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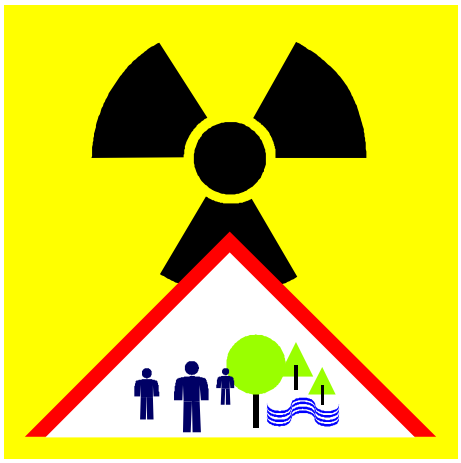

Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)

European Commission

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Radiation protection 97

RADIATION PROTECTION FOLLOWING IODINE-131 THERAPY

(Exposures due to out-patients or discharged in-patients)

1998

Directorate-General
Environment, Nuclear Safety
and Civil Protection

Contents

Foreword

The work of the European Commission in the field of radiation protection is governed by the Euratom Treaty and its implementing Council Directives.

The most significant of these is the Basic Safety Standards Directive (BSS) on the protection of exposed workers and the public (80/836/Euratom) revised in 1996 (96/29/Euratom).

In 1984, the Council of Ministers issued a Directive, supplementing the BSS, on the protection of persons undergoing medical exposures (84/466/Euratom). Revised in 1997, this was called the Medical Exposure Directive (MED) (97/43/Euratom). The MED is required to be transposed into national law no later than 13 May 2000.

According to Article 6.4.(b) of the BSS, dose limits shall not apply to exposure of persons as part of their own medical diagnosis or treatment nor to exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical diagnosis or treatment.

Justification and optimisation of the latter exposures are therefore even more important than for other exposures.

In the context of optimisation, dose constraints should be set for this group (Article 7.2).

This booklet is designed to give guidance on the assessment of dose constraints in the case of treatment with radioactive iodine (I-131) and on the drafting of instructions which practitioners can hand out to patients or their legal guardians with the aim of limiting the exposure of family and close friends.

It was developed with the assistance of the group of health experts established under Article 31 of the Euratom Treaty.

This guidance is not binding on Member States and has, by definition, a limited scope. It in no way claims to be an exhaustive scientific report dealing with all possible diseases and methods of treatment using iodine-131. It forms part of a number of technical guides drawn up to facilitate implementation of the MED.

The document is structured as follows:

A general introduction providing background information to the document is followed by a chapter on the effects of I^{131} therapy. Chapter 3 proposes ways of developing dose constraints and Chapter 4 deals with a number of relevant considerations to be taken into account whilst treating out-patients with I^{131} or discharging in-patients after such treatment. Finally, Chapter 5 gives guidance for medical practitioners on how to instruct and inform patients treated with I^{131}. Four annexes provide practical or more detailed information. Cross-references are made in the preceding chapters

It is my hope that this guide can be of help to the competent authorities in the Member States, medical practitioners, medical physicists and all those directly or indirectly involved in iodine-131 treatment.

Suzanne Frigren
Director Nuclear Safety and Civil Protection

1. INTRODUCTION

The Basic Safety Standards Directive (96/29/EURATOM) states that dose limits for members of the public do not apply to "*exposures of individuals, who are knowingly and willingly helping, other than as part of their occupation, in the support and comfort of in-patients or out-patients undergoing medical diagnosis or treatment"* (Article 6.4(b)). However, other basic principles such as justification of practices and optimisation of radiological protection do apply.

One of the most frequent applications in medicine giving rise to exposures to family, close friends and others (referred to in the legislation as "third persons") is the treatment of thyroid diseases using radioactive iodine.

A distinction should be made between I^{131} thyroid treatment for cancer and treatment for other diseases, such as hyperthyroidism.

In the former case, sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days. Besides, the patient usually needs medical care during this initial period. After two or three days, however, the patients' residual activity will be sufficiently low to justify their discharge from the hospital.

In the latter case, the exposure of family and other individuals deriving no direct health benefit from the exposure has to be justified on social, economic and psychological grounds, weighing these aspects against the risk incurred by these persons as a result of the exposure.

Some examples:

A number of patients tolerate isolation in a specially protected room in the hospital very poorly, while others regard this disruption of family life as unacceptable. If no specially protected room is available in the hospital, it is clear that keeping the treated patient may give rise to exposure of other patients. Accordingly, hyperthyroidism patients are treated as out-patients in some Member States. Of course, the economic aspect – keeping treated patients in the hospital is costly – plays an important role in this decision. Finally, it should be mentioned that only very few individuals will be exposed by a treated patient more than once in their life time.

Apart from justification, there is obviously a need to optimise the protection of other individuals so as to keep the dose as low as is reasonably achievable. In this context Article 7 of the BSS Directive requires that *'Dose constraints should be used, where appropriate, within the context of optimisation of radiological protection'* and that *'Guidance established by each Member State on the appropriate procedure to be applied to the individuals exposed as in Article 6.4(b) (and (c)) may include dose constraints'*.

Most Member States apply a type of dose constraint, often a derived residual activity constraint, to limit doses to other individuals from the treated patient. These levels of activity are used both for deciding if a patient may or may not be regarded as an out-patient and for the safe discharge of an in-patient from the hospital.

Within the Union, levels range from 95 MBq to 800 MBq of I^{131}, but in most Member States these are set between 400 and 600 MBq

In this connection, it should be pointed out that methods for treatment of thyroid diseases differ largely between the Member States.

This guide does not try to harmonise activity levels; instead, its purpose is to examine as fully as possible the different types of practice and to put forward a common approach for the application of activity levels.

Article 4 of the MED requires that *Member States shall ensure that appropriate guidance for exposures of individuals, who are knowingly and willingly helping, other than as part of their occupation, in the support and comfort of patients undergoing medical diagnosis or treatment, is established.* This provision applies to diagnostic radiology, radiotherapy and diagnostic and therapeutic nuclear medicine.

The group of individuals envisaged by Article 4 will be referred to in this document as *family and close friends*. This group comprises all those living under the same roof as the patient and those who visit the patient in the hospital or at his home. Other people who may come in contact with the patient will, from now on, be called *third persons* and are viewed as members of the public.

In addition, Article 4 of the MED requires that *In the case of a patient undergoing a treatment with radionuclides Member States shall ensure that the practitioner provides the patient or legal guardian, before leaving the hospital or clinic, with written instructions, as appropriate, on the reduction of doses to persons in contact with the patient and with information on the risk associated with ionising radiation.*

Many Member States have already developed such instructions outlining suitable behaviour for patients who have received radioiodine therapy. This paper takes into account the various instructions and suggests a European approach.

The instructions are intended to be followed both by out-patients and by in-patients, or their legal guardians, after discharge. They are addressed to medical practitioners treating the patient, general practitioners and the relevant competent authorities at national and local level. In this report some guidance is also given to these medical practitioners, who are required to provide advice and formulate recommendations for physicians and patients on ways of reducing the risks associated with ionising radiation.

