

Supplementary Table S1. Failure modes and effects analysis (FMEA) spreadsheet

Process map: Installation and calibration of source Radioactive source installed New source calibrated	Process map: Insertion Patient prepared for treatment Patient anatomy assessed through physical examination and ultrasound Applicator inserted into patient	Process map: Imaging Patient transferred Patient imaged CT Patient imaged MRI	Process map: Treatment planning CT and MRI images fused for reconstruction Target areas and organs at risk outlined Applicator reconstruction Plan optimization Treatment planning finished Plan checking
Process map: Treatment delivery Patient transferred Patient treated Applicator removed from patient			

FMEA of HDR brachytherapy schedule

1. Creating of process map for each treatment step (above)
2. Listing of possible failure modes for HDR brachytherapy (table below), then additional failure modes adding for each sub-process. Also, listing of the possible effect of each failure mode
3. Estimation of the magnitude of some fault condition using the conventional tolerance as a representative value
4. Occurrence estimate: The frequency required is the failure rate if the fault was not being detected and corrected. Most faults are random, so detection rate = failure rate. Ranked 1-10 using 'Scoring table' derived from Table 2 in TG-100

Severity and detectability estimates

Severity estimate:

Estimate the severity of each failure mode and use the table in the 'Scoring table' tab to rank the severity from 1 to 10, assuming that all treatment scores are affected

Detectability estimate:

Estimate the probability of a fault going undetected over a typical treatment process. Use 'Scoring table' tab to rank from 1 to 10, depending on the probability of detection

Process	Step	Failure mode	Potential failure effects	Failure mode magnitude greater than	Safety checks in place
Installation and calibration of source	Source stick out	Malfunction afterloader (Flexitron)	Radiation exposure to engineer		Radiation monitoring and local rules
	Source integrity compromised	Malfunction of source and/or the cable	Radiation contamination exposure to engineer and environment		Radiation monitoring, local rules and wipe test
	Source alignment	Incorrect source alignment	Position uncertainty in dose distribution	1 mm	Daily QC
	Dwell time calibration	Incorrect dwell time	Underdose/Overdose	0.5 s per dwell position/2 s per treatment plan	Daily QC
	Incorrect RAKR measurement	Incorrect factors	Underdose/Overdose	2%	1st and 2nd RAKR measurements
		Incorrect temperature and air pressure	Underdose/Overdose	0.3%/degree; 0.5%/5 mbar	Ensure thermal equilibrium
		Fault in measuring equipment	Underdose/Overdose	2%	¹³⁷ Cs constancy check
	Incorrect source information in TPS	Incorrect source type	Incorrect dose distribution		TPS QC
	Incorrect transfer of RAKR to TPS	Incorrect data transfer	Underdose/Overdose	2%	TPS QC
	Incorrect decay correction from source certification	Calculation error (e.g., incorrect decay calculation equation)	Underdose/Overdose	0.04% per hour	1 st and 2 nd RAKR measurements/TPS QC
Insertion	Staffing	Theatre or anesthetist/Nursing/Dr availability	Unable to proceed if alternatives are not suitable	Alternative treatment date	Radiographer pre-treatment check, pre-treatment MDM
	Patient identification	Wrong patient	Unintended insertion		WHO surgical timeout, patient identification
	Applicator placement	Applicator unavailable	Unable to proceed if alternatives are not suitable	Alternative treatment date	Radiographer pre-treatment checks, sterilization pathway
		Incorrect applicator choice	Underdose		Plan review
		Different applicator recorded	Incorrect dose distribution		Physicist planning check/Applicator library
		Applicator not connected correctly	Position uncertainty in dose distribution		Physicist planning check/Applicator library
		Sub-optimal insertion	Incorrect dose distribution, Underdose/Overdose		Plan review
		Perforation of uterus	Incorrect dose distribution, Underdose/Overdose		Plan review
	Patient transfer	Applicator shift	Incorrect dose distribution	Organ-dependent (5-6% per mm for D _{2cc} and D _{0.1cc} in ant-post shift, 4% per mm in other direction)	Plan review
	Patient recovery	Patient changes position	Trauma		Nursing check
Imaging	Patient transfer	Applicator shift	Incorrect dose distribution	Organ-dependent (5-6% per mm for D _{2cc} and D _{0.1cc} in ant-post shift, 4% per mm in other direction)	Physicist planning check/Applicator library
	Patient identification	Wrong patient	Unintended imaging		Patient identification

