



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

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

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	All Dosage Forms	Registered Therapeutic Good	Sterilization - Gamma Irradiation
Medical Device	Sterile	Not Applicable	Not Applicable	Sterilization - Gamma Irradiation
Human Tissue	Sterile	Not Applicable	Not Applicable	Sterilization - Gamma Irradiation
Human Tissue	Non Sterile	Not Applicable	Not Applicable	Irradiation

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

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/>



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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

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