According to the MED, the competent authorities shall lay down in national law or regulations an obligation to provide patients with relevant instructions. It is the responsible medical practitioner who must ensure that patients, or their legal guardians, are supplied with these instructions orally and in writing. However, it is clearly impossible for the medical practitioner to check whether or not the patient follows the instructions to the letter. Therefore, no responsibility rests with the medical practitioner as far as follow-up is concerned, as long as instructions were correctly given to the patient.

Medical practitioners should draw the attention of the patients to their responsibility towards family, friends and third persons.

Should the family of a patient not be willing to ‘support or comfort’ the patient at home, they should be treated as third persons and are automatically subject to the dose limits for the general public[1].

Further on in this guide, it is suggested that a fraction of the dose limit of 0,3 mSv be observed in this case.

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1 1 mSv in a year. In special circumstances, however, a higher effective dose may be authorised in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year.

2. EFFECTS OF I-131 THERAPY

This chapter gives a summary of background information on I-131 therapy and considerations for the assessment of dose constraints. More detailed information is given in Annex II.

2.1. Mechanism of the I-131 therapy

Two types of biological effects of ionising radiation are known: deterministic effects and stochastic effects. Deterministic effects are those caused by the decrease in or loss of organ function due to cell damage or cell death. For these effects threshold doses exist: the function of many organs and tissues is not affected by small reductions in the number of available healthy cells. Only if the decrease is large enough, will a clinically observable pathological dysfunction appear.

In the case of treatment of thyroid cancer, metastases, hyperthyroidism and euthyroid goitre, the objective is to bring about the cell-killing effect while not affecting other organs in such a way that deterministic effects occur.

Due to the capacity of thyroid cells to take up iodine thyroid diseases can be treated with radioactive iodine.

The β-emitting I-131 is often the radionuclide of choice for these treatments, although the associated γ-emission gives rise to exposures to other tissues and even to other individuals.

The probability of a radiation-induced fatal cancer for the average population has been estimated (ICRP-60) at approximately 5 percent per sievert[2] for low doses and at low dose rates and at 1 percent for serious genetic diseases. For elderly people, older than about 60 years, the probability seems to be 3 to 10 times lower. This is because the future life span of elderly people may not be long enough for the cancer to become apparent and it is also unlikely that genetic damage is passed to offspring. For children up to the age of 10 years, the probability of fatal cancer induction seems to be about 2-3 times higher.

For pregnant women the risk is the same as for the average population; however, the unborn child is assumed to have the same risk of developing a fatal cancer as young children. Deterministic effects have been observed after massive irradiation *in utero*, but dose levels incurred by family or close friends from a treated patient are far below the threshold for such effects.

As sensitivity to ionising radiation is different for different age categories, instructions to reduce the risk for these groups will also vary accordingly.

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2 This means that if 100 000 persons are exposed to 1 mSv it is assumed that 5 persons will have a radiation- induced fatal cancer. Equally, if the exposure of those 100 000 is 5 mSv, it is assumed that 25 persons will be affected

2.2. Doses to other people

Generally speaking, direct external radiation from the patient and exhalation of I-131 are possible sources of significant dose in other persons. Exposure to these sources should be prevented or reduced as far as is reasonably possible.

For the purpose of this document, we divide the individuals that may come in contact with a treated patient into two groups: the family and close friends on the one hand, and third persons on the other. The first group, including visitors, can be further divided into six categories: pregnant women, children up to 2 years old, children from 3 to 10 years of age, partners, partners above 60 years old and other individuals.

As explained before, these categories are chosen because (i) unborn children and children up to 10 years of age are more radiosensitive for cancer induction, (ii) small children up to about the age of 2 years often have more close physical contact with their parents and (iii) people older than about 60 year of age are less likely to express a cancer arising from ionising radiation. These differences are of special importance when considering instructions for patients.

3. DOSE CONSTRAINTS

For medical exposures, two types of system are used in the process of optimisation. Both are intended to reduce unnecessarily high doses. The first is a system of reference levels which is only applicable to diagnostic examinations and therefore not relevant to this document. The second is the concept of dose constraints.

Dose constraints (see also the guidance document 'Considerations on the Concept of Dose Constraints, joint report of NEA/EC Group of Experts') are ceiling levels for optimisation purposes. These are guideline forecasts which are not expected to be exceeded; they are not legal dose limits. As patients treated with radionuclides are sources of potential contamination and exposure to other people, instructions are needed as to their behaviour, with the aim of limiting doses to their family, close friends and to third persons. The ceiling levels used in this case are called dose constraints. 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 limits. Third persons, however, who have no relationship whatsoever with the patient and generally are occasional "victims" of the patient-source, do not benefit from the exposure at all and are therefore regarded as members of the public.

When patients are treated with radioactive substances, doses to family and close friends depend on the behaviour of the patient and their own behaviour. If certain rules are respected pre-set dose constraints can be met. The doses to third persons, however, who usually are not even aware of the fact that there is a source in the vicinity, depends totally on the behaviour of the patient.

As mentioned before, young children have a two to three times higher risk factor than the average population. So for an equal risk of stochastic effects the dose constraint for children and unborn children should be 2 - 3 times lower than for adults.

The risk factor for elderly people (60 to 80 years of age) is 3 to 10 times lower than for the average population. This gives the possibility of higher dose constraints for this age group.

As can be noted from table IV.2, Column C and D (Annex IV) most guidelines used to steer the behaviour of patients are adequate for adults and children above 10 years old, but are not suitable for small or unborn children. For the latter group special instructions should be given.

3.1. Dose Constraint levels for Iodine-131 treatment

Table 1 proposes dose constraints for family and close friends of out-patients, or discharged in-patients, after therapy with radionuclides.

The values given are set taking into account the following considerations:

1) Dose limits do not apply to medical exposures but they can be used as a reference value as to the acceptability of a certain exposure.

2) An exposure due to a patient-source will occur only once or twice in a lifetime of a typical individual.

3) The age of the exposed individual at the time of exposure plays a major role in the risk calculation.

Therefore,

- 1 mSv is an accepted upper level for the remainder of the pregnancy for the exposure of an unborn child whose mother is exposed during work (BSS), so using the same level seems to

be reasonable for the exposure *in utero* by a patient-source.

- Children up to 10 years old are assumed to have the same risk as unborn children, therefore 1 mSv seems to be an acceptable level for them as well.
- Children of 10+ and adults have a 2 to 3 times lower risk than younger children. In setting dose constraints for this group, it could be helpful to refer to the BSS. According to this Directive, in special circumstances, the dose limit for a member of the public in a single year is allowed to be higher than 1 mSv, provided that the average over a 5-year period does not exceed 1 mSv/y. As individuals on average will come into contact with a patient-source only once in their lifetime, it can be considered as a "special circumstance". Therefore, taking into account also potential exposures from other man-made sources than the patient-source during this period, a dose constraint of 3 mSv seems reasonable
- Adults of 60 years old have a 3 to 10 times lower risk than the average population and for individuals older than 65 years the risk is 5 to 10 times lower. Therefore a dose constraint for elderly people of 15 mSv is considered reasonable.

