unless the latter involves prolonged close contact, i.e. sitting directly next to others at distances much less than 1 m for several hours, which is an unlikely situation. It has been shown that even if the patient returned to work immediately and was an average of 1 m from a colleague for 8 h, the above value would indicate a total dose to the colleague of only 31 µSv/day [8]. No restrictions are necessary for up to 400 MBq.

For <sup>131</sup>I, the Department of Health does not intend to impose restrictions that will affect the ability to continue this simple and effective therapy on an out-patient basis. With careful instructions regarding behaviour, radiation doses to others can be restricted. If a patient and his or her partner use a double bed, then sleeping restrictions to limit the dose to 5 mSv are only necessary for activities above 400 MBq. For children, the dose constraint of 1 mSv is easily achievable for activities up to 400 MBq.

Although the policies in some EC countries are very restrictive, e.g. in Germany <sup>131</sup>I patients are hospitalised until their activity has fallen to 75 MBq, it is important that such restrictions can be justified in terms of their cost-effectiveness and also social benefit.

The Department of Health recognises that it is essential to continue <sup>131</sup>I on an out-patient basis. It is both cost-effective and more acceptable to the patients than surgery. Prolonged hospitalisation of such patients would also impose an excessive burden on the Health Services.

To conclude, if appropriate regulations and guidelines are adhered to, the impact of the release of radioactivity through the diagnostic and therapeutic use of nuclear medicine will be small, and the associated risk to the general public will be acceptable.

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