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MD Anderson Cancer Center
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Patient Safety in the Treatment Process

Applying TG-100 Methodology to SRS / SBRT

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Disclosures

AAPM Working Group on Prevention of Errors, Chair

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Clearly, we want to avoid patient harm.

We typically measure and respond to specific incidents of harm.

Can we do better?

Contents

Risk

Defining Risk

Risk is the likelihood a hazard causes harm to a patient.

What can go wrong?

How likely is it to go wrong?

What are the consequences if it goes wrong?

Risk Management

RT is adopting incident learning system (ILS)

- Reactive: identify after the fact, control only for the future
- Difficult to monitor low occurrence incidents

High risk industries identify, control and monitor hazards

Allows active management of the environment

- Manage the hazards that give rise to risk
- Create resilience for unexpected risks

Risk Assessment

Prospectively analyze hazards in a process.

For the RT treatment process, AAPM TG-100 uses:

- Process Mapping
- Failure Modes and Effects Analysis
- Fault Tree Analysis

Structured ways to prioritize risk and determine where to focus resources

SRS / SBRT is typically a complete course of radiation therapy (RT) delivered in 1 to 5 sessions (fractions).

SRS / SBRT requires greater precision and accuracy than conventionally fractionated RT => follow strict protocols for quality assurance (QA).

Published Guidance for Comprehensive QA

ACR–ASTRO Practice Parameter for the Performance of Stereotactic Body Radiation Therapy. Practice guidelines and technical standards. Reston, VA: American College of Radiology; 2014: 1-11.

ACR–ASTRO Practice Parameter for the Performance of Stereotactic Radiosurgery. Practice guidelines and technical standards. Reston, VA: American College of Radiology; 2014: 1-11.

Benedict SH, Yenice KM, Followill D, *et al*. Stereotactic body radiation therapy: the report of AAPM Task Group 101. *Med Phys*. 2010;37(8):4078-4101.

Keall PJ, Mageras GS, Balter JM, et al. The management of respiratory motion in radiation oncology report of AAPM Task Group 76. *Med Phys*. 2006;33(10):3874-3900.

Klein EE, Hanley J, Bayouth J, et al. Task Group 142 report: quality assurance of medical accelerators. *Med Phys*. 2009;36(9):4197-4212.

Solberg TD, Balter JM, Benedict SH, Fraass BA, Kavanagh B, Miyamoto C, Pawlicki T, Potters L, Yamada Y. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy. *Prac. Rad. Onc*. 2012; Mar 31;2(1):2-9.

“Central goal of patient safety is to avoid potential harm rather than compliance with systems and processes.”

Vincent C, Burnett S, Carthey J. The measurement and monitoring of safety. London: The Health Foundation. 2013 May 24;2013.

SRS / SBRT Process

Process Mapping

Visual illustration of the steps in a process

What is accomplished

How steps are related

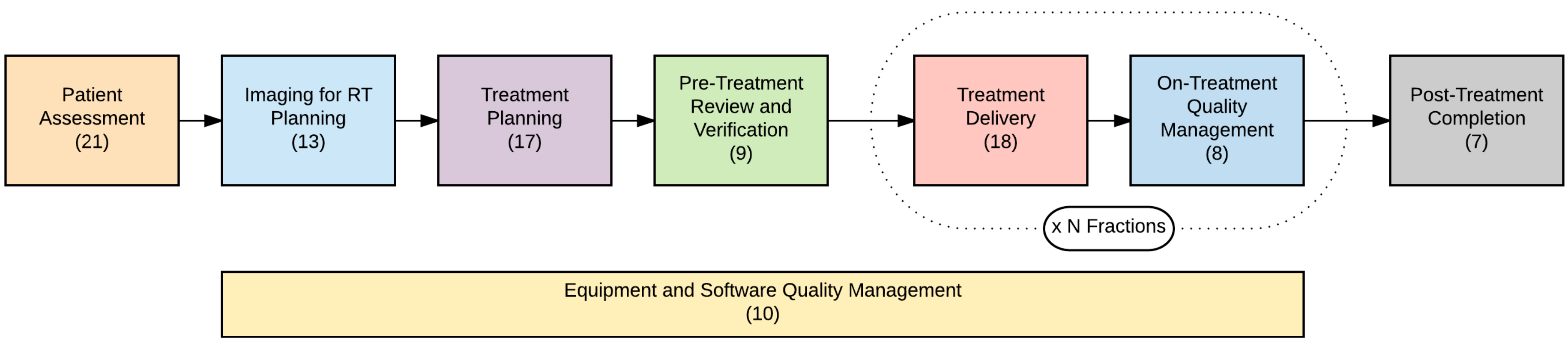
Process steps may be subdivided into sub-processes, and so on.

Generic SRS / SBRT Procedure

Imaging

Treatment Planning

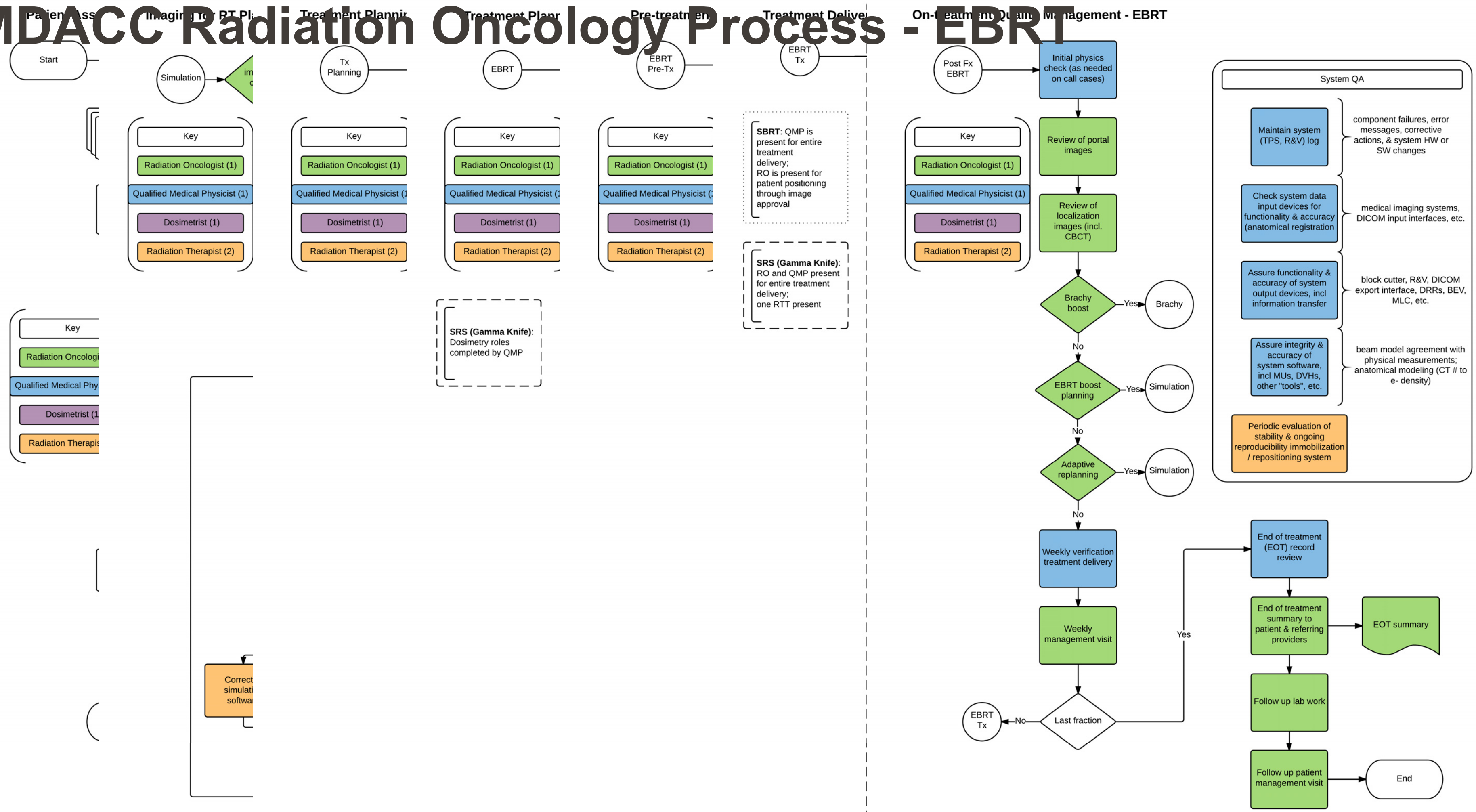
Dose Delivery



Adapted from Ford, E. C., *et al*. "Consensus recommendations for incident learning database structures in radiation oncology." *Medical physics* 39.12 (2012): 7272-7290.