Table 1 Proposed Dose Constraints [mSv] for family and close friends per treatment with iodine-131

Group of persons	Dose constraint
Children (including unborn children *)	1 mSv
Adults up to about 60 years old	3 mSv **
Adults 60+ years old	15 mSv

* Unborn children includes embryos and foetuses

** These levels are not expected to be applied to family and close friends comforting very ill in-patients, such as mothers taking care of hospitalised children

As the exposure of third persons is regarded as an exposure of members of the public, dose limits do apply. The dose limit for the public as mentioned in the BSS is a cumulative dose limit applying to the sum of all exposures of a member of the public. Consideration should be given to the fact that other man-made sources also may cause exposure to a particular individual and that the sum of all these exposures shall not exceed 1 mSv in a year.

Therefore, 0.3 mSv, being just a fraction of the dose limit, is recommended as the upper limit for this type of exposure.

4. TREATMENT OF OUT-PATIENTS AND DISCHARGE OF IN-PATIENTS

Certain requirements should be met when treating out-patients or discharging in-patients. The responsible medical practitioner is obliged to ensure that relevant dose measurements are performed, that instructions are given to patients - both orally and in writing - and that inquiries are made about the situation at home.

In the case of hyperthyroidism treatment, fractionated administration of the radionuclide over a short time period is not considered good practice because of higher cumulative doses to individuals helping or visiting the patient, as well as to the patient himself. Therefore, fractionated treatment, which is used in some countries to avoid hospitalisation, cannot be justified. Repeated administration may be necessary in some cases where a treatment proves to be inadequate to control the disease; however, this will not become evident until at least 4 months after the initial treatment (see also Annex II).

4.1. Pregnancy

Pregnancy is a contraindication for treatment with iodine-131. In general, the treatment should be postponed until after delivery, or other treatments such as surgery should be considered. However, if a serious threat to the mother occurs, and other types of treatments are not indicated, for example in the case of metastases, the detriment to the child due to the treatment should be weighed against the consequences for the mother if she is not treated.

4.2. Dose measurements

Treatment on an out-patient basis, or discharge of an in-patient will be permitted only if the dose to family and close friends and to third persons (the general public) due to the (residual) activity in the patient is not expected to exceed dose constraints approved by the competent authorities.

As a general rule, treatment of thyroid cancer using radioactive iodine will only be performed in conjunction with hospitalisation of the patient. The discharge of an in-patient should be in accordance with the requirements mentioned in this chapter.

Before discharging an in-patient from a hospital, the medical practitioner must ensure that the residual activity does not exceed pre-set levels. This can be done by dose measurements performed at 1 metre distance from the standing patient. Standard measurement protocols should be defined for this purpose. The decision to discharge the patient must be based on the measurement with the highest exposure rate, which in the case of hyperthyroidism usually is the thyroid area, but in the case of a large thyroid cancer with metastases may be situated at another level of the body.

The result of the measurement should be recorded.

For the treatment of an out-patient the same reasoning should be applied.

Annex II gives a number of coefficients for the conversion from activity to effective dose (Table II.1) and from dose rate to effective dose (Table II.2).

4.3. Instructions

The medical doctor, under whose responsibility the treatment is carried out, shall ensure that the patient or the legal guardian are provided with both oral and written instructions before the patient is treated. He shall explain the importance of complying with these instructions and discuss them in detail with the patient. This procedure must also be recorded in the patient’s medical record together with the contents of the instructions.

4.4. Patient condition

The medical practitioner responsible for the treatment and discharge should ensure that the instructions can be understood and followed by the patient and his family or close friends. The patient should be self-sufficient and capable of co-operating and complying with the instructions. In the special case of a non self-supporting, non co-operative or incontinent patient, or a patient who is prone to vomiting, out-patient treatment is not a desirable (safe) option. In this case, additional and very specific instructions regarding the behaviour of family and friends will have to be given, perhaps after consulting a radiation protection expert, ensuring that the residual activity will not give rise to doses above the Dose Constraints of Table 1.

4.5. Situation at home

One of the factors to be evaluated for out-patient treatment or the discharge of in-patients is the home environment in a socio-economic sense, which should be such as to allow the patient and his family or close friends to comply with the instructions received. Consideration should be given to the available living space; i.e., the number of rooms in the house, quality of sanitary installations, connection to mains sewerage, etc.

The medical practitioner responsible for the patient's treatment and discharge must ensure that the patient has been interviewed about these conditions and has had explained to him that the risk to any other individual is directly related to the distance between the patient and the individual, the time spent together in close contact, etc. The medical practitioner should take a decision based on that information but of course cannot be held responsible for errors if incorrect information is supplied by the patient.

4.6. Special circumstances

Should emergency surgery have to be performed on a patient to whom I-131 has been administered, or where such a patient has suffered a heart attack, he or she should be treated in the same manner as any other patient even if the (residual) activity is above the level at which discharge from hospital would be possible. Special advice should be sought from a medical physicist if one can be contacted. The same procedure should be followed if a patient has returned home after treatment and then requires emergency care. In that case, it is the duty of the patient or his family to immediately inform the person providing emergency treatment about the particular state the patient is in after treatment with I-131.

4.7. Death of the patient

Sometimes, a patient dies shortly after the administration of I-131. If an autopsy is performed on the body, or to protect family, friends and third persons during the laying out of the patient, when standing vigil by the coffin and during the funeral service, a qualified expert in radiation protection should be consulted to keep doses as low as is reasonably achievable.

Burial or cremation may be subject to restrictions set out in national legislation.

5. GUIDANCE FOR MEDICAL PRACTITIONERS ON INSTRUCTING DISCHARGED IN-PATIENTS OR OUT-PATIENTS

The following guidance is addressed to medical practitioners in hospitals and clinics and to general practitioners. The practitioner can find an example of written instructions for patients, accompanying persons or legal guardians in Annex I. These instructions should be handed out before treatment in order to ensure that there is adequate time to make any necessary arrangements at home. Oral explanation of the instructions is desirable and the patient should be encouraged to ask for further explanation if any doubt remains.

These instructions should be followed for appropriate periods of time depending on the maximum dose at a distance of 1 metre from the standing patient (possible dose conversion coefficients are given in Annex II).

Under exceptional circumstances, additional or different instructions may be necessary. In these situations advice should be asked from a medical physicist if one can be contacted.

GUIDANCE FOR THE MEDICAL PRACTITIONER

Table 2 proposes a number of periods of time during which patients (and family and friends) should observe these limitations on their behaviour.

The duration is function of the effective dose rate measured at 1 metre distance from any point of the body of the patient. However, other methods resulting in other time periods may be used (see e.g. LAZ95 and ETA 95)

Table 2 Effective dose rates at 1 metre distance, estimated corresponding (residual) activities and periods for instructions to be followed.

