

## <sup>131</sup>I therapy: Patient release criteria

### 1. Introduction

Throughout Europe, tens of thousands of patients benefit from treatments by radiopharmaceuticals containing iodine-131 every year. Their numbers continue to rise.

Iodine -131, used as iodide, serves as a highly selective and very efficient treatment for patients who suffer from either benign functional thyroid disorders or from thyroid cancer. In addition, I-131 in alternative chemical forms is used for the treatment of other malignant diseases such as neuro-endocrine tumours (131-MIBG) and primary liver cancer. (I-131-lipiodol).

Indications for these treatments are supported by an extensive evidence base so that their justification from a radiological protection point of view is well founded.

Clinical practice and administration protocols however, differ from one country to another as does the practical application of the optimisation principle. This holds especially true for decisions regarding the period after which the patient can be allowed to leave hospital following treatment. A patient treated for an over active thyroid condition will be treated as an outpatient in one country, whereas an equivalent treatment in a neighbouring country may necessitate up to a week hospitalisation time. The public are aware of these differences and this has given rise to a practice known as “medical tourism”, whereby patients travel to a different country to obtain treatment which better suits their economic or social circumstances.

Several international bodies have made recommendations on the maximum (residual) activity in patients going home after treatment with I-131:

- The *International Basic Safety Standards BSS*, (IAEA, 1996) state that “... a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below ...” after which a table is referred to, containing a guidance level for I-131 of 1100 MBq. In a footnote it is mentioned that 400 MBq is used in some countries as a measure of good practice.
- In *Radiation Protection following Iodine-131 therapy – exposures due to out-patients or discharged in-patients* (RP 97, EC, 1998), dose constraints are given for family members and other comforters and carers of ages up to 10: 1 mSv, ages 10 to 60: 3 mSv and ages over 60: 15 mSv. For members of the public, a dose limit of 0.3 mSv per treated patient is proposed. The 1 mSv dose constraint is likely met, if the (residual) activity is 400 MBq or less. Most important pathways (instructions kept) are normally external radiation of persons close to the patient and of persons handling the body of a deceased patients (e.g. during autopsy, laying out, burying or cremation).
- ICRP publication *Release of Patients After Therapy With Unsealed Radionuclides* (#94, ICRP, 2004) states (Chapter 11) “Since lifestyle habits differ between and even within countries, a single model for release criteria would not be appropriate optimisation. It is recommended that release of patients should be based on their family situation (rather than retained activity and the worst-case scenario). It is also recommended that when there are many contiguous countries, a uniform or similar approach to releasing patients should be developed.” Also, ICRP states (141) “... the EURATOM (1997) guidelines on radiation protection following iodine-131 therapy are quite restrictive...”
- Finally, in *Release Of Patients After Radionuclide Therapy* (Safety Reports Series #63, IAEA, 2009), in Tables 9 and 10 an overview is given of release criteria in different countries. Maximum (residual) I-131 activities for patients release range from 75 (Germany) to 1200 MBq (former US value).

When HERCA was created, Working Group 3 was asked to investigate the reasons behind the important cross border differences. In doing so, it soon became clear that they relate to differences in societal sensitivity, appraisal and values.

Allowing for treatments with shorter hospitalisation time or even as outpatients saves money for the national social security system. This may influence decisions to choose treatments using radioactive iodine rather than surgical alternatives, particularly in the case of thyroid disease. It may have similar impact for patients, where hospitalisation may impose unacceptable financial and social hardship.

On the other hand, the freshly treated patient who is released from hospital constitutes some radiological hazard to his environment, to members of the public and in particular to his family members.

This hazard which decreases with time will have to be weighted against the –equally time-dependant- advantages mentioned, in order to determine the appropriate time for release of the patient.

It soon became clear that objectively the same risk or advantage could be valued quite differently from one country to another, and these underlying differences result in quite different hospitalisation periods.

Although the working group was unable to achieve full consensus on criteria that determine hospitalisation duration, some agreement was reached regarding general principles and approach. The results of this consensus are presented.

## **2. General considerations**

The administration of unsealed radioactive substances to patients constitutes a risk of external exposure and may also constitute a risk of radioactive contamination to health care workers, non-professional carers and comforters and to other members of the public.

This is particularly true for I-131, an isotope which is frequently used in the treatment of benign thyroid disorders as well as in the treatment of different malignancies: Gamma-emission is responsible for the risk of external exposure close to the patient, which is the predominant risk, while the presence of radioiodine in all kinds of body fluids like urine, sweat, perspiration, saliva and breast milk constitutes the basis for an accessory risk of contamination,.

