

Safety Systems Analysis of
Brachytherapy Using STPA:
A Case Study in Radiation Oncology

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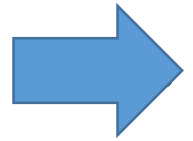
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Outline:

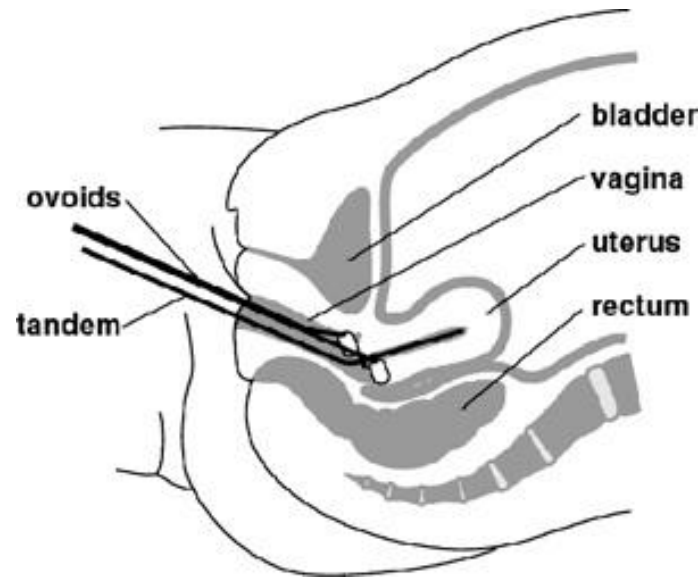


What is brachytherapy and how do I derive the control structure?

- Clinical workflow STPA Example: Analyzing a control action to develop a scenario.
- Management level STPA Example: Management influences on patient safety.

Our Case Study:

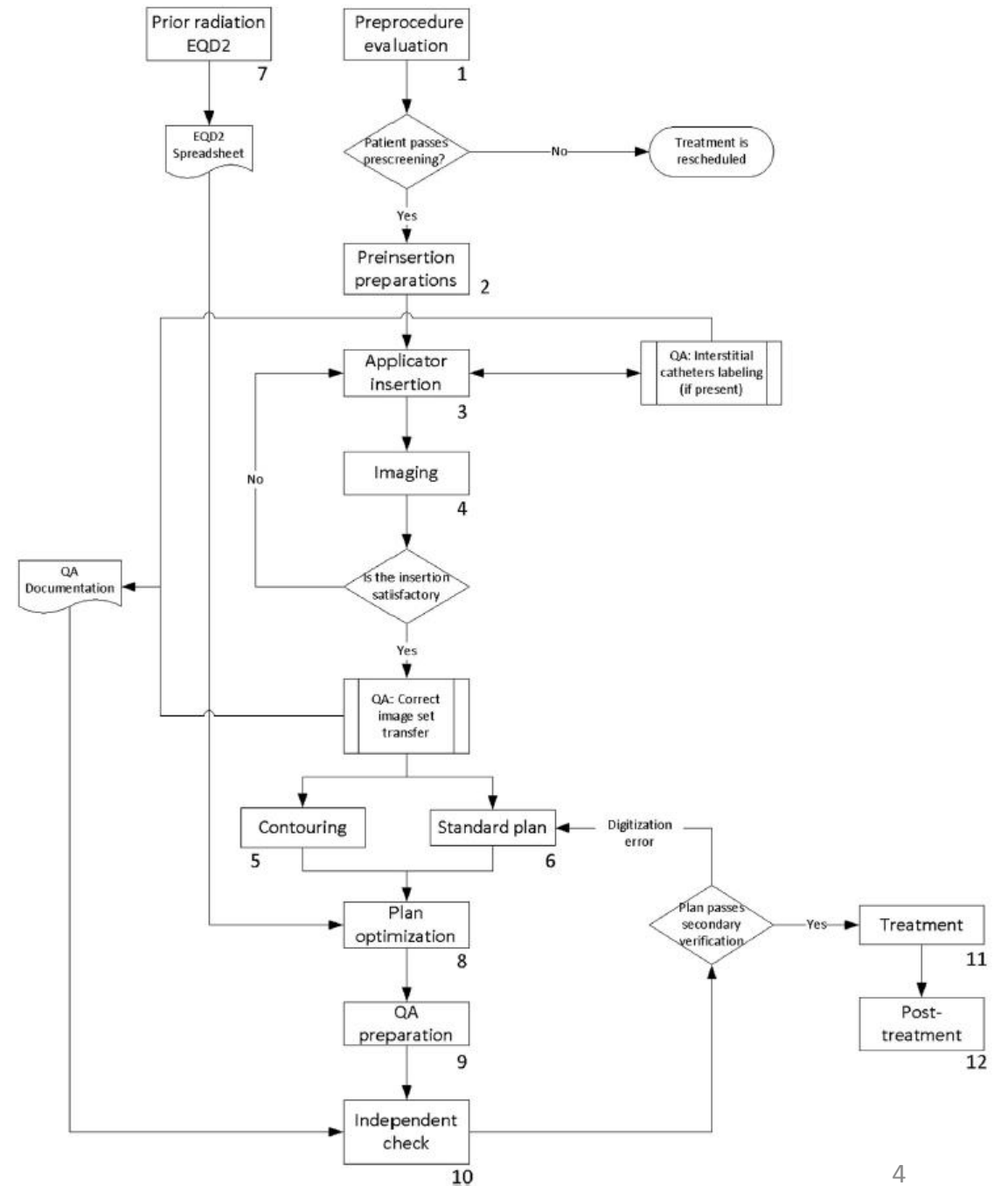
- Brachytherapy – An advanced cancer treatment where a High Dose Rate (HDR) radiation source is placed in or near a tumor.
- Observed cases of HDR Brachytherapy via Ring and Tandem applicator. A common procedure for patients with cervical cancer.