Effective dose rate at 1 metre distance from the patient [$\mu Sv.h^{-1}$ at 1 metre]	Corresponding to an estimated (residual) activity of *	Recommended periods for following instructions
< 40	< 800 MBq	3 weeks
< 20	< 400 MBq	2 weeks
< 10	< 200 MBq	1 week
< 5	< 100 MBq	4 days
< 3	< 60 MBq	24 hours after administration

* These values are based on the physical data mentioned in Annex III

The proposed time periods are based on residual activities in in-patients. The fast excretion phase of these patients is almost completed before discharge (the activity in the body will decrease more quickly during the first day than during the subsequent days). In the case of an out-patient, the residual activity equals the administered activity, but the fast excretion phase will take place when the patient is at home: This means that for comparable residual activities at the time of discharge, the doses to family and close friends will be higher in the case of discharged in-patients than for patients who were

treated on an out-patient basis. Using the above mentioned recommended restriction period is therefore a conservative approach in the case of out-patients.

Instructions:

In general:

The patient should stay as far away as possible from any person at home, at all times more than 1 metre and for extended periods of time more than 2 metres.

Toilet:

Patients (including men) should sit down while urinating. Toilet paper should be used to dry the genitals and the toilet always should be flushed afterwards. Hands should be washed, if possible within the toilet room, to avoid contamination of door handles, etc.

Young children (0-10 years old)

For children up to 10 years old the risk associated with the dose is higher than for the average population. Moreover, very young children often are in direct physical contact with their parents (or other adults) for many hours per day.

If young children are involved, patients should be informed of the extra risk to children.

Direct physical contact should be avoided as much as possible and, again, the greater the distance the better.

For this reason, very young children up to 2 years old should be cared for preferably in another house, by individuals other than the patient. If this is not possible, or if it is not desirable for psychological reasons, contact should be as short as possible.

After the recommended restriction period, it is strongly advised in the case of young children to avoid non-essential physical contact with the patient for a further week, especially in the case of hyperthyroidism patients who were treated as in-patients.

Partners and other people at home

There is no contraindication against direct physical contact (hugging or sex) but it should be restricted to about half an hour per day. It is however strongly advised that the patient should sleep alone. The distance between two adjacent beds should be at least 2 metres. Ensure that the patient's bed in one room is not placed against the same wall as a bed in an adjacent room. Otherwise, the distance between the beds will also be very small and the wall does not provide effective protection against this type of radiation.

Elderly partners:

For persons of the age of 60 years or more, the risk of radiation detriment is small. Therefore, only those measures that are easy to take should be encouraged.

Pregnant women:

In the case of pregnant partners of a treated patient, similar sleeping instructions as for 'partners and other people at home' should be given. In addition, in order to keep the dose to the unborn child as low as reasonably achievable, close physical contact during the day should also be minimised.

Breast-feeding:

If a nursing woman needs treatment with I-131, breast-feeding should always be ended before the treatment starts and should not be restarted after returning home.

Pregnancy:

Conception within four months of treatment with radioactive iodine could result in harm to the unborn child. The advice is therefore to avoid pregnancy during these four months. Since the spermatozoa of male patients can also be damaged, they should be advised not to father children for four months after administration of I-131.

Visitors:

For a short visit, for example a few hours, there is no need for special precautions other than keeping a safe distance and avoiding direct physical contact (see 'in general').

Visits by young children and pregnant woman should be discouraged.

Cutlery and crockery:

As the saliva and the natural secretions of patients are relatively highly contaminated with iodine, cutlery and crockery, towels, bed linen etc. used by the patients should not be used by others. After washing they are completely safe again. There is no need to wash them separately.

Transport:

During the first week alone, travelling by public transport should be restricted to about two hours per trip. If the patient takes a taxi she/he should be seated as far away from the driver as possible. Travelling with the same taxi driver should be restricted to about two hours in total. In the case of unavoidable longer trips by public transport, special advice should be given about reducing the dose to fellow travellers. For example, the patient could be advised to change seats to avoid sitting next to the same person for prolonged periods.

Social events:

Visits to cinemas and other social events where the patient is in close contact with other individuals for several hours should be avoided.

Jobs:

The following distinction should be made:

1) The employment of the patient requires close contact with colleagues or clients or other individuals. If the patient's work environment is a school or any other situation involving children younger than 10 years, the patient should without exception stay off work. In other circumstances, a minimum distance of 2 metres from other individuals should be respected for most of the time including lunch-time. If this is not possible, the patient should stay off work.

2) The employment of the patient does not necessitate close contact. In this case, the patient can go to work (limiting as much as possible close contact) except in the case of out-patients during the first two days after administration (the fast excretion phase).

3) The work performed by the patient could be affected by ionising radiation (development of photographic plates, radioimmunoassay, etc.). In this case, staying off work is not a question of limiting exposures of third persons and advice from a radiation protection expert should be sought.

If in doubt, the responsible medical practitioner should ask advice from a medical physicist s expert. The management should always be informed.

Table 3 gives examples for required number of days the patient should stay at home to restrict the dose to a colleague to **0,3** mSv. The authors consider the use of days as time unit appropriate.

Table 3 Example of calculated required number of days off work *) for a patient given I-131 so as to restrict the dose to a colleague to **0,3 mSv** for three different distances and hours per day and, for 4 levels of administered **) activities (MBq) *(Tho95)*

Hours per day	200 MBq	400 MBq	600 MBq	800 MBq
8 h at 1 m	4	10	13	15
4 h at 1 m	-	4	8	10
8 h at 2 m	-	-	3	4

*) A five-day working week is assumed. The values in the table relate to the total number of days (including weekends) before returning to work

**) These numbers of days are based on administered activities in out-patients. As explained in Chapter 5, in the case of in-patients the time periods after discharge should be somewhat longer

Hospital:

If, during the period of restrictions, the patient unexpectedly has to be hospitalised, the responsible medical practitioner and the responsible medical physicist should be informed about his situation immediately.

Annex

I. EXAMPLES OF WRITTEN INSTRUCTIONS TO BE PRESENTED TO PATIENTS OR THEIR LEGAL GUARDIANS BEFORE LEAVING THE HOSPITAL OR CLINIC AFTER TREATMENT WITH IODINE-131

The following instructions can be given to patients, their legal guardians or their family

INSTRUCTIONS ON THE BEHAVIOUR OF PATIENTS AFTER RADIOACTIVE IODINE THERAPY

You have been treated with radioactive iodine to cure a thyroid problem. Most of the iodine will leave your body through the urine. For several weeks, however, some of the iodine will stay inside your body, which means that you in turn can irradiate other people physically close to you.

It is your responsibility to protect relatives, friends, colleagues and others. The following questions and answers are designed to inform you about simple precautions to be taken.

Your doctor will inform (or has already informed) you how long you should follow these instructions.

1 What is the most important precaution?

Do not sit or stay close to any person either at home or at work. Try to maintain a distance of at least 1 metre. For long periods (more than one hour), stay 2 metres away.

2 What about contacts with pregnant women?

Contact with pregnant women should be minimised. Try to stay at least 2 metres away from a pregnant woman.

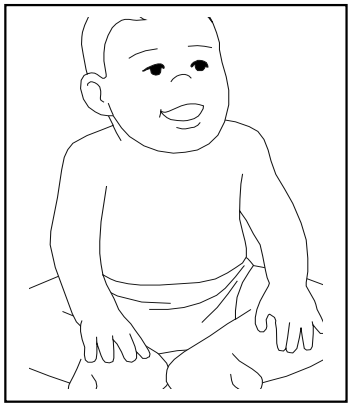
3 Is it safe to become pregnant / father children?