Delivering modern external beam radiation therapy is not so simple.

MDACC Radiation Oncology Process - EBRT



Adapted from Ford, E. C., *et al*. "Consensus recommendations for incident learning database structures in radiation oncology." *Medical physics* 39.12 (2012): 7272-7290.

Failure Modes and Effects Analysis

Fault Tree Analysis

Failure Modes and Effects Analysis (FMEA)

Vocabulary:

- Failure mode: how a part or process can fail
- Cause: a deficiency that results in a failure mode; source of variation
- Effect: impact on a person if the failure mode is not prevented or corrected

A multidisciplinary team (experts) generate actual and potential risks (without QC)

Especially useful for high-risk processes

Structured approach that links failure modes to an effect

Failure Modes and Effects Analysis (FMEA)

Steps:

- Identify ways a sub-process (or product) can fail, both known & potential
- Determine each failure mode's causes & effects
  - Assign a number to most severe (S) effect

TABLE II. Descriptions of the O, S, and D values used in the TG-100 FMEA.

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

- Determine likelihood each failure mode's occurrence (O) & detection (D)
- Calculate risk priority number (RPN) = O x S x D

Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Failure Modes and Effects Analysis (FMEA)

Rank the RPN values (highest to lowest)

Pick the 3 failure modes with the highest RPN values and highest S values

- RPN ≥ 100
- S ≥ 7

Propose process changes that would decrease the probability of occurrence, O

Propose QC that would decrease the probability of un-detectability, D

Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Completing FMEA MDACC Exercise (2013)

Asked a multidisciplinary team to complete a survey

- For each of the sub-process steps
- Did not ask specific causes

Estimating Failure Mode Scores
In columns 2-4 of Table 1, use Table A (provided separately) to fill in your best estimate the following scores:
O = Occurrence. The likelihood the failure would occur. (1-10)
D = Detectability. The likelihood the failure would go undetected. (1-10)
S = Severity. The severity of the consequences of the failure. (1-10)
Again, imagine the worst case scenario. Consider each failure independently

- Team reviewed results together and agreed in general the RPN rankings
- Purpose for ILS action scale

Process Step	Process Grouping	Process step
1.1	1. Patient assessment	Verification of patient ID by two methods
1.2	1. Patient assessment	Diagnosis definition including imaging and outside records
1.3	1. Patient assessment	Review and verification of pathology report
1.4	1. Patient assessment	Physical exam
1.5	1. Patient assessment	Clinical staging
1.6	1. Patient assessment	Evaluation of patient medical conditions
1.7	1. Patient assessment	Evaluation of special needs for radiotherapy (e.g., pacemakers)
1.8	1. Patient assessment	Evaluation of previous RT (including treatment port images and planning records)
1.9	1. Patient assessment	Evaluation of other treatment modalities (i.e., chemo, surgery)
1.10	1. Patient assessment	Decision to treat
1.11	1. Patient assessment	Entering patient information into radiation oncology information system
1.12	1. Patient assessment	Selection of clinical protocol
1.13	1. Patient assessment	Selection of clinical trial (if any)
1.14	1. Patient assessment	Patient consent
1.15	1. Patient assessment	Patient education
1.16	1. Patient assessment	Insurance evaluation
1.17	1. Patient assessment	Peer review of treatment decision (e.g., tumor board / chart rounds)
1.18	1. Patient assessment	Fiducial placement
1.19	1. Patient assessment	Evaluation/ordering of workup for IV contrast
1.20	1. Patient assessment	Social work and nutrition assessment
2.1	2. Imaging for RT planning	Verification of patient ID
2.2	2. Imaging for RT planning	Imaging decision (type and technique)
2.3	2. Imaging for RT planning	Physician directive for imaging technique and immobilization
2.4	2. Imaging for RT planning	Patient positioning
2.5	2. Imaging for RT planning	Construction of immobilization and ancillary devices
2.6	2. Imaging for RT planning	Documentation of patient positioning and immobilization and ancillary devices
2.7	2. Imaging for RT planning	Contrast administration
2.8	2. Imaging for RT planning	Primary image acquisition (CT)
2.9	2. Imaging for RT planning	Marking reference point on patient and/or localization device and in software
2.10	2. Imaging for RT planning	Utilization of other imaging modalities (i.e., MRI, US, PET)
2.11	2. Imaging for RT planning	Transfer of images to treatment planning system
2.12	2. Imaging for RT planning	Transfer of images to archiving system
3.1	3.Treatment planning	Registration of image sets
3.2	3.Treatment planning	Delineation of target(s)
3.3	3.Treatment planning	Delineation of organs-at-risk
3.4	3.Treatment planning	Preliminary prescription parameters, constraints & technique (i.e., physician intent)
3.5	3.Treatment planning	Physics consult
3.6	3.Treatment planning	Isocenter definition
3.7	3.Treatment planning	Dose distribution optimization
3.8	3.Treatment planning	Dose distribution calculation
3.9	3.Treatment planning	Preliminary evaluation of treatment plan by physicist
3.10	3.Treatment planning	Preliminary evaluation of treatment plan by physician
3.11	3.Treatment planning	Iteration of treatment plan
3.12	3.Treatment planning	Set up for image-guidance/motion management
3.13	3.Treatment planning	Final plan and prescription approval by physician
3.14	3.Treatment planning	Plan information transfer to radiation oncology information system
3.15	3.Treatment planning	Scheduling treatment session(s)
3.16	3.Treatment planning	Archiving of the treatment plan (images, RT dose and RT structures)

7.1	7. Post-treatment completion	Verification of patient ID
7.2	7. Post-treatment completion	Final chart check
8.1	8. Equipment and software quality management	Acceptance testing
8.2	8. Equipment and software quality management	Commissioning
8.3	8. Equipment and software quality management	Application/system training
8.4	8. Equipment and software quality management	Ongoing quality management (e.g., daily, monthly, annual QA, etc.)
8.5	8. Equipment and software quality management	Preventive maintenance (PM)
8.6	8. Equipment and software quality management	Equipment repair and software changes/updates
8.7	8. Equipment and software quality management	Post-repair/changes verification
8.8	8. Equipment and software quality management	Documentation of quality management
8.9	8. Equipment and software quality management	Respond to medical device alerts

Completing FMEA
Treatment Planning – O, D, S

Process step	O ave	D ave	S ave	O*D*S
Registration of image sets	4.0	4.4	6.5	113.8
Delineation of target(s)	4.5	4.6	9.3	194.3
Delineation of organs-at-risk	3.6	3.8	8.5	115.5
Preliminary prescription parameters, constraints & technique (i.e., physician inte	4.6	3.8	6.5	112.7
Physics consult	3.8	4.4	3.8	62.9
Isocenter definition	4.6	3.3	7.7	115.2
Dose distribution optimization	3.5	4.1	6.3	91.4
Dose distribution calculation	3.5	3.5	7.7	93.9
Preliminary evaluation of treatment plan by physicist	4.1	4.4	5.3	96.3
Preliminary evaluation of treatment plan by physician	3.9	4.4	6.7	113.0
Iteration of treatment plan	3.9	4.0	5.2	80.1
Set up for image-guidance/motion management	4.3	4.1	5.7	99.3
Final plan and prescription approval by physician	4.0	3.0	5.8	70.0
Plan information transfer to radiation oncology information system	4.4	3.5	7.3	112.3
Scheduling treatment session(s)	4.4	3.5	5.0	76.6
Archiving of the treatment plan (images, RT dose and RT structures)	3.3	4.5	2.8	41.4