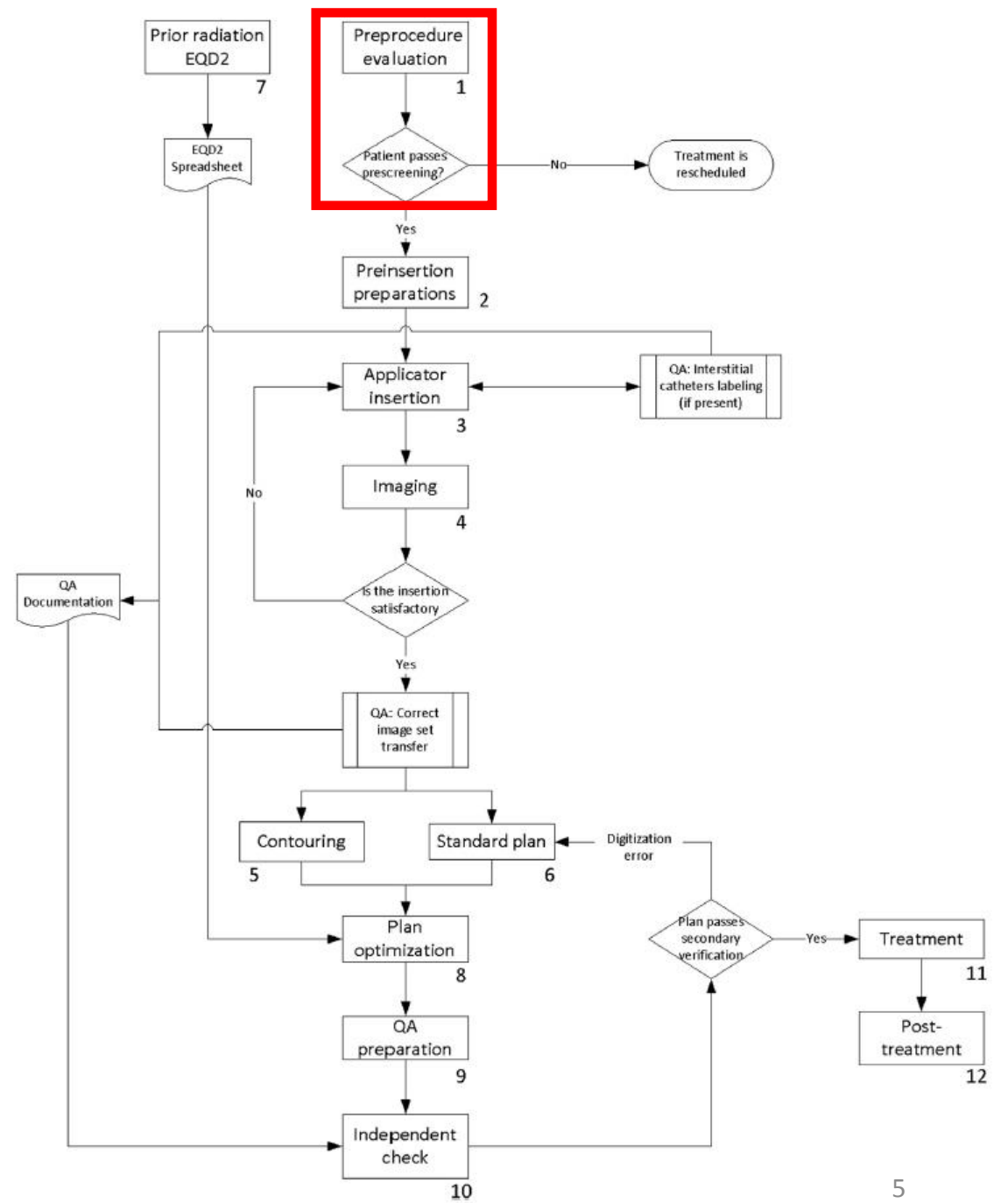
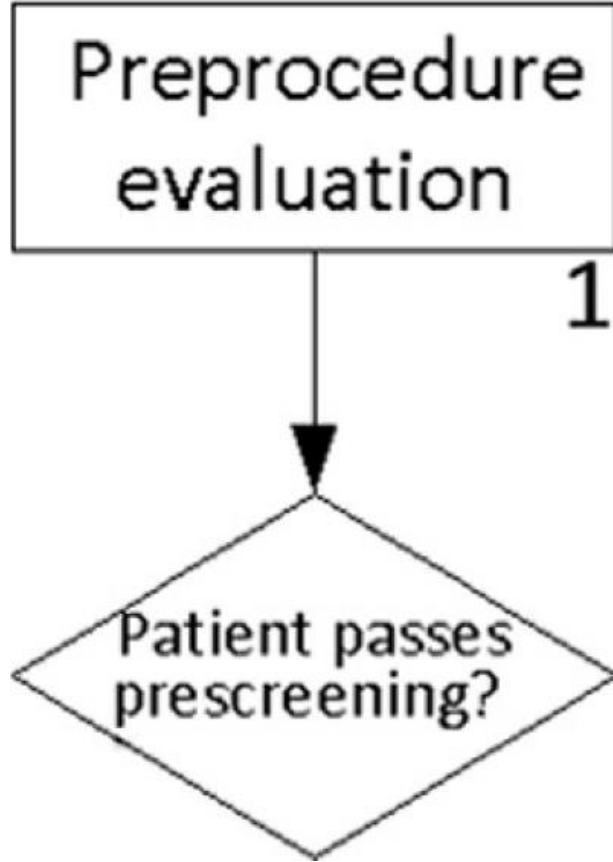