Some of the iodine will remain in your body for four months. During this time period you should not become pregnant or father children.

4 Can I still see my children and care for them?

If your children are under ten years old, please avoid close contact (such as hugging or holding) whenever possible.

The risk is higher for young children than for adults, therefore play it safe and avoid unnecessary contact for an additional week on top of the recommended period.



5 What about infants?

Children under two years old should be looked after by someone else. If possible, arrange for them to stay with relatives or friends.

6 Can I go on with breast-feeding?

Radioactive iodine is passed on in breast milk for quite a long time. **Therefore, breast-feeding must be stopped completely**!

7 Can I be in close contact with my partner or other people at home?

Any close contact such as hugging or sex should be limited to half an hour a day. You should sleep in a separate bed. Beds should be 2 metres apart, even if there is a wall separating them. This is because the walls of a house do not provide good protection against this type of radiation.

8 What if my partner is pregnant?

If your partner is pregnant, it is important to avoid close contact with her.

9 Do the precautions also apply to those over 60?

For those over 60 years, the risk is much lower than for other people. Special precautions are for that reason less important.

10 Can I receive visitors?

Short visits, less than two hours, create no problem. Keeping a distance of about 2 metres and preferably avoid close contact. You should discourage visits by young children and pregnant women.

11 Can I go to work?

Most people can go to work. If, by the nature of your work, you are within 2 metres of the same individual(s) for more than two hours per day, you should seek advice from your doctor.

You should in any case inform your manager.

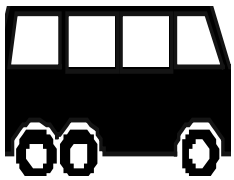
12 What if I am a nursery school teacher?

Nursery school teachers, or others who are in close contact with young children during working hours, should stay off work. Your doctor will indicate the required period of time for this restriction.

13 Can I go to the movies or other entertainment?

Preferably not. Avoid visiting cinemas and other social events where you are close to other people for more than one hour.

14 May I use public transport?



For one week you should restrict public transport to journeys lasting no more than two hours. Longer trips should only be undertaken if unavoidable. In that case, try to find a place where you can sit alone. Ask your doctor for advice if the trip is longer.

15 What about using a taxi?

Sit in the back on the opposite side from the driver. Do not spend more than two hours with any one taxi driver.

16 Can I use the same toilet as other people?

Yes, but spilling of urine must be avoided. Therefore, (also for men) pass urine while seated. Always dry your genitals with toilet paper and flush the toilet. It is also important to wash your hands straightaway, even when only urinating.

17 What about cutlery, crockery, bed linen, towels etc.

Radioactive iodine also leaves the body in the saliva and the sweat of patients. Therefore cutlery, crockery, towels, bed linen etc. should not be shared with others. After washing they are completely safe. There is no need to wash them separately.

18 What happens if I have to go to hospital?

If you have to go to hospital unexpectedly, please inform the doctor that you have been treated with radioactive iodine recently. This applies even when it is the same hospital where you were treated.

IF IN DOUBT, YOU SHOULD ALWAYS ASK THE ADVICE OF THE DOCTOR TREATING YOU.

II. BACKGROUND INFORMATION ON I-131 RADIOTHERAPY

II.1 Biological effects of ionising radiation

There are two types of biological effects of ionising radiation: deterministic effects and stochastic effects. Deterministic effects are those caused by the decrease in or loss of organ function due to cell damage or cell death. For these effects, threshold doses exist. The function of many organs and tissues is not affected by small reductions in the number of available healthy cells. Only if the decrease is large enough, will there be a clinically observable pathological dysfunction.

In the case of treatment of thyroid cancer or metastases, hyperthyroidism and goitre, the cell killing effect in some or all cells of the thyroid gland or in the metastases is the desired effect. Other organs should not be affected in such a way that deterministic effects will occur. Therefore β-emitting I-131 is often the radionuclide chosen for these treatments, although the associated γ-emission exposes also other organs of the patient and other people.

Stochastic effects are those that result from radiation-induced changes in cells that retain their ability to divide. These modified cells sometimes initiate a malignant transformation of a cell, leading to the development of a malignant clone and eventually to a clinically observable cancer. The delay between initiation and the disease may extend from a few years (e.g. leukaemia, thyroid cancer) to several decades (e.g. colon and liver cancer). Also genetic effects may be initiated due to the irradiation of germ cells.

For stochastic effects, no threshold dose is assumed and the probability of their occurrence is believed to be proportional to the dose (linear dose-effect relationship in the low dose/ low dose rate range). Therefore the probability of their induction should be reduced as far as possible by keeping the dose as low as possible. The dose received by persons living close to the treated patient is relatively low. There will therefore be no deterministic effect and the risk of a stochastic effect is quite low.

The natural cancer incidence in Europe is about 25 %. The probability of a radiation-induced fatal cancer has been estimated (ICRP-60) at approximately 5 percent per sievert [3] for the low dose/ low dose rate situation and 1 percent per sievert for serious genetic diseases. Depending on the organ involved, curable cancers can also be induced. For elderly people, older than about 60 years, the probability of such effects seems to be 3 times lower and for those above 65 years even about 5 - 10 times lower. This is because the future life span of elderly people may not be long enough for the cancer to become apparent. Moreover, they will be unlikely to pass on genetic damage to their offspring. For children up to the age of 10 years, the probability of fatal cancer induction seems to be about 2-3 times higher. For pregnant women, the risk is the same as for the average population, but the unborn child is assumed to have the same risk of developing a fatal cancer as young children. Instructions for all of these groups are different.

Deterministic effects have been observed after irradiation in utero, but the dose levels that could be received by family or close friends are far below the thresholds for such effects.

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3 This means that if 100 000 persons are exposed to 1 mSv it is assumed that 5 persons will have a radiation induced fatal cancer. Equally, if the exposure of those 100 000 is 5 mSv, it is assumed that 25 persons will be affected

II.2 Metabolism of I-131

Stable iodine

Iodine is an essential component of thyroid hormones, so the thyroid gland takes up iodine very easily. Normally, iodine is supplied to the body in foodstuffs and drinking water, and a normal dietary intake hardly ever results in excessive amounts of iodine intake. After intake, iodine will be concentrated in the thyroid tissue and used for the synthesis of hormones. If an additional amount of iodine is presented to the body, an average of about 25 % of this intake will be directly taken up by the thyroid. This amount is strongly dependent on the normal daily intake through the diet. With a low daily intake the amount of uptake can easily be 50 %. With a high daily intake the uptake may be as little as 5 - 10 %. The rest leaves the body quite quickly, within some days, mostly in the urine but also in other excretions, such as faeces, sweat, saliva and breath. The iodine used by the thyroid gland is slowly released from the hormones into the body fluids and can recirculate. It is finally excreted from the body within a period of a few months.

Radioactive iodine

As the body does not differentiate between stable and radioactive iodine, I-131 behaves in the same manner as stable iodine. This means that a large part of the intake will be concentrated in the thyroid within 24 to 48 hours. During the initial retention and recycling period that the radioactive iodine is in the body, it irradiates the thyroid tissue, resulting in death of tumour cells in the case of thyroid cancer or of a substantial amount of normal thyroid cells in the case of benign thyroid diseases.

