



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

## Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions

### Licence Number:

MI-03122004-LI-000275-1

### Granted to:

Australian Nuclear Science and Technology Organisation  
ABN: 47 956 969 590

### Manufacturing Site Address:

Building 23D New Illawarra Road  
LUCAS HEIGHTS NSW 2234

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

- Manufacturing authorisations are limited to Gamma irradiation using Cobalt-60 as the source.
- For the manufacture of Medicines and Human Tissues:
  - This licence requires that the licence holder maintain records of the validation of each process and, if relevant, the requirements of the Product marketing Authorisation. ANSTO is required to maintain records that links them as an approved service provider for the treatment step of a product manufacturing process. An evidentiary record that details suitability of the irradiation process, or equivalent, must be obtained from the product sponsor and filed, prior to undertaking the treatment of goods.

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production: Allan Perry

Quality Control: Justin Bryan Davies

**Originally Granted: 10 February 1993**

**Date Revised: 10 August 2023**

This licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.  
This licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.  
The status of an Australian licence may be viewed at <https://www.ebs.tga.gov.au/>