Process Map:

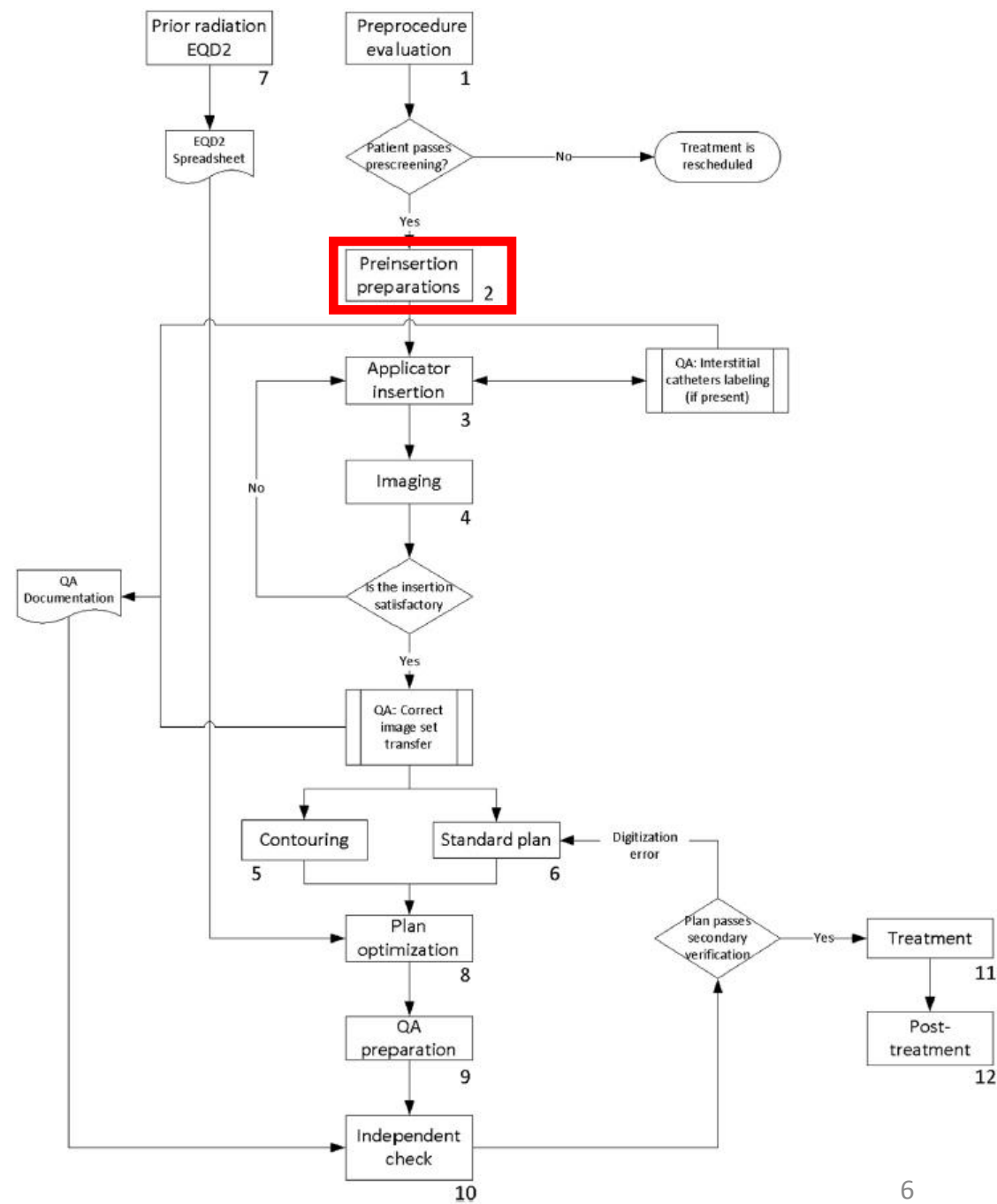
Source:

Damato et al. "Redesign of process map to increase efficiency: Reducing procedure time in cervical cancer brachytherapy." *Brachytherapy* (2015)

