Supplementary Table S2. Failure modes and effects analysis (FMEA) questionnaire

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

Process map - Treatmen

Patient transferred

Patient treated

Applicator removed from

FMEA of HDR brachytherapy schedule

1. Creating of process map for each treatment step (above)

Process	Step	Failure mode	Potential failure effects	Failure mode magnitude greater than	Safety checks in place	Likelihood of occurrence (1-10)	Likelihood of non-detection (1-10)	Severity (1-10)
Installation and calibration of source	Source stick out	Malfunction afterloader (Flexitron)	Radiation exposure to engineer		Radiation monitoring and local rules			
	Source integrity co	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 [1]	Daily QC			

	Dwell time calibrati	Incorrect dwell time	Underdose/Overdose	0.5 s per dwell position/2 s per treatment plan	Daily QC			
	Incorrect RAKR me	Incorrect factors	Underdose/Overdose	2% [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% [2]	^{137}Cs constancy check			
	Incorrect source inf	Incorrect source type	Incorrect dose distribution		TPS QC			
	Incorrect transfer o	Incorrect data transfer	Underdose/Overdose	2% [2]	TPS QC			
	Incorrect decay correction from source certification	Calculation error (e.g., incorrect decay calculation equation)	Underdose/Overdose	0.04% per hour	1st and 2nd 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 identificatio	Wrong patient	Unintended insertion		WHO surgical timeout, patient identification			

	Applicator placem	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) [3]	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) [3]	Physicist planning check/Applicator library			

	Patient identificatio	Wrong patient	Unintended imaging		Patient identification			
	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) [4]	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) [3]	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) [5]	Physicist planning check			
		Incorrect fusion	Incorrect dose distribution/Incorrect dose reporting	Registration error, 1.8 mm [6]	Physicist planning check			

Treatment planning	Voluming	Incorrect target volume delineation	Incorrect dose distribution, Underdose/Overdose	9% (inter-observer) [2]	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) [2]	Doctor peer review			
		Accidental contour change after Dr delineation	Incorrect dose distribution, un 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) [3]	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) [3]	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}) [2]	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					
		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			
Treatment delivery	Plan import	Incorrect or lost data transfer	Unable to treat		Radiographer pre-treatment check			
	Treatment preparat	Decay calculated incorrectly	Incorrect dose distribution, Underdose/Overdose		Radiographer pre-treatment check			

	Patient transfer	Applicator shift	Incorrect dose distribution					
	Patient identificatio	Wrong patient	Unintended treatment		Radiographer pre-treatment check			
	Patient setup	Organ at risk change	Incorrect dose distribution, Overdose	10% (HR-CTV D_{90}) [7]				
		Incorrect connection to applicator or afterloader	Incorrect dose distribution, Underdose/Overdose		Radiographer pre-treatment check/ Machine interlock			
	Treatment	Unable to deliver treatment	No treatment delivered					
		Unreviewed plan or incorrect plan 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			

References								

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