In order to guarantee a sufficient radiological protection for all persons confronted with the treated patient, a number of conditions have to be fulfilled. Compelling international radiation protection standards<sup>1</sup> demand that the exposure to persons due to the patient-borne activity stays below certain limits: 1 mSv per year for members of the public, 100 mSv / 5 years for the professionally exposed health care workers

For non-professional carers and comforters dose limits as such do not apply, but a dose constraint is used instead. Such a constraint is source-related and is usually set at around 5 mSv for adult<sup>2</sup> volunteers who are in closest contact to the patient.

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<sup>1</sup> International Basic Safety Standards BSS, (IAEA, 1996) and Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation

<sup>2</sup> It is debatable whether children can be seen as “carers and comforters”: their presence may undoubtedly be of some benefit to the patient and may also be in their own interest, but whether they are capable of giving the necessary “informed consent” is highly questionable.

According to Radiation Protection #97 (EC, 1997), the dose to carers and comforters will be less than 1 mSv (corresponding to the value for ages up to 10) if 400 MBq is used as a maximum activity for patients going home. This dose may be expected to scale linearly with the activity. Values for the maximum (residual) activity in patients going home currently range from 95 to 800 MBq in the EU member states. Adhering to a maximum activity level of 800 MBq, along with appropriate instructions, may therefore be expected to keep the dose for carers and comforters below a value of 2 mSv per treatment.

The practical approach depends not only of radiological parameters such as the administered activity, but will to a large extent depend on individual patient characteristics such as age, physical, psychological and mental status, family composition and living conditions, professional activities etc.

Country-specific differences may lead to the adaption of values lower than those proposed in paragraphs 2.point 3 and 2.point 4 below.

### 3. Practical rules

- 2- 1. Prior to treatment, general oral and written information is given to the patient and/or relatives or accompanying persons and/or responsible persons (in case of a child or person who cannot be held responsible for his actions). This information includes recommendations and instructions on how to minimize the risks arising from irradiation and contamination due to the use of the radio-pharmaceutical.
- 2- 2. This oral and written information should be repeated, commented and adapted to the patient's personal situation, at the time the patient leaves the treatment unit.
- 2- 3. Hospitalisation is recommended for administered activities  $\geq 800$  MBq
- 2- 4. A patient can be released from hospital if both criteria below are met:
  1. If the dose rate emitted by the patient is less than the dose rate corresponding to an administered activity of 800 MBq. In practice that could be  $\leq 40 \mu\text{Sv h}^{-1}$  measured<sup>3</sup> at mid-thoracic height, at a distance of 1 meter from and right in front of the patient.
  2. If the patient is ready, willing and able to follow the recommendations and instructions provided with the information discussed in the above
- 2- 5. Specific situations may lead to the application of more severe release criteria or, otherwise stated, prolonged hospitalisation. The release of the patient will thus be determined on an individual basis, decided *-in fine-* by the responsible medical practitioner advised by a medical physics expert. Such situations may arise from:
  - Patient's physical condition (such as urinary incontinence)
  - Patients mental condition (such as dementia)
  - Patients socio-economical condition (such as the "unavoidable" presence of pregnant women or young children, at the same place where the released patient stays, the patient sharing a prison cell with others,...)
  - Psycho-social conditions where the practitioner gets the distinct impression that the recommendations and instructions given, although understood, will not be followed by the patient and/or the relatives of the patient and/or responsible persons.

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<sup>3</sup> This measurement should be done with suitable and properly calibrated instruments, under the supervision of the medical physics expert.

2- 6. At hospital before releasing the patient, the medical practitioner makes sure that a declaration<sup>4</sup> is handed over to the patient, stating that a given activity (X MBq) of I-131 was administered to the patient at a given moment (date) and informing where further explanations can be obtained (contact details). This declaration is provided in English and, where applicable, also in the local language(s).

2- 7. A quality management approach is applied to keep record of all relevant information on all the above mentioned transactions, measurements and considerations.

#### **4. Responsibilities**

The medical practitioner, a medical doctor specialised in nuclear medicine and/or radiotherapy, has to assume the final and overall responsibility for the treatment considered.

As specified by the competent national authority, the referring doctor shares responsibility with the practitioner for the justification process. It should be noted however that whatever the treatment proposal or prescription by the referrer may be, it is the practitioner who ultimately decides on the appropriateness of the treatment and the individual justification.

Justification should be according to the relevant professional guidelines (appropriateness criteria), unless specific reasons necessitate a deviation from these general rules of good practice. Where this is the case, the underlying reasons should be recorded explicitly in the patient file.

In the process of justification, specific attention should be devoted to the issues of (possible) pregnancy. Consideration should be given to the overall medical condition of the patient and the implications of treatment or delay. The referring physician remains responsible for the patient's long-term overall care, while responsibilities relating to the exposure belong to the nuclear medicine specialist/radiotherapist. Where appropriate, female patients should be advised that breastfeeding should cease.