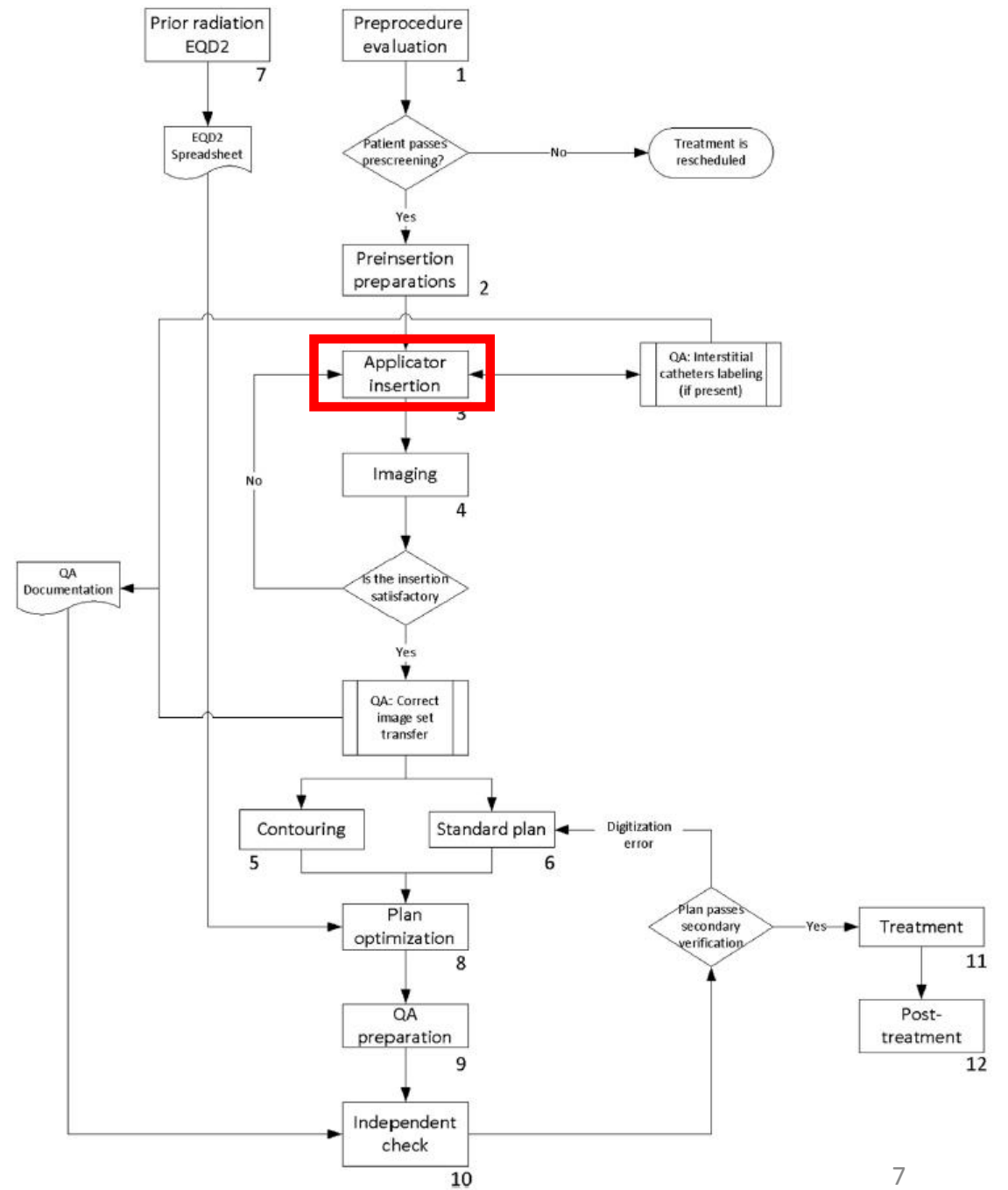


