APPENDIX 3R

LOT 18 SPECIFICATION
BRACHYTHERAPY SEEDS AND ASSOCIATED ACCESSORIES

1. Introduction

1.1. This Lot is for the supply of brachytherapy seeds and associated accessories including seeds supplied singularly or in strands and accessories used alongside and for the application of seeds, including but not limited to drapes, brachytherapy needles, brachytherapy grids and endocavity balloons.

1.2. The core line in this Lot is low dose rate brachytherapy seeds.

1.3. All product line(s) must be supplied to meet customer required implant date.

2. Low Dose Rate Brachytherapy Seeds

2.1. Low Dose Rate Brachytherapy seeds intended for permanent implantation to the tumour site of a patient supplied in single seeds or strands of seeds.

2.2. Seeds must have a diameter between 0.8mm and 1.2mm.

2.3. Seeds must have a length between 3.6mm and 5.4mm.

2.4. The active radionuclide used must be either I-125 or Pd-103 or Cs-131.

2.5. Seeds and strands must be supplied sterile and individually packaged for single use.

2.6. The Reference Air Kerma Rate and activity of the seeds must be appropriate for the intended use and must be specified by the provider in appropriate units.

2.7. The uncertainty of the reference air kerma rate shall be no greater than 8% with a coverage factor of 2 corresponding to 95% uncertainty (reference American Association of Physicists in Medicine (AAPM) Task Group 43).

2.8. Each seed or strand must be individually assayed in accordance to the updated AAPM Task Group 43 guidance with the calibration traceable to a nationally recognised primary standard.

2.9. Upon delivery a sealed source certificate including leak test certification for the radioactive source supplied must be provided to the customer.

2.10. Radioactivity must be uniformly distributed along the length of the seed.

2.11. The seeds and strands must be supplied sealed within shielding suitable for their level of radiation.

2.12. The seeds and strands must be resistant to corrosion:
  2.12.1. From common solvents before use.
  2.12.2. Once implanted in the patient.

2.13. Seeds must have validated source model for use within planning system.