Completing FMEA
MDACC Exercise (2013) Calculating RPN

Process Step	Process Grouping	Process step	O ave	D ave	S ave	O*D*S
1.5	1. Patient assessment	Clinical staging	2.5	3.3	4.8	39.3
1.7	1. Patient assessment	Evaluation of special needs for radiotherapy (e.g., pacemakers)	4.3	3.5	6.0	89.3
1.8	1. Patient assessment	Evaluation of previous radiotherapy treatments (including treatment port images	3.4	4.5	6.0	91.1
1.9	1. Patient assessment	Evaluation of other treatment modalities (i.e., chemo, surgery)	3.0	3.0	4.7	42.0
1.11	1. Patient assessment	Entering patient information into radiation oncology information system	4.5	4.3	4.3	82.9
1.12	1. Patient assessment	Selection of clinical protocol	2.8	3.3	3.2	28.3
1.13	1. Patient assessment	Selection of clinical trial (if any)	3.4	3.6	2.8	34.7
1.14	1. Patient assessment	Patient consent	4.5	2.5	5.7	63.8
1.18	1. Patient assessment	Fiducial placement	3.8	3.9	5.8	84.8
1.19	1. Patient assessment	Evaluation/ordering of workup for IV contrast	4.0	4.5	4.2	75.0
2.1	2. Imaging for RT planning	Verification of patient ID	2.6	3.8	7.7	75.5
2.2	2. Imaging for RT planning	Imaging decision (type and technique)	3.5	4.6	3.0	48.6
2.3	2. Imaging for RT planning	Physician directive for imaging technique and immobilization	5.4	5.1	2.7	73.5
2.4	2. Imaging for RT planning	Patient positioning	4.0	5.9	6.2	144.9
2.5	2. Imaging for RT planning	Construction of immobilization and ancillary devices	3.3	5.4	3.0	52.4
2.6	2. Imaging for RT planning	Documentation of patient positioning and immobilization and ancillary devices	4.4	5.6	4.7	114.8
2.7	2. Imaging for RT planning	Contrast administration	3.6	4.4	4.7	74.0
2.8	2. Imaging for RT planning	Primary image acquisition (CT)	3.6	4.0	6.2	89.4
2.9	2. Imaging for RT planning	Marking reference point on patient and/or localization device and in software	4.3	4.8	6.5	131.2
2.10	2. Imaging for RT planning	Utilization of other imaging modalities (i.e., MRI, US, PET)	3.5	4.8	3.7	61.0
2.11	2. Imaging for RT planning	Transfer of images to treatment planning system	3.4	3.9	7.2	93.7
2.12	2. Imaging for RT planning	Transfer of images to archiving system	2.6	4.9	2.3	29.9
3.1	3.Treatment planning	Registration of image sets	4.0	4.4	6.5	113.8
3.2	3.Treatment planning	Delineation of target(s)	4.5	4.6	9.3	194.3
3.3	3.Treatment planning	Delineation of organs-at-risk	3.6	3.8	8.5	115.5
3.4	3.Treatment planning	Preliminary prescription parameters, constraints & technique (i.e., physician inte	4.6	3.8	6.5	112.7
3.5	3.Treatment planning	Physics consult	3.8	4.4	3.8	62.9
3.6	3.Treatment planning	Isocenter definition	4.6	3.3	7.7	115.2
3.7	3.Treatment planning	Dose distribution optimization	3.5	4.1	6.3	91.4
3.8	3.Treatment planning	Dose distribution calculation	3.5	3.5	7.7	93.9
3.9	3.Treatment planning	Preliminary evaluation of treatment plan by physicist	4.1	4.4	5.3	96.3
3.10	3.Treatment planning	Preliminary evaluation of treatment plan by physician	3.9	4.4	6.7	113.0
3.11	3.Treatment planning	Iteration of treatment plan	3.9	4.0	5.2	80.1
3.12	3.Treatment planning	Set up for image-guidance/motion management	4.3	4.1	5.7	99.3
3.13	3.Treatment planning	Final plan and prescription approval by physician	4.0	3.0	5.8	70.0
3.14	3.Treatment planning	Plan information transfer to radiation oncology information system	4.4	3.5	7.3	112.3
3.15	3.Treatment planning	Scheduling treatment session(s)	4.4	3.5	5.0	76.6
3.16	3.Treatment planning	Archiving of the treatment plan (images, RT dose and RT structures)	3.3	4.5	2.8	41.4

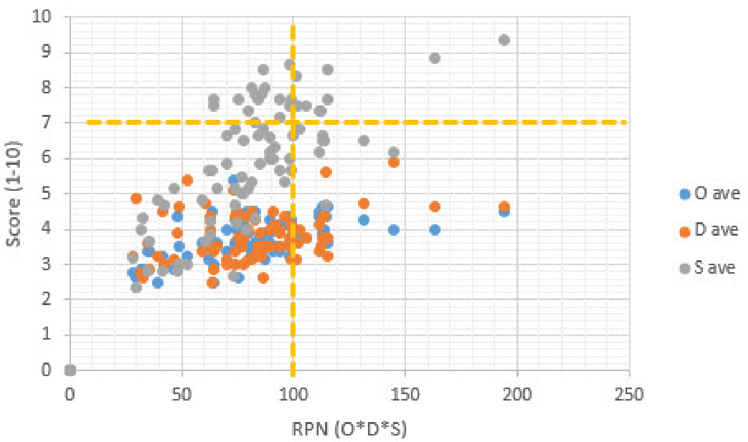
4.1	4. Pretreatment review and verification	Physics plan review	4.5	3.4	7.3	111.4
4.2	4. Pretreatment review and verification	Independent dose calculation	3.6	3.5	6.8	86.7
4.3	4. Pretreatment review and verification	Plan data transfer to treatment unit	3.1	3.5	8.0	87.5
4.4	4. Pretreatment review and verification	Verification of parameters at treatment unit	3.3	3.4	7.7	84.1
4.5	4. Pretreatment review and verification	Pretreatment patient specific plan measurement (e.g., IMRT QA)	3.6	3.5	6.7	84.6
4.6	4. Pretreatment review and verification	Physics verification/approval	3.8	4.0	6.8	102.5
4.7	4. Pretreatment review and verification	Physician plan peer review (e.g., chart rounds)	3.4	4.5	5.3	81.0
4.8	4. Pretreatment review and verification	Therapists chart check	3.6	3.4	4.8	59.1
5.1	5. Treatment delivery	Verification of patient ID	2.5	3.4	7.7	64.7
5.2	5. Treatment delivery	Time-out (e.g., verification of clinical parameters, treatment consent, etc.)	3.3	3.1	8.0	81.3
5.3	5. Treatment delivery	Prepare patient for treatment (medications, IV, anesthesia, sedation, etc.)	2.9	2.8	4.0	31.6
5.4	5. Treatment delivery	Selection of intended course/session	3.4	3.3	7.8	85.9
5.5	5. Treatment delivery	Plan information transfer to treatment unit	3.0	2.9	7.5	64.7
5.6	5. Treatment delivery	Selection of intended field	3.9	3.1	8.3	100.9
5.7	5. Treatment delivery	Patient positioning and immobilization	4.4	3.8	6.0	98.4
5.8	5. Treatment delivery	Setting treatment accessories and treatment unit parameters	3.8	3.6	7.5	102.0
5.9	5. Treatment delivery	Validation of treatment accessories and treatment unit parameters	3.8	3.8	7.5	105.5
5.10	5. Treatment delivery	Image-guided verification	4.0	3.0	6.5	78.0
5.11	5. Treatment delivery	Utilization of motion management system	4.3	3.4	5.2	74.1
5.12	5. Treatment delivery	Physician verification before treatment	4.0	3.5	5.5	77.0
5.13	5. Treatment delivery	In vivo dosimetry	2.9	2.6	4.3	32.7
5.14	5. Treatment delivery	Treatment delivery	3.9	2.6	8.5	86.5
5.15	5. Treatment delivery	Intratreatment monitoring	3.1	3.5	5.7	62.0
5.16	5. Treatment delivery	Record of treatment delivery	3.6	3.0	6.8	74.3
5.17	5. Treatment delivery	Monitor evaluation of special needs (e.g., pacemaker protocol)	4.4	4.1	6.2	111.3
6.1	6. On-treatment quality management	Initial physics check	3.4	3.1	6.7	70.3
6.2	6. On-treatment quality management	Review of portal images	4.1	3.1	7.7	98.8
6.3	6. On-treatment quality management	Review of localization images (including CBCT)	3.5	3.1	7.3	80.2
6.4	6. On-treatment quality management	Adaptive replanning	2.9	3.1	5.2	46.4
6.5	6. On-treatment quality management	Weekly physics chart check	4.1	4.0	5.7	93.5
6.6	6. On-treatment quality management	Weekly physician management visit, social work, nutrition and nursing	3.4	2.9	3.7	35.6
6.7	6. On-treatment quality management	Weekly therapist chart check	3.8	4.0	4.2	63.0
7.1	7. Post-treatment completion	Verification of patient ID	3.9	3.5	6.6	89.5
7.2	7. Post-treatment completion	Final chart check	4.4	3.9	2.8	48.0
8.1	8. Equipment and software quality management	Acceptance testing	3.3	3.3	7.8	82.7
8.2	8. Equipment and software quality management	Commissioning	3.3	3.5	8.7	98.6
8.3	8. Equipment and software quality management	Application/system training	4.1	3.8	5.0	77.3
8.4	8. Equipment and software quality management	Ongoing quality management (e.g., daily, monthly, annual QA, etc.)	3.6	3.3	7.0	82.5
8.5	8. Equipment and software quality management	Preventive maintenance (PM)	3.6	3.5	5.2	65.6
8.6	8. Equipment and software quality management	Equipment repair and software changes/updates	3.8	4.0	6.7	100.0
8.7	8. Equipment and software quality management	Post-repair/changes verification	4.0	4.6	8.8	163.4
8.8	8. Equipment and software quality management	Documentation of quality management	4.5	4.4	4.0	78.8
8.9	8. Equipment and software quality management	Respond to medical device alerts	3.6	3.6	7.5	98.6