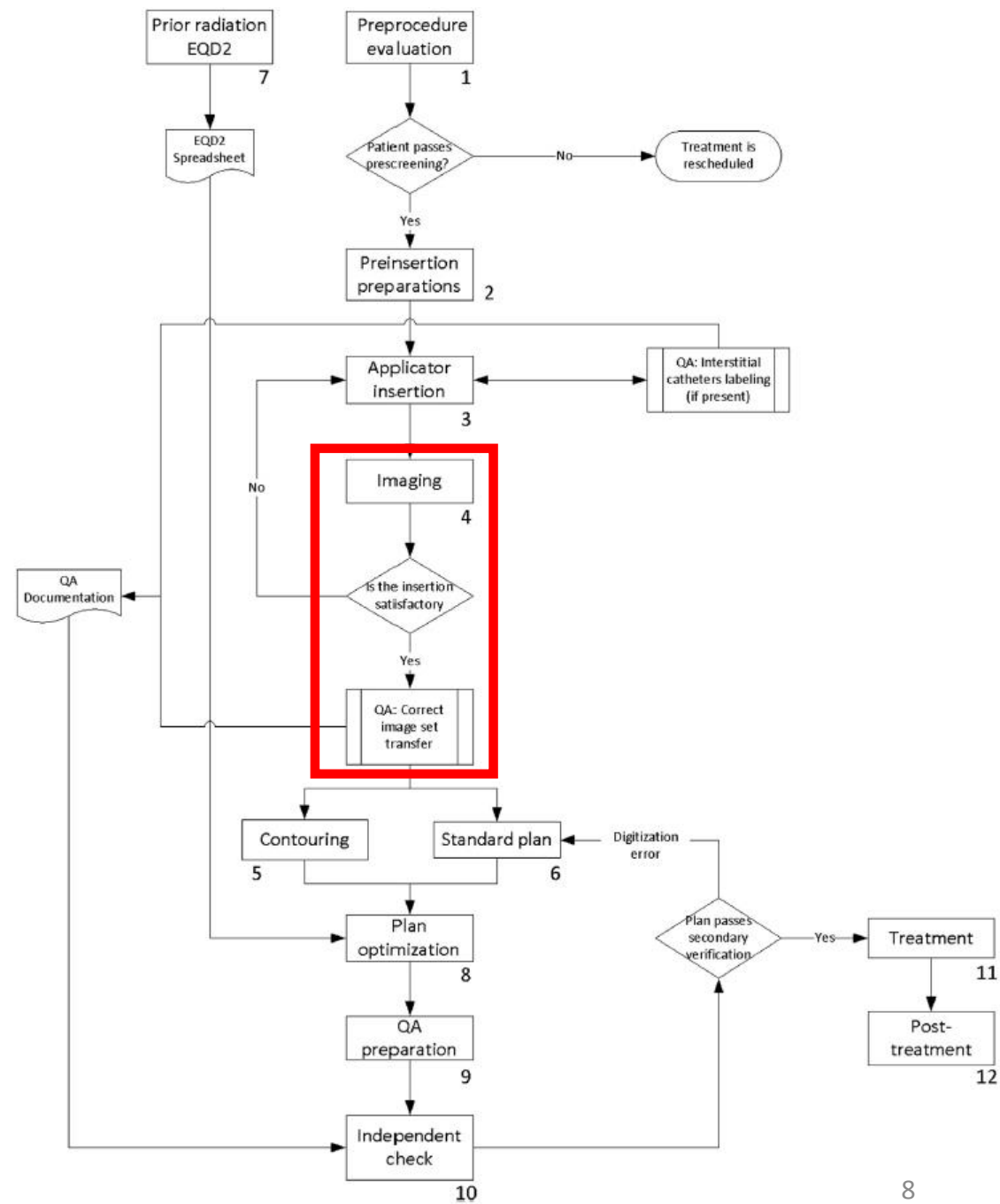