The licensee of the hospital or department where the treatment takes place is responsible for providing an appropriate and functioning infrastructure and facilities within which medical exposures can take place. These should be checked regularly by a radiation physics expert. The results of these checks should be recorded and remedial action undertaken promptly, when deviations are observed.

The licensee is responsible also for correct staffing, i.e. a sufficient number of adequately informed and specifically trained members of personnel. This should include the availability of a medical physics expert, who is responsible for medical dosimetry and with others will ensure the correct functioning of the measuring equipment and the adequacy of the measuring protocols used.

The medical practitioner can delegate specific practical aspects of the treatment to other healthcare professionals who are adequately trained and clearly instructed. These include the inquiry with regard to the possible pregnancy status, the information of the patient at different stages of the treatment, the administration of the radiopharmaceutical, etc. The delegation of such activities to these healthcare professionals necessitates instructions and supervision by the practitioner, who still carries the legal responsibility.

As indicated above, the family doctor of the patient, correctly informed by the practitioner, carries the responsibility for the patients' overall care, including the care subsequent to his discharge from hospital. This would be the case, for instance if the patient needs to be (re)hospitalized or dies. The family doctor should ensure that persons, who might get exposed to any radiological risk generated by the patient or his mortal remains, are timely and adequately informed. Further advice should be sought

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<sup>4</sup> This declaration may take the form of a leaflet or wallet card and will serve essentially for explaining the origin of any detected activity at radiation detector gate controls. It may also be useful in case of accidents with possible hospital (re-)admission or even in the case of decease of the patient.

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from a radiation protection and/or medical physics expert at the hospital where the treatment was offered.

Some responsibility lays with the patient himself and those within his immediate social environment, in particular the family members. They should observe the recommendations provided by the practitioner and thus ensure the radiological protection of themselves and others directly involved, particularly children who may come into contact with the patient in the days immediately after discharge from hospital.

The family doctor, or any other medical doctor contributing to the patient's care, should intervene if they would notice that these recommendations are not correctly understood or applied by the patient and/or his family.

**Appendix 1 : Tables from Safety Reports Series #63, IAEA, 2009:**

**TABLE 9. SOME NATIONAL MAXIMUM ACTIVITIES FOR PATIENT RELEASE**

Radionuclide	Retained activity (MBq)					
	USA	Germany [64]	Sweden [65]	Finland [71]	Japan [67]	Australia [45]
	NRC [47], NUREG-1556 [68]					
Phosphorus-32	<sup>a</sup>		1200			1200
Strontium-89	<sup>a</sup>				200	300
Yttrium-90	<sup>a</sup>		1200		1200	4000
Iodine-131	1200 <sup>b</sup>	75	600	800	500	600
Samarium-153	26 000					4000

<sup>a</sup> Value not given because of minimal exposure of the public.

<sup>b</sup> Historic value prior to change in approach to that based on 5 mSv. See Annex II.

**TABLE 10. EXAMPLES OF OTHER IODINE-131 RELEASE CRITERIA**

Country or organization	Release limit for I-131 (MBq)
BSS*	1100 (guidance level)
European Thyroid Association	800
Japan	500 or <30 µSv/h at 1 m
Germany	250 (based on 3.5 µSv/h at 1 m)
Other EU Member States	95–800, mostly 400–600

\* The revised BSS are not expected to contain numerical values.

## Appendix II: results of HERCA-WG3 survey

	H duration for Thyroid cancer (days)	Hyperthyroidism	information	Info given by	Structures of unit	Attitude for deceased people
<b>Belgium</b>	<b>2</b>	<b>Outpatients</b>	<b>Yes</b>	<b>NM practitioner but also Radiographers nurses, RP officer Physicist ...</b>	<b>Many differences from 0 To "hard" constraints</b>	<b>No rational Lots of differences</b>
<b>France</b>	<b>2</b>	<b>Outpatients</b>	<b>Yes</b>			
<b>Germany</b>	<b>2</b>	<b>2</b>	<b>Yes</b>			
<b>Ireland</b>	<b>4</b>	<b>Outpatients</b>	<b>Yes</b>			
<b>Lithuania</b>	<b>Depending on patient</b>	<b>Outpatients (400MBq)</b>	<b>Yes</b>			
<b>Latvia</b>	<b>Depending on patient</b>	<b>-</b>	<b>Yes</b>			
<b>Norway</b>	<b>2</b>	<b>Outpatients</b>	<b>Yes</b>			
<b>Romania</b>	<b>7</b>	<b>4</b>	<b>Yes</b>			