Australian Government

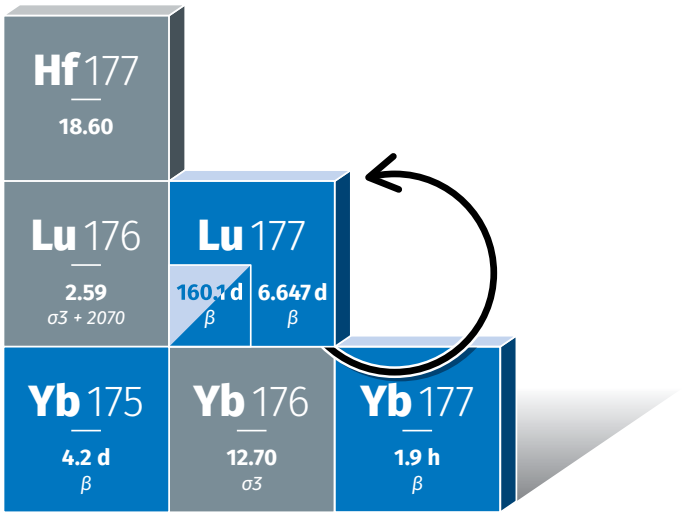
ANSTO

Non-carrier added **Lutetium Chloride (n.c.a. Lu-177)**

Science. Ingenuity. Sustainability.

GMP non-carrier added Lutetium-177

Non-carrier added (n.c.a.) Lu-177 is emerging as a radioisotope of choice for targeted radionuclide therapy due to its ideal parameters for therapy and minimal waste management requirements.



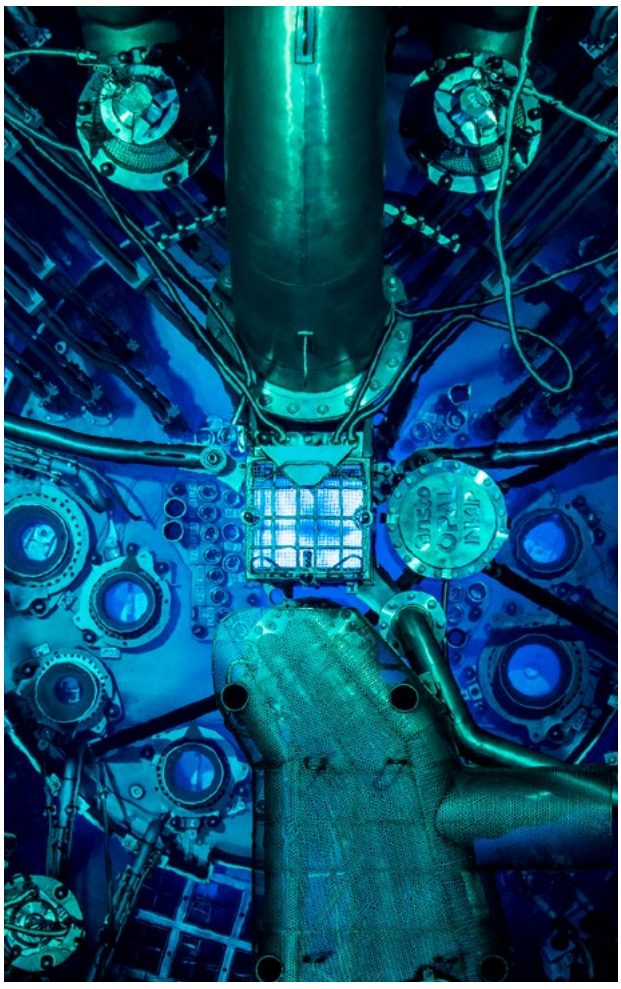
n.c.a. Lu-177 is a medium-energy β-emitter (E_{max}=0.498 MeV) with maximal tissue penetration of 2 mm, which results in the efficient deposition of the energy in tumour lesions and minimises damage to surrounding healthy tissue.

Additionally, it emits low-energy γ-rays which allow scintigraphy and subsequent dosimetry with the same therapeutic compound, making n.c.a Lu-177 a theranostically desirable radioisotope.