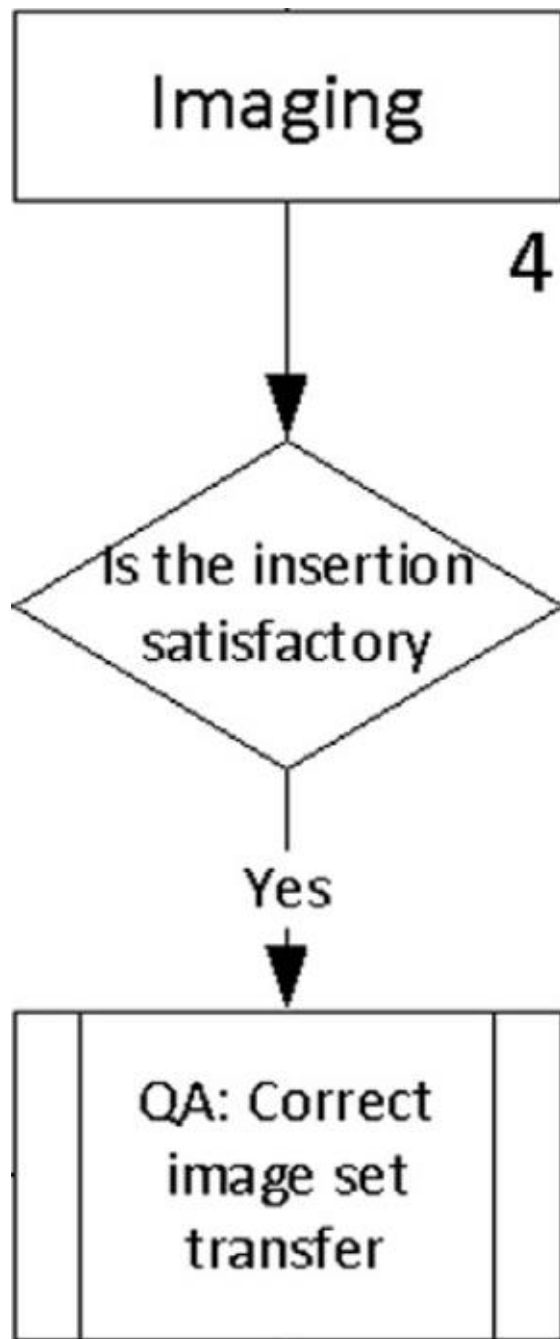