**Treatment
planning**

Imaging	Incorrect patient orientation	Incorrect dose reporting		Physicist planning check
	Incorrect imaging acquisition	Imaging insufficient to plan	0.8 mm any point in a slice (CT slice thickness)	Radiographer imaging check/Physicist planning check
	Incorrect or missing marker wires	Incorrect applicator reconstruction	Organ-dependent (5-6% per mm for D _{2cc} and D _{0.1cc} in ant-post shift, 4% per mm in other direction)	Radiographer imaging check/Physicist planning check
	Poor image quality	Incorrect applicator reconstruction/Poor fusion/Incorrect voluming		Radiographer imaging check/Physicist planning check
Imaging export	Incorrect or lost data transfer	Unable to plan		Physicist planning check
Imaging import	Incorrect or lost data transfer	Unable to plan		Physicist planning check
Co-registration and fusion	Fusion of images from different patients	Incorrect dose distribution/Incorrect dose reporting	5-10% (OAR)	Physicist planning check
	Incorrect fusion	Incorrect dose distribution/Incorrect dose reporting	Registration error, 1.8 mm	Physicist planning check
Voluming	Incorrect target volume delineation	Incorrect dose distribution, Underdose/Overdose	9% (inter-observer)	Doctor peer review
	Incorrect margin applied	Incorrect dose distribution, Underdose/Overdose		Doctor peer review/Physicist planning check
	Incorrect organ at risk delineation	Incorrect dose distribution, Underdose/Overdose	5-11% (inter-observer)	Doctor peer review
	Accidental contour change after Dr delineation	Incorrect dose distribution, Underdose/Overdose		Physicist planning check
Planning	Co-ordinate system origin	Incorrect dose reporting		Physicist planning check
	Incorrect applicator reconstruction	Incorrect dose distribution, Underdose/Overdose	Organ-dependent (5-6% per mm ant-post shift, 4% per mm in other direction)	Physicist planning check
	Incorrect needle reconstruction	Incorrect dose distribution, Underdose/Overdose	Organ-dependent (5-6% per mm ant-post shift, 4% per mm in other direction)	Physicist planning check
	Equipment documentation incorrect (needle labeling error)	Incorrect dose distribution, Underdose/Overdose		Physicist planning check/Plan review/Radiographer pre-treatment check
	Error in optimization	Incorrect dose distribution, Underdose/Overdose		Physicist planning check
	Incorrect data transfer	Incorrect dose distribution, Underdose/Overdose		Physicist planning check
	Incorrect dose calculation	Incorrect dose distribution, Underdose/Overdose	3% (HR-CTV D ₉₀)	Treatment planning system QC/Physicist planning check/Independent dose check
	Incorrect prescription	Underdose/Overdose		Physicist planning check
Plan review	DVH mismatch with EQD ₂ Gy spreadsheet	Incorrect dose reporting		Physicist planning check
Checking	Missed from checking	Incorrect dose distribution, Underdose/Overdose		

Treatment delivery

	Incorrect or failed independent dose check	Incorrect dose distribution, Underdose/Overdose	
Plan export	Incorrect or lost data transfer	Unable to treat	Radiographer pre-treatment check
Plan import	Incorrect or lost data transfer	Unable to treat	Radiographer pre-treatment check
Treatment preparation	Decay calculated incorrectly	Incorrect dose distribution, Underdose/Overdose	Radiographer pre-treatment check
Patient transfer	Applicator shift	Incorrect dose distribution	
Patient identification	Wrong patient	Unintended treatment	Radiographer pre-treatment check
Patient setup	Organ at risk change	Incorrect dose distribution, Overdose	10% (HR-CTV D ₉₀)
	Incorrect connection to applicator/afterloader	Incorrect dose distribution, Underdose/Overdose	Radiographer pre-treatment check/Machine interlock
Treatment	Unable to deliver treatment	No treatment given	
	Unreviewed plan or incorrect plan being delivered	Patient treated with Dr plan approval	Radiographer pre-treatment check
	Partial treatment delivery	Incorrect dose distribution, Underdose	
	Source stick	Incorrect dose distribution, Underdose/Overdose, unintended radiation exposure to patient and staff	Emergency procedure training
	Applicator removal	Trauma	Radiographer/Doctor check