Completing FMEA
MDACC Exercise (2013) Ranking RPN

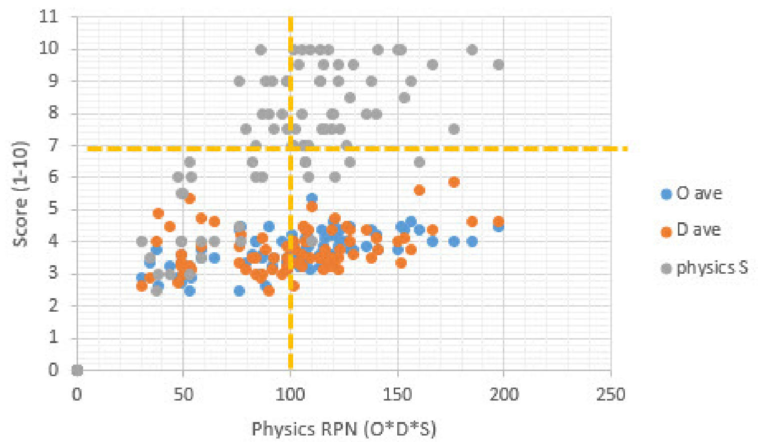
Process Step	Process Grouping	Process step	O ave	D ave	S ave	O*D*S	Process Group rank	Overall rank	
3.2	3.Treatment planning	Delineation of target(s)	4.5	4.6	9.3	194.3	1	1	
8.7	8. Equipment and software quality management	Post-repair/changes verification	4.0	4.6	8.8	163.4	1	2	
2.4	2. Imaging for RT planning	Patient positioning	4.0	5.9	6.2	144.9	1	3	
2.9	2. Imaging for RT planning	Marking reference point on patient and/or localization device and in software	4.3	4.8	6.5	131.2	2	4	
3.3	3.Treatment planning	Delineation of organs-at-risk	3.6	3.8	8.5	115.5	2	5	
3.6	3.Treatment planning	Isocenter definition	4.6	3.3	7.7	115.2	3	6	
2.6	2. Imaging for RT planning	Documentation of patient positioning and immobilization and ancillary devices	4.4	5.6	4.7	114.8	3	7	
3.1	3.Treatment planning	Registration of image sets	4.0	4.4	6.5	113.8	4	8	
3.10	3.Treatment planning	Preliminary evaluation of treatment plan by physician	3.9	4.4	6.7	113.0	5	9	
3.4	3.Treatment planning	Preliminary prescription parameters, constraints & technique (i.e., physician inte	4.6	3.8	6.5	112.7	6	10	***
3.14	3.Treatment planning	Plan information transfer to radiation oncology information system	4.4	3.5	7.3	112.3	7	11	
4.1	4. Pretreatment review and verification	Physics plan review	4.5	3.4	7.3	111.4	1	12	
5.17	5. Treatment delivery	Monitor evaluation of special needs (e.g., pacemaker protocol)	4.4	4.1	6.2	111.3	1	13	
5.9	5. Treatment delivery	Validation of treatment accessories and treatment unit parameters	3.8	3.8	7.5	105.5	2	14	
4.6	4. Pretreatment review and verification	Physics verification/approval	3.8	4.0	6.8	102.5	2	15	
5.8	5. Treatment delivery	Setting treatment accessories and treatment unit parameters	3.8	3.6	7.5	102.0	3	16	
5.6	5. Treatment delivery	Selection of intended field	3.9	3.1	8.3	100.9	4	17	
8.6	8. Equipment and software quality management	Equipment repair and software changes/updates	3.8	4.0	6.7	100.0	2	18	
3.12	3.Treatment planning	Set up for image-guidance/motion management	4.3	4.1	5.7	99.3	8	19	
6.2	6. On-treatment quality management	Review of portal images	4.1	3.1	7.7	98.8	1	20	
8.2	8. Equipment and software quality management	Commissioning	3.3	3.5	8.7	98.6	3	21	
8.9	8. Equipment and software quality management	Respond to medical device alerts	3.6	3.6	7.5	98.6	4	22	
5.7	5. Treatment delivery	Patient positioning and immobilization	4.4	3.8	6.0	98.4	5	23	
3.9	3.Treatment planning	Preliminary evaluation of treatment plan by physicist	4.1	4.4	5.3	96.3	9	24	***
3.8	3.Treatment planning	Dose distribution calculation	3.5	3.5	7.7	93.9	10	25	
2.11	2. Imaging for RT planning	Transfer of images to treatment planning system	3.4	3.9	7.2	93.7	4	26	
6.5	6. On-treatment quality management	Weekly physics chart check	4.1	4.0	5.7	93.5	2	27	
3.7	3.Treatment planning	Dose distribution optimization	3.5	4.1	6.3	91.4	11	28	
1.8	1. Patient assessment	Evaluation of previous radiotherapy treatments (including treatment port images	3.4	4.5	6.0	91.1	1	29	
7.1	7. Post-treatment completion	Verification of patient ID	3.9	3.5	6.6	89.5	1	30	***
2.8	2. Imaging for RT planning	Primary image acquisition (CT)	3.6	4.0	6.2	89.4	5	31	
1.7	1. Patient assessment	Evaluation of special needs for radiotherapy (e.g., pacemakers)	4.3	3.5	6.0	89.3	2	32	
4.3	4. Pretreatment review and verification	Plan data transfer to treatment unit	3.1	3.5	8.0	87.5	3	33	
4.2	4. Pretreatment review and verification	Independent dose calculation	3.6	3.5	6.8	86.7	4	34	
5.14	5. Treatment delivery	Treatment delivery	3.9	2.6	8.5	86.5	6	35	
5.4	5. Treatment delivery	Selection of intended course/session	3.4	3.3	7.8	85.9	7	36	
1.18	1. Patient assessment	Fiducial placement	3.8	3.9	5.8	84.8	3	37	***
4.5	4. Pretreatment review and verification	Pretreatment patient specific plan measurement (e.g., IMRT QA)	3.6	3.5	6.7	84.6	5	38	
4.4	4. Pretreatment review and verification	Verification of parameters at treatment unit	3.3	3.4	7.7	84.1	6	39	
1.11	1. Patient assessment	Entering patient information into radiation oncology information system	4.5	4.3	4.3	82.9	4	40	***

Completing FMEA
MDACC Exercise (2013) RPN vs. S

Divisional RPN



Physics RPN



Completing FMEA
MDACC Exercise (2013) RPN ≥ 100

Process step	O ave	D ave	S ave	O*D*S
Delineation of target(s)	4.5	4.6	9.3	194.3
Post-repair/changes verification	4.0	4.6	8.8	163.4
Patient positioning	4.0	5.9	6.2	144.9
Marking reference point on patient and/or localization device and in software	4.3	4.8	6.5	131.2
Delineation of organs-at-risk	3.6	3.8	8.5	115.5
Isocenter definition	4.6	3.3	7.7	115.2
Documentation of patient positioning and immobilization and ancillary devices	4.4	5.6	4.7	114.8
Registration of image sets	4.0	4.4	6.5	113.8
Preliminary evaluation of treatment plan by physician	3.9	4.4	6.7	113.0
Preliminary prescription parameters, constraints & technique (i.e., physician inte	4.6	3.8	6.5	112.7
Plan information transfer to radiation oncology information system	4.4	3.5	7.3	112.3
Physics plan review	4.5	3.4	7.3	111.4
Monitor evaluation of special needs (e.g., pacemaker protocol)	4.4	4.1	6.2	111.3
Validation of treatment accessories and treatment unit parameters	3.8	3.8	7.5	105.5
Physics verification/approval	3.8	4.0	6.8	102.5
Setting treatment accessories and treatment unit parameters	3.8	3.6	7.5	102.0
Selection of intended field	3.9	3.1	8.3	100.9
Equipment repair and software changes/updates	3.8	4.0	6.7	100.0