Preinsertion preparations



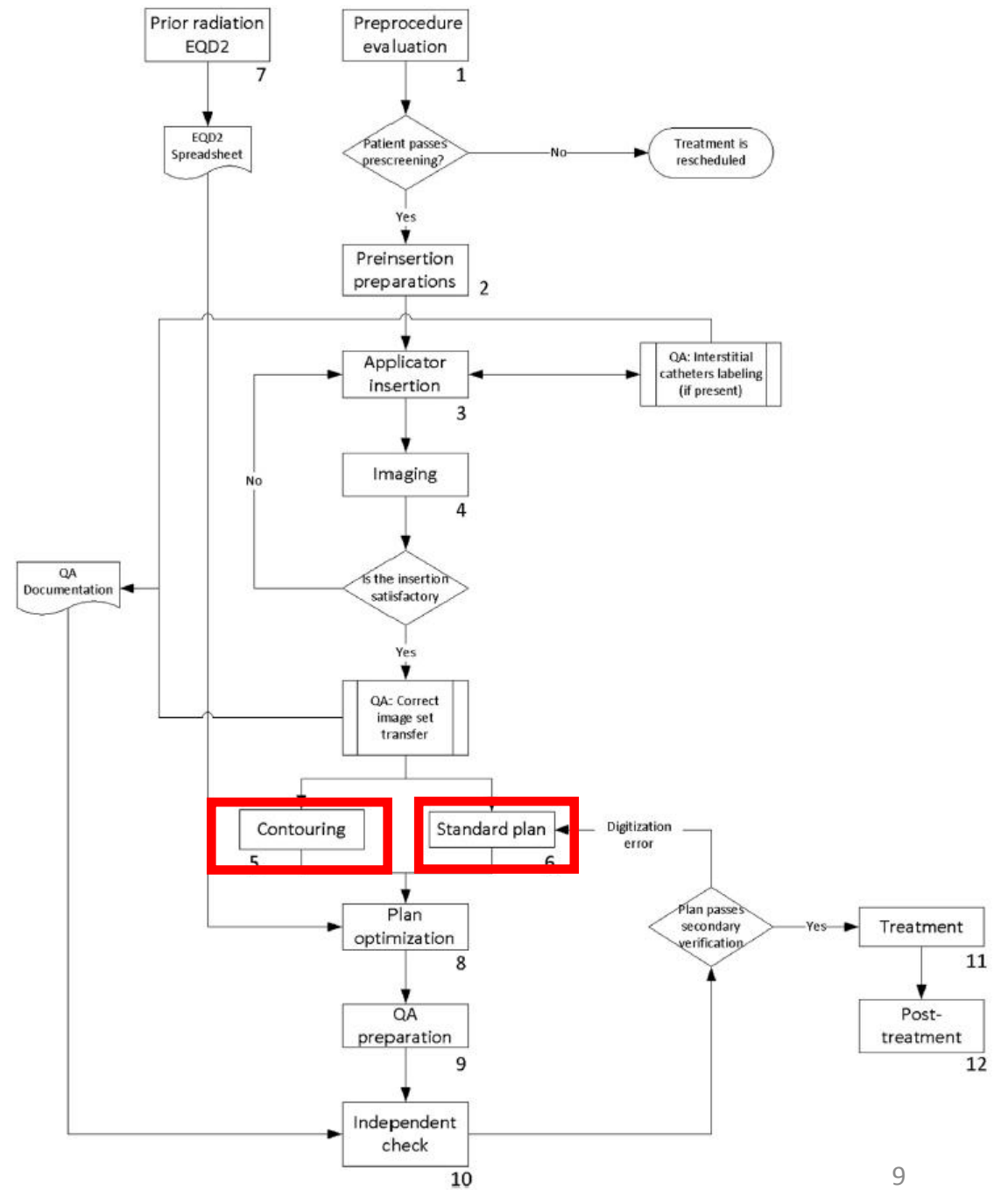
