



Survey results on lutetium 177 use

Question to ERPAN
July 2014





Question from ASN to ERPAN

July 2014

Context

Lutetium 177 could soon be used by nuclear medicine departments in routine operation in France.

2 questions

- What are the **justification** arguments used in particular pursuant to Article 55 of Directive 2013/59/Euratom Council of 5 December 2013 which requires that "[...] Member States shall ensure that [...] **new types of practices involving medical exposure are justified in advance before being generally adopted** [...]. "
- What are the **radiation protection measures** required to nuclear medicine users, including : radiation protection measures for workers and patients, use of activity meters, waste and effluent management (^{177}Lu and $^{177\text{m}}\text{Lu}$) and detection of contamination ?





Question from ASN to ERPAN July 2014

- **5 answers** : Sweden, Belgium, Swizerland, Luxembourg and Czech Republic
- **Lu-177 is used in 2 countries Sweden and Belgium**





Answer from Sweden

Justification

Lu-177 is used at three university hospitals.

It has been used since 2005 and 378 administrations were done in 2012.

At least four thesis about dosimetry and therapy procedures have been written.

The process for introducing Lu-177 in nuclear medicine does not differ from any other radiopharmaceutical.

The use has to be approved by the Medical Products Agency either as a marketing license or for research purposes.

In Sweden any use of radiation on humans for research has to be approved by an **ethics committee** after the local radiation protection committee has judged dosimetry protocols and patient information.

Radiation protection measures

Laboratory work and routines for patient administration are **the same for all radiopharmaceuticals.**



Answer from Belgium

Justification

Justification from the radioprotection point of view **by the Superior Health Council (August 2012)**, including the following specific recommendations : **hospitalization** of patients until the dose rate is less than $20 \mu\text{Sv} / \text{h}$ at one meter distance ($10 \mu\text{Sv} / \text{h}$ for some people close)

Radiation protection measures (1)

- As to our knowledge, mostly pure Lu177 is used. Although this is more expensive for procurement of the product, it limits the amount of radioactive waste, because one can make more use of the decay-storage principle
- All radiation protection measures need to be approved by an authorised inspection organisation
- The rooms for treatment with Lu177 need to be specified



Answer from Belgium

Radiation protection measures (2)

- **Specific training for medical personnel** with respect to the applicable procedures
- **Measures to avoid dispersion** of the radioactive material
- The **limits for release** of radioactive material need to be respected
- All exposures for medical purposes need to be performed under the **responsibility of a physician** who received a specific authorisation.
- **The patient receives specific information and instructions before leaving the hospital**, according to the recommendation of the Superior Health Council and a measurement, performed by a dedicated person has to be done before patient release
- There has to be a **specific dosimetry for the patient**
- The presence/availability of an **expert in medical radiophysics** required
- Adequate **quality Control** of the pharmaceutical product



Answer from Switzerland

Justification

None of the radiopharmaceuticals containing ^{177}Lu are presently authorized in Switzerland.

A part of the application form for **clinical trials** and **compassionate use** deals with the justification of the use of the new product (discussion of **profite/risk, advantages with respect to alternative methods**).

Radiation protection measures

Regarding the radiation protection measures, the **requirements** for radiopharmaceuticals containing ^{177}Lu are **-unspecifically-** defined in 3 decrees : decree on radiation protection, decree on the use of unsealed radioactive sources (limits) and decree on instruments for measuring ionizing radiation



Answer from Luxembourg and Czech Republic

No use of ^{177}Lu





French recommendations September 2014

Lutetium 177 is used in **clinical trials** and shortly in **compassionate use** : the Ethics Committee has to assess the justification.

Procedures and documents (**risk analysis, workstation studies, training, appropriate radiation protection equipment...**) should be updated following the use of Lutetium 177, like for each new radionuclide. The license needs to be updated by ASN.

Specific requirements for **effluent management** :

- If the radiopharmaceutical is excreted in urine (for example Lutathera[®]), the patient is **hospitalized** in a room designed for treatment with iodine 131. In this room, the toilet (urine) is connected to dedicated tanks. The tanks can be discharged after checking that the **limit of 100 Bq/L** is respected.



French recommendations September 2014

Specific requirement for **waste management** (2) :

- In France, a radionuclide that has a half-life greater than 100 days has specific management rules. Waste must be sent to a dedicated storage place and authorized by the ASN.. There is no threshold of exemption

- **$T_{1/2}$ lutetium 177m = 160 days**

Exceptionally for clinical trials (small number of patients), the nuclear medicine department can manage its wastes as household waste

- An impact assessment is carried out by IRSN