The physical half-life of radioactive iodine is about 8 days. This means that half of the amount of radioactive iodine decays within 8 days. The main decay product is xenon-131, which is rapidly washed out of the body. In addition, damaged thyroid cells lose their capacity to organify iodine and consequently, the iodine is released back to the blood stream, resulting in excretion. Thus, radioactive iodine is removed from the body reasonably quickly, due either to radioactive decay or to metabolic excretion. The total amount of radioactive iodine reduces to half its original value [4] at a rate which depends on the state of disease: between 1 day, in the case of thyroid cancer and total ablation of thyroid tissue, and 7 days for patients with euthyroid goitre. In the case of hyperthyroidism, the effective half-life is about 4-5 days.

Figure II.1 gives I-131 excretion curves for thyrotoxicosis, cancer therapy and cancer follow up. This figure shows the differences in excretion rate and (related) retention in the body during the 20 days following administration.

[4] This is called the effective half-life. This is based on the physical half-life and the biological half-life, dependent on metabolism.

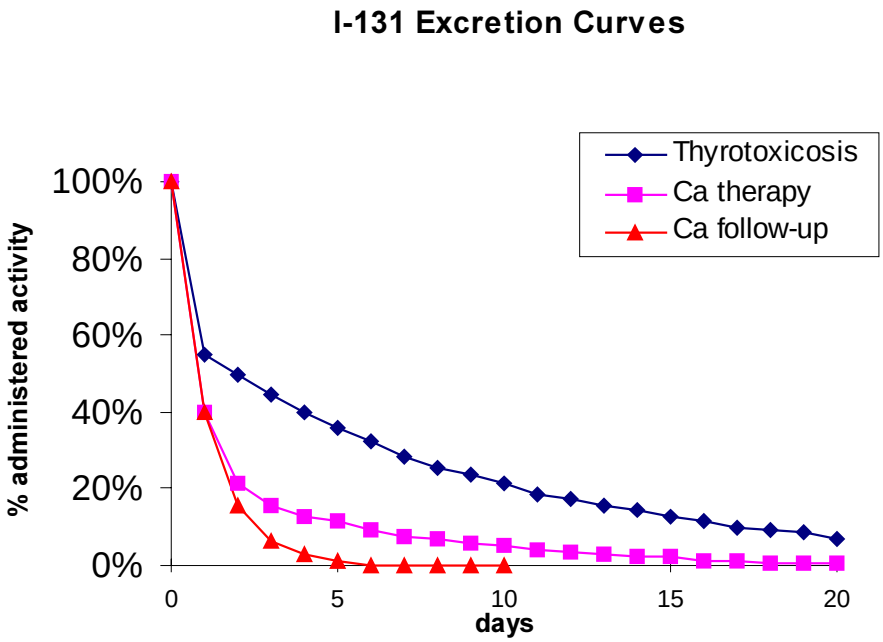

Figure II.1 I-131 excretions curves in percentages of administered activities for thyrotoxicosis, cancer therapy and cancer follow up (metastases or return) *[Hil91]* and *[Bar96]*

II.2.1 Mechanism of I-131 treatment

Due to the ability of thyroid cells to take up iodine, some thyroid diseases can be treated with radioactive iodine. In particular, hyperthyroidism and thyroid cancer and, in some cases, euthyroid goitre are treated in this way.

II.2.1.1 Hyperthyroidism

The treatment of hyperthyroidism with iodine-131 is based on the uptake by hyperactive thyroid cells and the damaging and destruction of these cells by β-radiation. This results in fewer functioning thyroid cells and therefore in normal or even below-normal thyroid function. For this treatment the administered activity is usually under 1000 MBq of I-131.

The uptake of iodine by the hyperactive thyroid is 50 - 70 %, depending on the level of hyperfunction and the normal daily intake of iodine with foodstuffs. The level of exposure of the thyroid needed depends on the degree of hyperthyroidism and can vary by orders of magnitude.

Repeated administrations of small activities (100 MBq) are not beneficial to the patient and may result in inadequate treatment of the hyperthyroid state. In elderly people, this is to be avoided because of the adverse effects of excess thyroid hormones on the cardiovascular system. In addition, fractionating the treatment means that the total administered activity has to be increased to achieve the desired effect and this results in higher cumulative doses to the patient and to family and close friends. Fractionating of treatment, sometimes adopted in order to avoid hospitalisation, therefore cannot be justified.

II.2.1.2 Euthyroid goitre

Some goitres (strumas) are euthyroid, which means that the thyroid is enlarged although function is normal according to clinical and biochemical parameters. However, these goitres may displace other organs or tissues because of the increased volume. One possible therapy is the reduction of the thyroid tissue volume with radioactive iodine. However, due to the large volume of the thyroid, high levels of activity up to 3000 MBq I-131 may be necessary. If the treatment is successful, surgery can be avoided.

II.2.1.3 Thyroid cancer

In the case of thyroid cancer, the first choice for treatment is surgery. However, it is often impossible to remove all the cancer tissue and metastases may develop. Therefore, even after surgery, a treatment with radioactive iodine usually is applied to kill the remaining cancer cells.

Thyroid cancer cells lose part of their capacity for iodine uptake and also the organification process is disturbed. As a result, the uptake of iodine in thyroid cancer cells is lower than in normal thyroid tissue. In some Member States, after surgical removal of cancerous thyroid tissue, an initial activity of about 3000 MBq is given to ablate the thyroid bed remnants. A much higher administration, up to 8000 MBq I-131, is then necessary to treat any metastases. If there is no normal tissue left after surgery, but metastases exist, high activities are given immediately. Repeated treatment might be necessary in either case.

As only a small amount of thyroid tissue remains after the surgical treatment and the uptake is disturbed, only a small proportion of the administered activity will be taken up. In cases where the thyroid or tumour tissue is not concentrating the iodine, usually about 80 % of the administered activity will be excreted within 48 hours (see Figure II.1). If 5000 MBq is administered to treat thyroid carcinoma, the residual activity in the patient will be less than 1000 MBq and 750 MBq within 48 and 72 hours respectively. In cancer patients with a large total volume of metastases, the excretion takes much longer.

II.3 Doses received by family, close friends and third persons

If the (residual) activity in a patient going home is 400 MBq I-131 or less, the dose to family and close friends, provided they carefully comply with the instructions given them, will almost always be below 1 mSv (see Chapter 5).

Seven prominent pathways of exposure of family and close friends (medical exposures) and third persons e.g. taxi drivers, people at work, passers by, etc. (exposures of the public) can be distinguished:

1 external irradiation of persons close to the patient

2 internal contamination of persons close to the patient by inhalation of iodine-131 aerosols which have been exhaled by the patient

3 internal contamination of persons close to the patient by excreted iodine-131 through direct contact, inhalation or ingestion

4 internal contamination of third persons by the radioactive iodine reaching them through sewerage or direct discharges to surface water

5 external irradiation of third persons in emergency situations such as urgent surgery or treatment of the patient.

6 internal contamination of third persons through the ashes of the cremated body

7 external irradiation of third persons when an autopsy is performed or the body of the deceased person is laid out, buried or cremated.