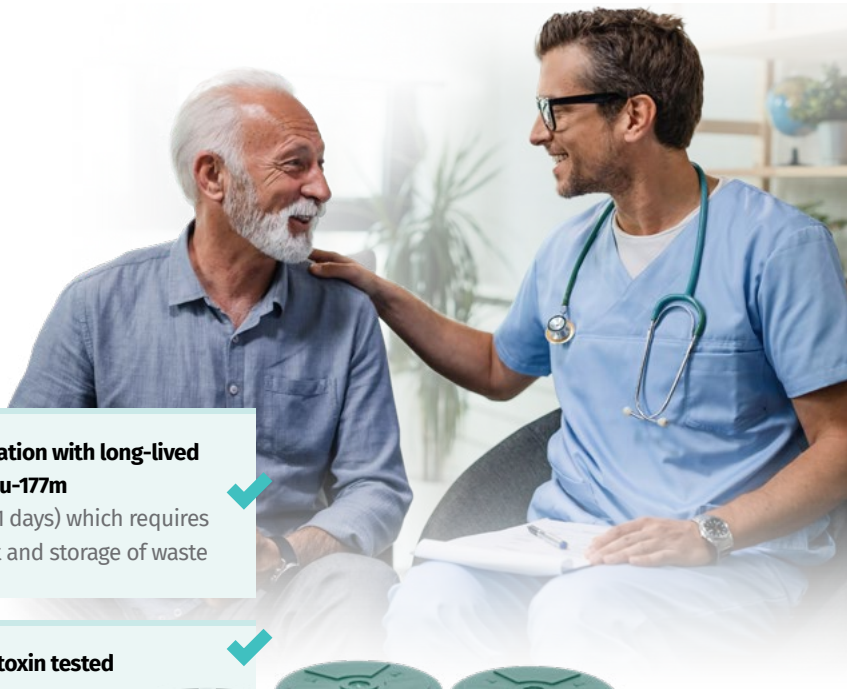
ANSTO's n.c.a. Lu-177 is manufactured to Good Manufacturing Practice (GMP) standards and utilises highly enriched ytterbium-176 as a starting material.

This provides the highest specific activity and radionuclidic purity and a non-carrier added product that is suitable for radiolabelling biomolecules, such as peptides and antibodies.

There is an additional benefit in that no long-lived metastable Lu-177m is co-produced during the manufacturing process, thereby reducing significant radioactive waste storage and disposal issues.



ANSTO's OPAL multi-purpose reactor.



Key advantages

Specific activity of 4-5 times higher than carrier added Lu-177
which offers preconditions for an efficient radiolabelling reaction

No contamination with long-lived metastable Lu-177m
(half-life 160.1 days) which requires management and storage of waste

Significantly longer shelf-life

Sterile, endotoxin tested

ANSTO has additional arrangements in place for security of supply

Lutetium Chloride (Lu-177)

Product Specifications

Element	**Lutetium**
Nuclide	**Lu-177**
Half-life	**6.647** days
Main mode of decay	**Beta**
Decay energy	E_{max} = **0.498** MeV
Chemical form	$LuCl_3$
Diluent	**0.04M HCl** solution
Activity concentration	**20 - 200** GBq/mL *at customer calibration*
Activity	**10 - 50** GBq per vial
Specific activity	**Refer to Certificate of Analysis** (COA)
Packaging	**2 mL V vial,** stoppered and crimp capped

Purity, Release and Storage

PARAMETER	VALUE
Radionuclidic purity	**≥ 99.9%** Lu-177 **≤ 0.07%** Lu-177m **≤ 0.1%** Yb-175 **≤ 0.01%** Total others *at product expiry*
Radiochemical purity	**≥ 99%** $^{177}Lu^{3+}$
Radiolabelling yield	**(^{177}Lu Dotate) ≥ 99%**
Chemical purity	**≤ 1 µg/GBq** Copper **≤ 0.5 µg/GBq** Iron **≤ 0.5 µg/GBq** Lead **≤ 1.0 µg/GBq** Zinc *at product expiry*
Sterility	**Sterile** (autoclaving)
Bacterial endotoxins (LAL)	**< 175 EU/dose**
Storage	**Room temperature**
Product expiry	**14 days** from production

Lutetium-177 is a radioisotope.

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