Completing FMEA
MDACC Exercise (2013) S ≥ 7

Process step	O ave	D ave	S ave	O*D*S
Delineation of target(s)	4.5	4.6	9.3	194.3
Post-repair/changes verification	4.0	4.6	8.8	163.4
Commissioning	3.3	3.5	8.7	98.6
Delineation of organs-at-risk	3.6	3.8	8.5	115.5
Treatment delivery	3.9	2.6	8.5	86.5
Selection of intended field	3.9	3.1	8.3	100.9
Plan data transfer to treatment unit	3.1	3.5	8.0	87.5
Time-out (e.g., verification of clinical parameters, treatment consent, etc.)	3.3	3.1	8.0	81.3
Selection of intended course/session	3.4	3.3	7.8	85.9
Acceptance testing	3.3	3.3	7.8	82.7
Isocenter definition	4.6	3.3	7.7	115.2
Review of portal images	4.1	3.1	7.7	98.8
Dose distribution calculation	3.5	3.5	7.7	93.9
Verification of parameters at treatment unit	3.3	3.4	7.7	84.1
Verification of patient ID	2.6	3.8	7.7	75.5
Verification of patient ID	2.5	3.4	7.7	64.7
Validation of treatment accessories and treatment unit parameters	3.8	3.8	7.5	105.5
Setting treatment accessories and treatment unit parameters	3.8	3.6	7.5	102.0
Respond to medical device alerts	3.6	3.6	7.5	98.6
Plan information transfer to treatment unit	3.0	2.9	7.5	64.7
Plan information transfer to radiation oncology information system	4.4	3.5	7.3	112.3
Physics plan review	4.5	3.4	7.3	111.4
Review of localization images (including CBCT)	3.5	3.1	7.3	80.2
Transfer of images to treatment planning system	3.4	3.9	7.2	93.7
Ongoing quality management (e.g., daily, monthly, annual QA, etc.)	3.6	3.3	7.0	82.5

Propose process changes to decrease likelihood of occurrence (O).

Propose quality control to decrease likelihood of un-detectability (D).

Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Fault Tree Analysis (FTA)

Evaluate the propagation of failures

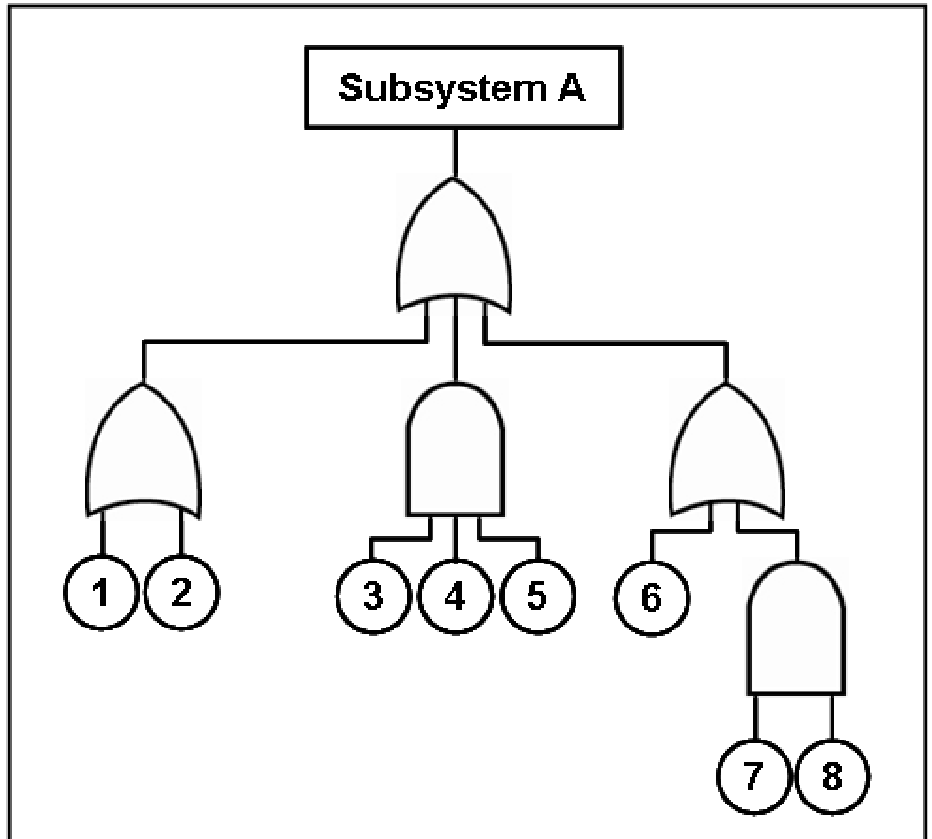
- Gives visual representation of propagation of a failure in the process
- Helps identify intervention strategies to mitigate the FMEA identified risks

Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Fault Tree Analysis (FTA)

Steps

- Define the undesired event
- Understand the system
- Construct the fault tree
- Evaluate the fault tree
- Control the identified hazards

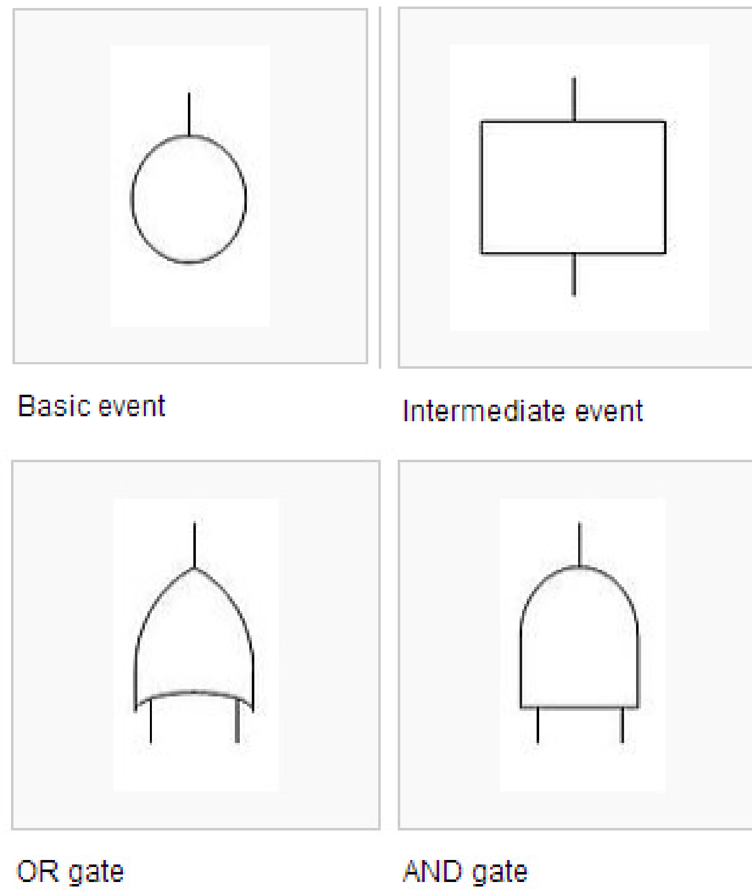


Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Fault Tree Analysis (FTA)

Events in a fault tree are associated with statistical probabilities

- AND gate probability of output:
  - P(A and B) = P(A∩B) = P(A) P(B)
- OR gate probability of output:
  - P(A or B) = P(AUB) = P(A) + P(B) - P(A∩B)



Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, Mutic S, Palta JR, Rath F, Thomadsen BR, Williamson JF. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics. 2016 Jul 1;43(7):4209-62

Utilization of Process Maps, FMEA, and FTA enable development of your Quality Management program.

Comprehensive QA Program
MDACC Exercise (2013) – Improvements in Progress

Immobilization and Simulation Devices	QMP, RO present
Treatment Planning System	**Committee review required prior release**
Treatment Delivery Unit	QMP peer review QA
Ancillary Systems for Imaging and Motion Management	**Improved engineering notifications**
Patient-specific Treatment Delivery Parameter Validation	**Improved SRS / SBRT treatment checklist**
	RTT time out process & checklist
Other – *RO Treatment Planning*	Dosimetry checklist
Other – *Treatment Delivery*	***RO Peer review***

Experience

Physics Contribution

International Journal of Radiation Oncology biology • physics
www.redjournal.org

Failure Mode and Effect Analysis for Delivery of Lung Stereotactic Body Radiation Therapy

Julian R. Perks, Ph.D., Sinisa Stanic, M.D., Robin L. Stern, Ph.D., Barbara Henk, R.N., M.S.N., Marsha S. Nelson, R.N., M.B.A., Rick D. Harse, R.T.T., Mathew Mathai, B.S., C.M.D., James A. Purdy, Ph.D., Richard K. Valicenti, M.D., M.A., Allan D. Siefkin, M.D., and Allen M. Chen, M.D.