Pathways 1 and 7 can give rise to relatively high doses. Pathway 2 is not always recognised, but can give a substantial dose, not only to those in the immediate vicinity of the patient but also to all those present in the same room. Good ventilation may help in this case. Under normal conditions, if the

patient is not incontinent and is able to urinate without spilling urine, pathway 3 gives rise to doses about two orders of magnitude less than pathways 1 or 7; otherwise, it will be a pathway of concern. As iodine-131 has a physical half-life of 8 days, pathway 4 is negligible. Since there is a possibility of a relatively high dose due to pathway 5, advice should be sought from the responsible radiation protection expert whenever this situation occurs. Pathway 6 does not give a significant dose because almost all the iodine will be dispersed in the air. There is no need to advise against cremation.

Finally, in most circumstances, direct external radiation from the patient and exhalation of I-131 will be possible sources of a significant dose in other persons. These pathways of exposure should be prevented, reduced and, as far as possible, controlled.

For the calculations of doses following intakes of iodine the dose conversion coefficients in Table II.1 could be used.

Table II.1 Dose Conversion Coefficients in Sv/Bq for inhalation and ingestion based on ICRP Publication 72 *[ICR96]*

Age group	Inhalation [Sv/Bq]	Ingestion [Sv/Bq]
< 1 year	$7{,}2 \times 10^{-8}$	$1{,}8 \times 10^{-7}$
1 - 2 years	$7{,}2 \times 10^{-8}$	$1{,}8 \times 10^{-7}$
2 - 7 years	$3{,}7 \times 10^{-8}$	$1{,}0 \times 10^{-7}$
7 - 12 years	$1{,}9 \times 10^{-8}$	$5{,}2 \times 10^{-8}$
12 - 17 years	$1{,}1 \times 10^{-8}$	$3{,}4 \times 10^{-8}$
adults	$7{,}4 \times 10^{-9}$	$2{,}2 \times 10^{-8}$

Table II.2 gives some approximate conversions for the maximum cumulative external effective dose to persons exposed to patients containing ^{131}I; the maximum being accumulated over time from discharge of the patient from hospital to infinite decay of the radioiodine. The maximum figure assumes that the person exposed to the patient remains face to face with, and at a distance of 1 m from, the patient at all times, night and day. Usually, this is not the case in real life.

Table II.2 Maximum cumulative external effective dose [mSv] to other persons * at 1 m from iodine therapy patients, dependent on the effective half-life in the body of the patient. The maximum figure assumes that the person exposed to the patient remains face to face with, and at a distance of 1 m from, the patient at all times, night and day

Effective dose rate at 1 m ***	Estimated (residual) activity in the body **	Maximum cumulative external effective dose to other persons dependent on the effective half-life of I-131 remaining in the patient's body		
[µSv • h^{-1}]	[MBq]	50 h	100 h	150 h
		mSv	mSv	mSv
10	200	0,7	1,5	2,3
20	400	1,5	3,0	4,5
40	800	3,0	6,1	9,0

* The equivalent AP values for children will be higher by a factor of approximately 1,1 (ICRP-74) *[ICR96]*

** This can be either the administered activity in the case of an out-patient or the residual activity at the moment of release of an in-patient. In the first case, there will be two excretion phases with different effective half-lives

*** Some dosimeters record the air kerma rate in mGy/h. For this purpose the air kerma rate can assumed to be the same as the effective dose rate

People close to patient can be roughly divided into two groups: the family and close friends, and third persons. The group "family and close friends", including visitors, can be further divided into six categories: pregnant women, children up to 2 years old, children from 3 to 10 years of age, partners, partners above 60 years old and other persons.

These categories are chosen because (i) unborn children and children up to 10 years are more radiosensitive to cancer induction, (ii) small children up to about 2 years of age more often have close physical contact with their parents and (iii) people older than about 60 years of age are less likely to express a cancer arising from ionising radiation. These differences are of special importance when considering the instructions on how behaviour should be modified.

II.3.1 Dose estimates in family and close friends

II.3.1.1 Hyperthyroidism treatment

Minimal, maximal and average estimated doses are given in the literature, based on measurements or calculations (Bertil Arvidsson *[Arv96]*, Thomson and Harding *[Tho95]*) and ODoherty *[ODo94]* of the doses to persons close to treated hyperthyroidism patients.

Table IV.1 in Annex IV shows that overall the doses due to residual activities (column D) are about a factor of two higher than those due to the same amount of recently administered activity (column B).

Table IV.2 in Annex IV provides other data from the same literature sources. For the purpose of this document, doses in this table are normalised to residual activities in the body of 400 MBq at the time of discharge, or, in the case of out-patients, administration is normalised to 400 MBq residual activities using a factor 2 based on table IV.1.

Based on the above mentioned amounts, the following conclusions can be made:

- doses where no restriction was imposed (such as keeping distance) vary from 20 to far less than 1 mSv.

- if people follow the suggested instructions, doses will rarely exceed 1 mSv in the total period after discharge.

II.3.1.2 Thyroid cancer treatment

The discharge levels in Member States are based on residual activities which are estimated based on air kerma rates. Following thyroid cancer treatment the discharge levels vary from 5 - 40 µSv/h at 1 metre from any point of the body (see Chapter 5). For these treatments, no literature is available about measured doses to persons at home, after the discharge of the patient from the hospital. The calculated doses for family and close friends depend on the method used and on assumptions of behaviour. Beekhuis et al *[Bee92]* calculated that with a residual activity of 400 MBq in the body at the time of discharge, a person who remains permanently at 1 metre distance from the patient is liable to receive a total dose of about 5 mSv. This dose will decrease by a factor of at least 5 to 10 for children and third persons respectively if more realistic behaviour is envisaged.

Doses to other individuals due to a given residual activity in a discharged in-patient treated for thyroid cancer do not necessarily match doses due to an equal administered activity in an out-patient treated for hyperthyroidism. This can be explained by the fact that the fast excretion phase of the former is over before he leaves the hospital and also by the fact that excretion rates in the slow phase differ (see Figure II.1).

III. DOSIMETRIC ASPECTS OF I-131 THERAPY

III.1 Exposure of others by penetrating radiation from I-131 in the body of patients

The penetrating gamma rays coming from I-131 in the body of the patient can give rise to external exposures of persons close to the patient. The external dose rate may be measured using an ionisation chamber and the value converted to an equivalent dose-rate at the given time. The measured dose rate is usually taken as the highest reading at the level of greatest uptake in the patient. For a thyrotoxic patient, this will normally be at the level of the thyroid but for a patient treated for thyroid metastases, this may be elsewhere in the body.

If a measurement is not possible, an upper limit of the external dose-rate may be estimated from the expected residual activity in the patient at a certain moment in time and using 66 $m^2\,\mu Sv\,h^{-1}\,GBq^{-1}$ as the dose rate constant from a point source for I-131. This constant gives the ambient dose equivalent at 1 m from a I-131 point source with a strength of 1 GBq. In practice, the value calculated from the point source is higher than the actual value, as the source is more diffuse and some attenuation will take place in the patient. The ambient dose equivalent is designed to estimate the effective dose under a wide range of circumstances.

