



Responsibilities under Agreement for Service Work

Attachment A

F-3656

RESPONSIBILITIES		
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 devices	No	Yes
7. Product/packaging specification and qualification	No	Yes
8. Preparation of irradiation process specification	Yes	No
9. Designation of permitted holding periods	No	Yes
10. Integrity of reprocessed materials (reprocessing may diminish stability, utility and safety of products or materials)	No	Yes
11. Placement of radiation-sensitive labels (visual indicators for minimum 25 kGy only) <ul style="list-style-type: none"> • on goods inside container • on outside of container 	No Yes	Yes, if required No
12. Dosimetric monitoring and calibration of irradiation process	Yes	No
13. Calibration of dosimeters with traceability to national standard	Yes	No
14. Microbiological indicators, placement, recovery and testing	No	Yes, if required
15. Product quality control	No	Yes
16. Product release	to client	for sale and distribution
17. Product bioburden, sterility and pyrogen testing	No	Yes
18. Customer job records <ul style="list-style-type: none"> a. Retention of electronic copies of customer job records for a minimum of 10 years, unless advised otherwise. b. Retention and disposal of original irradiation or dosimetry report. 	Yes No	No Yes
19. Maintenance of all other irradiation and dosimetry records	Yes	No
20. Retention samples of materials and products	No	Yes
21. Investigation of complaints	Irradiation only	All other
22. Shipment specifications and compliance with regulatory safety practices	No	Yes
23. Notification of amendments to contract for irradiation processing. ANSTO will only process goods authorised by this contract	Yes	Yes