University of California Davis Medical Center, Sacramento, CA

Received Mar 22, 2011, and in revised form Aug 29, 2011. Accepted for publication Sep 12, 2011

Table 2 Risk factors associated with particular treatment steps

Step in process	Failure mode	Likelihood of occurrence	Likelihood of detection	Severity	Risk priority number
Improper laser marking of patient	Patient alignment checked to ceiling laser when couch rotated	2	4	10	80
Automatic setup failure	Incorrect calibration of couch motors	1	7	10	70
CBCT scan isocenter misaligned	Difference with beam isocenter	1	6	10	60
Documentation of couch coordinates	Transcription error	2	2	10	40
Machine faults leading to interlocks	Loss of beam	5	1	8	40
Overly large CBCT shifts	Shifts should all be less than 1 cm	4	1	10	40
SBRT frame at isocenter	Transcription error in coordinates	2	1	10	20
Improper laser marking of patient, reassessed values after procedural changes	Patient alignment checked to ceiling laser when couch rotated	1	2	10	20
Incorrect CT data	If patient rescanned because of clinical change	2	1	10	20
Patient moves during treatment	Repositioning of patient	2	1	10	20

Abbreviations: CT = computed tomography; CBCT = cone-beam computed tomography.

Perks, J. R., Stanic, S., Stern, R. L., Henk, B., Nelson, M. S., Harse, R. D., ... & Chen, A. M. (2012). Failure mode and effect analysis for delivery of lung stereotactic body radiation therapy. *International Journal of Radiation Oncology* Biology* Physics, 83(4), 1324-1329.*

Experience

Physics Contribution

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International Journal of Radiation Oncology biology • physics

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CBCT isocenter misalignment
-> vigilent IGRT QA

Automatic setup failure -> frame agreement within 2 mm CBCT

Improper laser marking or transcription error for couch movements
-> instituted dry run to test need to translate patient away from iso

Patient movements during treatment -> considering infrared surface tracking

Instituted checklists

Reviewed staffing levels

Perks, J. R., Stanic, S., Stern, R. L., Henk, B., Nelson, M. S., Harse, R. D., ... & Chen, A. M. (2012). Failure mode and effect analysis for delivery of lung stereotactic body radiation therapy. *International Journal of Radiation Oncology* Biology* Physics, 83(4), 1324-1329.*

Experience

Original Report

Application of failure mode and effects analysis to intracranial stereotactic radiation surgery by linear accelerator

Laura Masini MD [a], Laura Donis MD [a], Gianfranco Loi PhD [b], Eleonora Mones PhD [b], Elisa Molina RT [a], Cesare Bolchini RT [a], Marco Krengli MD [a, c,*]

[a] *Department of Radiotherapy, University Hospital Maggiore della Carità, Novara, Italy*
[b] *Department of Medical Physics, University Hospital Maggiore della Carità, Novara, Italy*
[c] *Department of Translational Medicine, University of Piemonte Orientale, Novara, Italy*

www.practicalradonc.org

Table 2 Failure modes with the highest risk probability number (RPN) for which corrective measures were adopted

Step	Failure mode	Effect	S	O	D	RPN	Corrective measure
Preparation of the treatment room	Choice wrong collimator	Treatment of smaller or larger volume	9	4	5	180	Second check by a physician, a physicist, and a radiation therapist.
Localization with LTLF device with patient in treatment position	Wrong coordinates on LTLF device	Treatment of wrong location	9	3	5	135	Exportation isocenter data to the localization independent system: Vision RT
Contouring GTV and OARs	Wrong volume	GTV underdosage or OARs over dosage	7	2	5	70	Contours review
Clinical and radiologic documentation assessment	Exchange of clinical documentation and/or images	Wrong prescription	7	3	3	63	Cross-checks physician-nurse

D, detectability; GTV, gross tumor volume; LTLF, laser target localizer frame; O, occurrence; OARs, organs at risk; RPN, risk probability number; RT, radiation therapy, S, severity.

Masini, L., Donis, L., Loi, G., Mones, E., Molina, E., Bolchini, C., & Krengli, M. (2014). Application of failure mode and effects analysis to intracranial stereotactic radiation surgery by linear accelerator. *Practical radiation oncology, 4(6), 392-397.*

Experience

Original Report

Application of failure mode and effects analysis to intracranial stereotactic radiation surgery by linear accelerator

Laura Masini MD [a], Laura Donis MD [a], Gianfranco Loi PhD [b], Eleonora Mones PhD [b], Elisa Molina RT [a], Cesare Bolchini RT [a], Marco Krengli MD [a, c,*]

[a]*Department of Radiotherapy, University Hospital Maggiore della Carità, Novara, Italy*
[b]*Department of Medical Physics, University Hospital Maggiore della Carità, Novara, Italy*
[c]*Department of Translational Medicine, University of Piemonte Orientale, Novara, Italy*

Received 22 November 2013; revised 27 January 2014; accepted 29 January 2014

Wrong collimator selection

-> instituted bar code reader

Isocenter localization

-> utilize infrared surface tracking for independent localization system verification

Target and OAR contours -> contour peer review

RO consults similar patients -> cross-check clinical documentation

Training, roles & responsibilities

Scheduling of treatments

Masini, L., Donis, L., Loi, G., Mones, E., Molina, E., Bolchini, C., & Krengli, M. (2014). Application of failure mode and effects analysis to intracranial stereotactic radiation surgery by linear accelerator. *Practical radiation oncology, 4(6), 392-397.*

Experience

Changes perceptions of risk

Physics Contribution

Practical Implementation of Failure Mode and Effects Analysis for Safety and Efficiency in Stereotactic Radiosurgery

International Journal of Radiation Oncology biology • physics

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Kelly Cooper Younge, PhD,* Yizhen Wang, MS,* John Thompson, BS,[†] Julia Giovinazzo, BA,[†] Marisa Finlay, MD,[†] and Raxa Sankreacha, MS*

*Departments of *Department of Radiation Oncology, University of Michigan, Ann Arbor, Michigan and [†]Radiation Oncology, Trillium Health Partners - Credit Valley Hospital Site, Mississauga Halton/ Central West Regional Cancer Program, Mississauga, ON, Canada*

Received Oct 28, 2014, and in revised form Dec 4, 2014. Accepted for publication Dec 12, 2014.

Table 2 Presumed high-risk items before FMEA

Failure mode	S	O	D	RPN
Patient orientation incorrect on MRI	10	5	4.3	212.5
kV/CBCT isocenter out of tolerance	7.7	5.3	1.5	61
Incorrect jaw size used for treatment	10	2.5	2.3	56.3
Incorrect cone size used for treatment	8.8	2.3	2.3	44.3
Plan not completed on time	3.3	3.8	2.3	27.4

Abbreviations: CBCT = cone beam computed tomography; D = detectability; FMEA = failure mode and effects analysis; MRI = magnetic resonance imaging; O = occurrence; RPN = risk priority number; S = severity.

Table 3 Highest ranking failure modes for SRS

Failure mode	S	O	D	RPN
Patient moves during treatment	6.8	7	4.8	228
Patient orientation incorrect on MRI	10	5	4.3	212.5
Incorrect volumes in contours/variability in contouring	6.5	5.5	5.8	207
Mask does not immobilize sufficiently	7.5	7.3	3.5	192
Contours accidentally changed during review	7.3	3.5	6.3	161

Abbreviations: D = detectability; MRI = magnetic resonance imaging; O = occurrence; RPN = risk priority number; S = severity; SRS = stereotactic radiosurgery.