III.2 Absorbed doses in patients

The absorbed dose to the patient depends on the activity of the radionuclide administered, its physical properties (i.e. the type and energy of emissions and the physical half-life) and its chemical properties together with the pathology of the patient (which will determine the distribution and retention of the radioactive material in the body).

III.3 Absorbed dose to organs

Iodine -131 emits both beta particles and gamma rays at every decay event. The beta particles are so called non-penetrating particles and will deposit their energy in a relatively short path-length in human tissue. The gamma rays are indirectly ionising and more penetrating, but the secondary electrons produced will deposit their energy in a short path-length. These energy depositions result in absorbed doses to the organs in which the radionuclide is localised and to adjacent organs in the body of the patient.

Although it is not possible to determine with accuracy the magnitude and distribution of the internal dose delivered from unsealed sources, comparisons of experimental and calculated absorbed doses have shown parallelism within 20 % to 60%, sufficient at least for radiation protection purposes (ICRP-53) *[ICR87]*.

Examples of absorbed dose to different organs of a patient administered ^{131}I as sodium iodide (NaI) are given in Table III.1, assuming a comparatively simple model for two different percentages of initial uptake in the thyroid [ICRP 53]. The absorbed dose per unit activity to the thyroid is highlighted. According to Table II.2, the thyroid dose to an adult thyrotoxic therapy patient would be about 300 Gy assuming 55% uptake of a 400 MBq administered activity for a 20 g thyroid. It will actually be a little less than this value if the slightly reduced effective half-life for hyperthyroid patients is taken into account.

Table III.1 Examples of absorbed dose to various organs per unit activity $Na^{131}I$ administered to normal adults with a 20 g thyroid / mGy MBq^{-1} [ICRP 53] *(ICR87)*, dependant on the uptake

Organ	15 % uptake	55 % uptake
Bladder wall	5.2E-01	2.9E-01
Breast	4.3E-02	9.1E-02
Stomach wall	4.6E-01	4.6E-01
Small intestine	2.8E-01	2.8E-01
Lungs	5.3E-02	1.3E-01
Ovaries	4.3E-02	4.1E-02
Red marrow	5.4E-02	1.2E-01
Testes	2.8E-02	2.6E-02
Thyroid	**2.1E+02**	**7.9E+02**

IV. CALCULATED AND MEASURED DOSES TO PERSONS IN THE VICINITY OF HYPER-THYROIDISM PATIENTS

Minimal, maximal and average estimated doses are given in the literature, based on measurements or calculations (Bertil Arvidsson *[Arv96]*, Thomson and Harding *[Tho95]*) and ODoherty *[ODo94])* of the doses to persons close to patients treated for hyperthyroidism.

Table IV.1 shows that overall the doses due to residual activities (column D) are about a factor of two higher than those due to the same amount of recently administered activity (column B). Table IV.2 gives other data obtained from the same literature. For the purposes of this document, doses in this table are normalised to residual activities in the body of 400 MBq at the time of discharge, or, in the case of out-patients, the administered activity is normalised to 400 MBq residual activities using a factor of 2. It should be noted that the doses are only approximations since they depend on uptake and retention.

Table IV.2 shows that the median levels, with minor restrictions, in column A are about the same as the average levels in column D with restrictions. The maximum values (with minor restrictions) in column B are also close to the maximum calculated values without restrictions in column E.

The measured median values with minor restrictions are probably the result of ‘normal’ behaviour of people. However, column B shows that particular behaviour can give rise to much higher doses.

Because of this, instructions should be based on the maximum values in the columns B and E.

Table IV.1 Total doses due to either administered (columns A, B) or residual activities (columns C, D) of 400 MBq, extrapolated from measurements for 1 week calculated to infinity. Patients were told the most important precautions to take. All values are rounded and normalised to an administered or rest activity at the moment of discharge of 400 MBq
(Bertil Arvidsson *[Arv96])*.

		Doses extrapolated from measurements for 1 week With major restrictions for one week [Arv96] [mSv]			
		Administered activity of 400 MBq		**Residual** activity of 400 MBq	
		Range	Median	Range	Median
Exposed persons		A	B	C	D
Infants	0-2 y	0,6 - 0,9	0,7	0,8 - 1,6	1,3
Children	3-10 y	0,1 - 1,5	0,3	0,2 - 4,9	0,6
Partners	< 60 y	0,3 - 3,1	0,7	0,7 - 5,6	1,4
	60 y	1,4 - 1,5	1,4	2,0 - 3,1	2,5
Other adults		0,2 - 0,5	0,3	0,4 - 1,0	0,6

Table IV.2 Measured and calculated total doses due to administration of I-131 normalised to 400 MBq residual activities (columns D, E and F) of 400 MBq, extrapolated from measurements over 2 months, 1 week or calculated to infinity. All values are rounded and based on the mentioned references. All values are rounded and normalised to an administered or residual activity at the time of discharge of 400 MBq
(Thomson and Harding *[Tho95]*, ODoherty *[ODo94]* and Bertil Arvidsson *[Arv96])*

		Median / max doses **extrapolated** from measurements up to 2 months [Tho95] **With minor restrictions**[d] based on 400 MBq residual activity [assuming 50 % retention] [mSv]		Doses **extrapolated** from measurements for 1 week[b] [Arv96] **With major restrictions** for one week Residual activity of 400 MBq [mSv]		Doses **calculated** to infinity [ODo94] **Without restrictions** based on 400 MBq residual activity[a] [mSv]
		Median	Max[e]	Range	Median	
Exposed persons		A	B	C	D	E
Infants	0-2 y	2	20	0,8 - 1,6	1,3	20 [c]
Children	3-10 y	1,0	8	0,2 - 4,9	0,6	6-11.5
Partners	< 60 y	8	24	0,7 - 5,6	1,4	18,5
	60 y			2,0 - 3,1	2,5	
Other adults		2	6	0,4 - 1,0	0,6	2,2

Footnotes see next page

Footnotes for Table IV.2

a Total dose 600 MBq administered with 66 % retention, which for this purpose is considered to be the same as 400 MBq residual activity

b If the restrictions are extended till all activity in the body has disappeared the figures do not change significantly except for infants (median 0,4 mSv)

c Dose estimate to an infant being bottle fed throughout the ‘treatment period’ is 5 to 7 mSv for an administered activity of about 800 MBq, supposing 5 hours’ close contact every 24 hours.

d General instructions were given; the result was normal behaviour with care being given occasionally.

e Maximum means that the value mentioned could be an outlier

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ABSTRACT

The Basic Safety Standards Directive (96/29/EURATOM) and the Medical Exposures Directive (97/43/EURATOM) both present requirements on the protection of individuals exposed due to medical exposures when helping or assisting patients other than as part of their occupation. This guide discusses I-131 therapy. It provides physical data on the radionuclide, it's effects on human beings, proposes ways of developing dose constraints to be set for family and close friends of the treated individual and for third persons. It also provides practitioners with a number of relevant considerations to be taken into account whilst treating patients with I-131 and gives practical examples how to instruct patients and family and friends on correct behaviour. Four annexes give more detailed information on specific issues discussed in the main document.