

SPECIFICATION OF GMP RESPONSIBILITIES AS DEFINED BY THERAPEUTIC GOODS ACT 1989		
ITEM	ANSTO	CUSTOMER
1. Nomination of critical processing parameters:- minimum dose, maximum dose and temperature requirements	No	Yes
2. Delivery of absorbed radiation dose	Yes	No
3. Notification of handling and storage precautions of hazardous material	No	Yes
4. Selection and validation of sterilising dose	No	Yes
5. Listing and/or registration of therapeutic goods	No	Yes
6. Approval from Therapeutic Goods Administration to sell therapeutic goods or therapeutic devices	No	Yes
7. Product/packaging specification and qualification	No	Yes
8. Installation qualification	Yes	No
9. Process qualification	To standard ANSTO packaging	To client specific packaging
10. Preparation of irradiation process specification	Yes	No
11. Designation of permitted holding periods	No	Yes
12. Integrity of reprocessed materials (reprocessing may diminish stability, utility and safety of products or materials)	No	Yes
13. Placement of radiation-sensitive labels (visual indicators for minimum 25 kGy only)		
13.1 on goods inside container	No	Yes, if required
13.2 on outside of container	Yes	No
14. Dosimetric monitoring and calibration of irradiation process	Yes	No
15. Calibration of dosimeters with traceability to national standard	Yes	No
16. Microbiological indicators, placement, recovery and testing	No	Yes, if required
17. Product quality control	No	Yes
18. Product release	to client	for sale and distribution
19. Product bioburden, sterility and pyrogen testing	No	Yes
20. Maintenance of irradiation and dosimetry records	Yes	No
21. Retention samples of materials and products	No	Yes
22. Investigation of complaints	Irradiation only	All other
23. Shipment specifications and compliance with regulatory safety practices	No	Yes
24. Notification of amendments to contract for irradiation processing. ANSTO will only process goods authorised by this contract	Yes	Yes