Younge, K. C., Wang, Y., Thompson, J., Giovinazzo, J., Finlay, M., & Sankreacha, R. (2015). Practical implementation of failure mode and effects analysis for safety and efficiency in stereotactic radiosurgery. *International Journal of Radiation Oncology* Biology* Physics, 91(5), 1003-1008.*

Experience

Physics Contribution

Practical Implementation of Failure Mode and Effects Analysis for Safety and Efficiency in Stereotactic Radiosurgery

Kelly Cooper Younge, PhD,* Yizhen Wang, MS,* John Thompson, BS,[†] Julia Giovinazzo, BA,[†] Marisa Finlay, MD,[†] and Raxa Sankreacha, MS*

*Departments of *Department of Radiation Oncology, University of Michigan, Ann Arbor, Michigan and [†]Radiation Oncology, Trillium Health Partners - Credit Valley Hospital Site, Mississauga Halton/Central West Regional Cancer Program, Mississauga, ON, Canada*

International Journal of Radiation Oncology biology • physics
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Received Oct 28, 2014, and in revised form Dec 4, 2014. Accepted for publication Dec 12, 2014.

Mask fitting -> monitor pre-treatment and post-treatment imaging

Patient orientation on MRI -> additional staff checks

Contours -> additional auto comparison of approved versus final plan

Contours -> mandatory peer review prior to treatment planning

Younge, K. C., Wang, Y., Thompson, J., Giovinazzo, J., Finlay, M., & Sankreacha, R. (2015). Practical implementation of failure mode and effects analysis for safety and efficiency in stereotactic radiosurgery. *International Journal of Radiation Oncology* Biology* Physics, 91(5), 1003-1008.*

Experience

Validating FMEA output against incident learning data: A study in stereotactic body radiation therapy

F. Yang,[a] N. Cao, L. Young, J. Howard, W. Logan, T. Arbuckle, P. Sponseller, T. Korssjoen, J. Meyer, and E. Ford
Department of Radiation Oncology, University of Washington Medical Center, Seattle, Washington 98195

(Received 16 November 2014; revised 8 March 2015; accepted for publication 12 April 2015; published 15 May 2015)

Criterion-based FMEA compared with incidents reported in ILS

-> 61% (20/33) identified by FMEA

->39% (13/33) not identified by FMEA

->Significantly lower RPNs

Table II. Failure modes and causes predicted by FMEA with RPN ≥ 150.

Failure mode/cause	Severity	Occurrence	Detectability	RPN
SBRT dose constraints not updated	8	7	6	336
Physicians give planning objectives to dosimetrists using a generic template that is not appropriate for the patient, e.g., objectives for patients receiving retreatment will differ.				
Contours not cleaned	7	6	8	336
Either physicians or dosimetrists forget to run the contour cleanup tool in TPS, causing extraneous or erroneous objects being encompassed in the finalized contours.				
Miscommunication about reirradiation cases	7	7	6	294
Physicians fail to inform dosimetrists with regard to the patient's RT history, resulting in possible reirradiation of anatomical sites that have been treated previously.				
Wrong scan protocol used	7	8	5	280
Patients are imaged with protocols deviating from what physician intends during simulation, e.g., wrong contrast injection protocols are used.				
Wrong primary image set	7	8	4	224
For 4D CT cases, an image set other than the designated primary image set (e.g., the averaged scan) is imported into TPS for planning.				
Wrong primary image set	7	5	6	210
Patients have multiple sets of images residing in TPS and a wrong image set is chosen as the primary for contouring and planning.				
Wrong trial sent to MQ	8	6	4	192
Multiple trials of the same treatment plan exist in TPS and a trial other than the one approved by physicians is transferred to the teletherapy units for treatment.				
Wrong OAR contours used	6	7	4	168
Multiple OAR contours exist in TPS without the finalized version being clearly labeled, leading to a wrong set of contour selected for use in treatment planning.				

Note: TPS = treatment planning system; RT = radiation therapy; MQ = MOSAIQ; OAR = organ at risk.

Yang, F., Cao, N., Young, L., Howard, J., Logan, W., Arbuckle, T., ... & Ford, E. (2015). Validating FMEA output against incident learning data: A study in stereotactic body radiation therapy. *Medical physics, 42(6), 2777-2785.*

Experience

16 / 91 steps surface imaging

25 / 167 had RPN >100

-> 1 related to surface imaging

Use systematic approach to FMEA (e.g., HAZOP or SHERPA)

Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery

Ryan P. Manger,[a)] Adam B. Paxton, Todd Pawlicki, and Gwe-Ya Kim
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(Received 13 November 2014; revised 22 March 2015; accepted for publication 4 April 2015; published

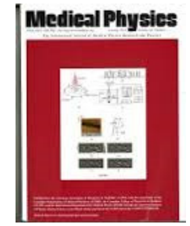


Table IV. Top ten failure modes ranked by RPN.

Rank	Step	Potential failure modes	Potential cause of failure	Potential effects of failure	O	S	D	RPN
1	31. Contour critical structures	Inaccurate contours	Poor image quality Poor registration Insufficient training	Excessive dose to critical structure	6	8	6	288
1	79. Apply CBCT couch shifts	Inaccurate CBCT–CT registration	Poor image quality Inattention.	Geometric miss	6	8	6	288
3	29. Previous tx CT registered to planning CT	Inaccurate CT–CT registration	Failed to save registration. Registration error	Retreat previous target.	5	8	7	280
4	39. Review OAR statistics	Critical structure doses not checked	Inattention	Excessive dose to critical structure	5	8	6	240
4	29. Previous tx CT registered to planning CT	Not done	Inattention	Retreat previous target	5	8	6	240
4	33. Insert Rx and contour target volumes	Contours accidentally changed by planner	Contours not locked	Underdosing of target volume	6	8	5	240
7	23. Images labeled with acquisition date and technique	Incorrect date label	Transcription error	May cause confusion and/or affect MD decision making	5	6	7	210
8	84. Monitor SIG indicated offsets to ensure patient position is within tolerance	SIG system fails to detect patient movement	SIG system failure	Geometric miss	3	8	8	192
9	59. Ensure SRS QA has been completed (Winston–Lutz, etc.) (P)	SRS QA not checked	Inattention	System out of tolerance	6	6	5	180
9	60. Ensure daily	IGRT QA not checked	Inattention	System out of tolerance	6	6	5	180

Manger, R. P., Paxton, A. B., Pawlicki, T., & Kim, G. Y. (2015). Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery. *Medical physics, 42(5), 2449-2461.*

Experience

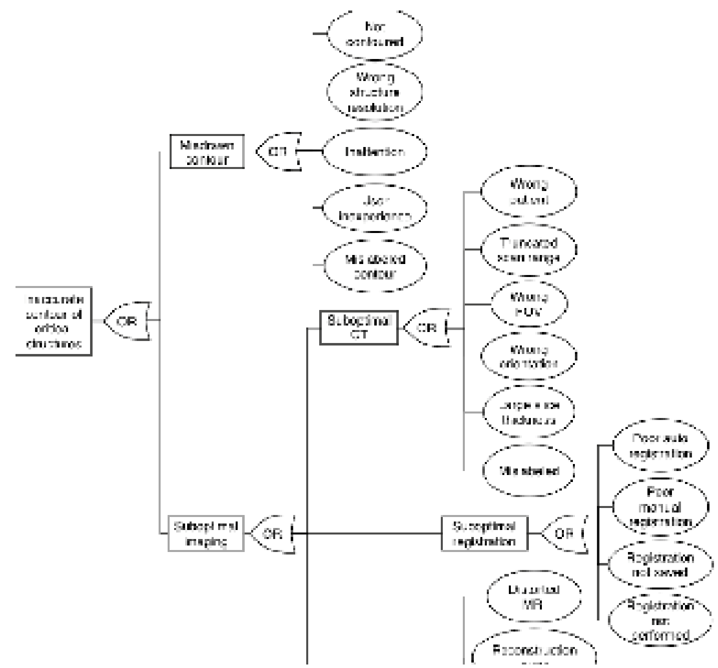
Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery

Ryan P. Manger,[a] Adam B. Paxton, Todd Pawlicki, and Gwe-Ya Kim
Department of Radiation Medicine and Applied Sciences, University of California, San Diego, La Jolla, California 92093 and Moores Cancer Center, 3855 Health Sciences Drive, La Jolla, California 92093

(Received 13 November 2014; revised 22 March 2015; accepted for publication 4 April 2015; published 20 April 2015)

TABLE V. Top five SIG-specific failure modes ranked by RPN.

Rank	Step	Potential failure modes	Potential cause of failure	Potential effects of failure	O	S	D	RPN
8	84. Monitor SIG indicated offsets to ensure patient position is within tolerance	SIG system fails to detect patient movement	SIG system failure	Geometric miss	3	8	8	192
26	84. Monitor SIG indicated offsets to ensure patient position is within tolerance	Not done	Inattention	Geometric miss	4	8	4	128
26	61. Ensure surface imaging cameras are within tolerance	Not checked	Inattention	System may be out of tolerance	6	4	4	96
26	84. Monitor SIG indicated offsets to ensure patient position is within tolerance	Not all metrics were monitored	Mental lapse	Patient position out of tolerance on the unmonitored axis	4	6	4	96
30	84. Monitor SIG indicated offsets to ensure patient position is within tolerance	SIG system indicates movement, yet patient did not move	SIG system isocenter drift	Prolong treatment to investigate movement	10	3	3	90



Manger, R. P., Paxton, A. B., Pawlicki, T., & Kim, G. Y. (2015). Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery. *Medical physics, 42(5), 2449-2461.*

Experience suggests Standardized Operating Procedures (SOPs) for major steps are critical to patient safety.

Safety Checklist
Medical Physics Practice Guideline 4.a

Role of checklists

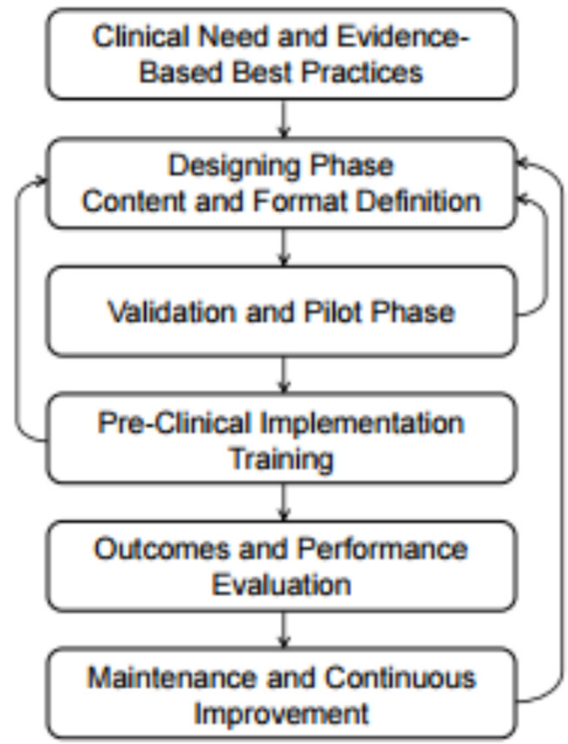
Organizational influences on checklists: safety culture

Teamwork is essential

Development & Implementation

Revision

Maintenance



de los Santos LE, Evans S, Ford EC, Gaiser JE, Hayden SE, Huffman KE, Johnson JL, Mechalakos JG, Stern RL, Terezakis S, Thomadsen BR. Medical Physics Practice Guideline 4. a: Development, implementation, use and maintenance of safety checklists. Journal of Applied Clinical Medical Physics. 2015 May 8;16(3).

Safety Checklist
Medical Physics Practice Guideline 4.a

Use of checklists

TABLE 1. Checklist approaches with corresponding redundancy strategies (i.e., initial configuration redundancy or mutual redundancy). The clinical examples provide situations or processes where these approaches can be utilized.

Checklist Approach	*Redundancy*	*Example*
Static parallel or call-do	None ("cook book" approach)	Procedure to set up a water tank
Static sequential with verification	Initial configuration	Plan check process
Static sequential with verification and confirmation	Initial configuration and mutual	SBRT procedural pause
Dynamic	Initial configuration, mutual or "cook book" approach	HDR emergency procedure

Design recommendations

- Content
- Workflow, layout & format
- Physical characteristics (e.g., font, text color, shading)

de los Santos LE, Evans S, Ford EC, Gaiser JE, Hayden SE, Huffman KE, Johnson JL, Mechalakos JG, Stern RL, Terezakis S, Thomadsen BR. Medical Physics Practice Guideline 4. a: Development, implementation, use and maintenance of safety checklists. Journal of Applied Clinical Medical Physics. 2015 May 8;16(3).

Safety Checklist Samples

Appendix 1 – Recommendations to Guard Against Catastrophic Failures in SRS and SBRT

Procedure and Tests	Principal	Primary Review	Secondary Review
1. Commissioning Treatment Devices and Planning Systems			
Machine output calibrations and factors in accordance with relevant guidelines (TG-51, TG-101, TG-142).	Physicist	2nd physicist	Independent assessment (RPC, etc.)
Treatment planning system commissioning should include test cases similar to those encountered in SBRT (TG-53).	Physicist	2nd Physicist	Physicists and Dosimetrists
2. Patient Selection			
Patient selection should be in accordance with an approved clinical protocol.	Physician	Physicians and Physicists	ALL
3. Patient Simulation			
Patient simulated in accordance with approved protocol (immobilization and respiratory management) and supervised by physician.	Simulation Therapist	Physician	Physicists and Dosimetrists
4. Patient Treatment Planning			
Verify the patient information, treatment site, and prescription.	Dosimetrist	Physician	All
Verify correct positioning of the high dose and intermediate regions of isodose plan relative to targets.	Dosimetrist	Physician	Physicist
Verify the reference images and any shift information - physician determines IGRT technique.	Dosimetrist	Physicist	ALL
5. Pre-Treatment Quality Assurance			
Verify that the correct version of the patient's treatment plan is approved, sent to treatment management system, and used for patient-specific QA.	Dosimetrist	Physicist	ALL
Perform a thorough chart review.	Therapist	Physicist	ALL
Perform a complete chart check including review of information in treatment management system, field apertures in treatment management system, and check of dose to verify TPS calculation.	Dosimetrist	Physicist	ALL
Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins.	Physicist	Physicist	ALL
6. Treatment Delivery			
Halt a procedure if the operator is unclear about what is being done.	ALL	ALL	ALL
Perform a check of treatment parameters before start of each treatment against a fixed version of the treatment plan.	Therapist	2nd Therapist	ALL
Perform a time out prior to treatment delivery.	Therapist	2nd Therapist	ALL
Assess patient clinically during course of SBRT to identify any acute effects	Physician, Therapist, and Nurse	Physician, Therapist, and Nurse	
7. Quality Performance and Improvement			
Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (annually and after any software or hardware changes)	Physicist	2nd Physicist	Physicists and Dosimetrists

Prostate SBRT Checklist

Patient ______
MR number ______

Simulation
Special immobilization device used? ☑ ☐
Rectal balloon used? ☐ ☑

Treatment Plan
Brainlab couch included: Y
Field ID in Pinnacle (A B C...): Y
Gantry angles (182, 178, 182): Y
DVHs ok: Y
Isocenter DICOM coord (mm): (x.xx yy.yy zzz.zz)
Bladder volume in CT (cc): ###

DVH Guidelines
PTV V100% (40Gy) > 95%
Rectum V100% (40Gy) < 5%
V90(36Gy) < 14%
V80(32 Gy) < 20%
V50(20 Gy)< 50%
Bladder V100% (40Gy) < 10%
V90(36Gy) < 15%
V80(32 Gy) < 20%
V50(20 Gy)< 40%
Femoral h V40 (16Gy) < 10%
Small bow V50 (20Gy) < 1%

Mosaiq
Prescription: stereotactic, every other d: Y
Beam time: 4 min Tolerance: SML(: Y
Reference CT structures & isocenter: Y

CAT Setup: Y

IMRT QA: Y

ExacTrac Setup
Isocenter coordinate checked: Y
Field ID, beam mapping: Y

Treatment Delivery	**Fraction 1**	**Fraction 2**	**Fraction 3**	**Fraction 4**	**Fraction 5**
Immbolization device used?	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N
Rectal balloon used?	☐ Y ☑ N	☐ Y ☑ N	☐ Y ☑ N	☐ Y ☑ N	☐ Y ☑ N
Bladder filling (cc with US)					
Bowel/sigmoid colon/rectum ok					
Special notes:					
Physicist present					
Date					
Setup approved by MD	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N	☑ Y ☐ N
Physician signature					
Date					

Solberg TD, Balter JM, Benedict SH, Fraass BA, Kavanagh B, Miyamoto C, Pawlicki T, Potters L, Yamada Y. Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy. *Practical Radiation Oncology*. 2012; Mar 31;2(1):2-9.

Program Monitoring Patient Safety

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Program Monitoring Patient Safety

Past Harm

- SafetyLink ILS
- Outcomes

Reliability

- Improved standardized protocols and guidelines

Sensitivity to Operations

- Daily Coms
- Team operation huddles

Anticipation and Preparedness

- Checklists
- Safety culture
- Staffing indicators (absence rates)

Integration and Learning

- Walk-rounds
- Patient surveys
- Chart audits, dashboards
- ILS and RCA

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