Applicator insertion



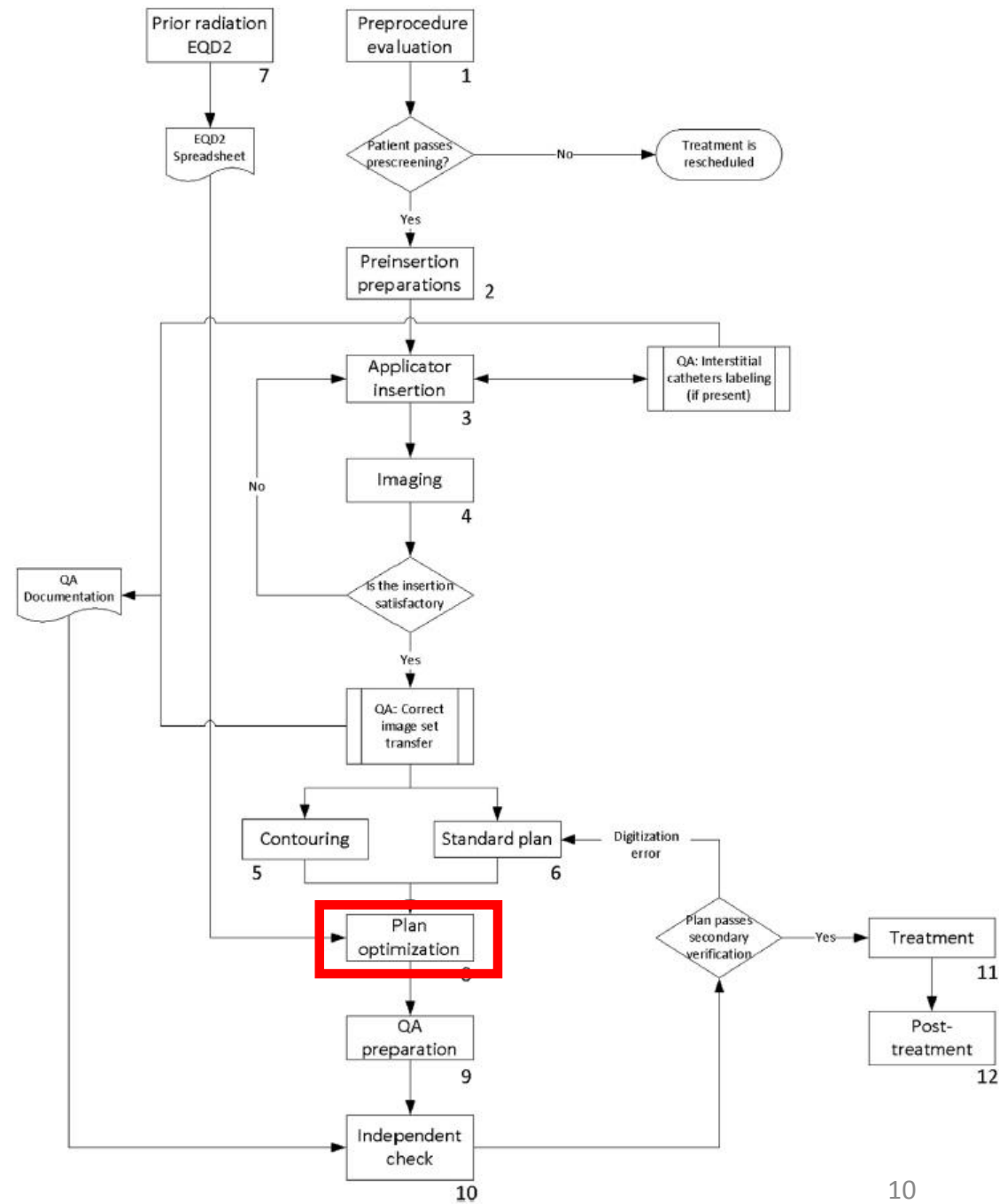


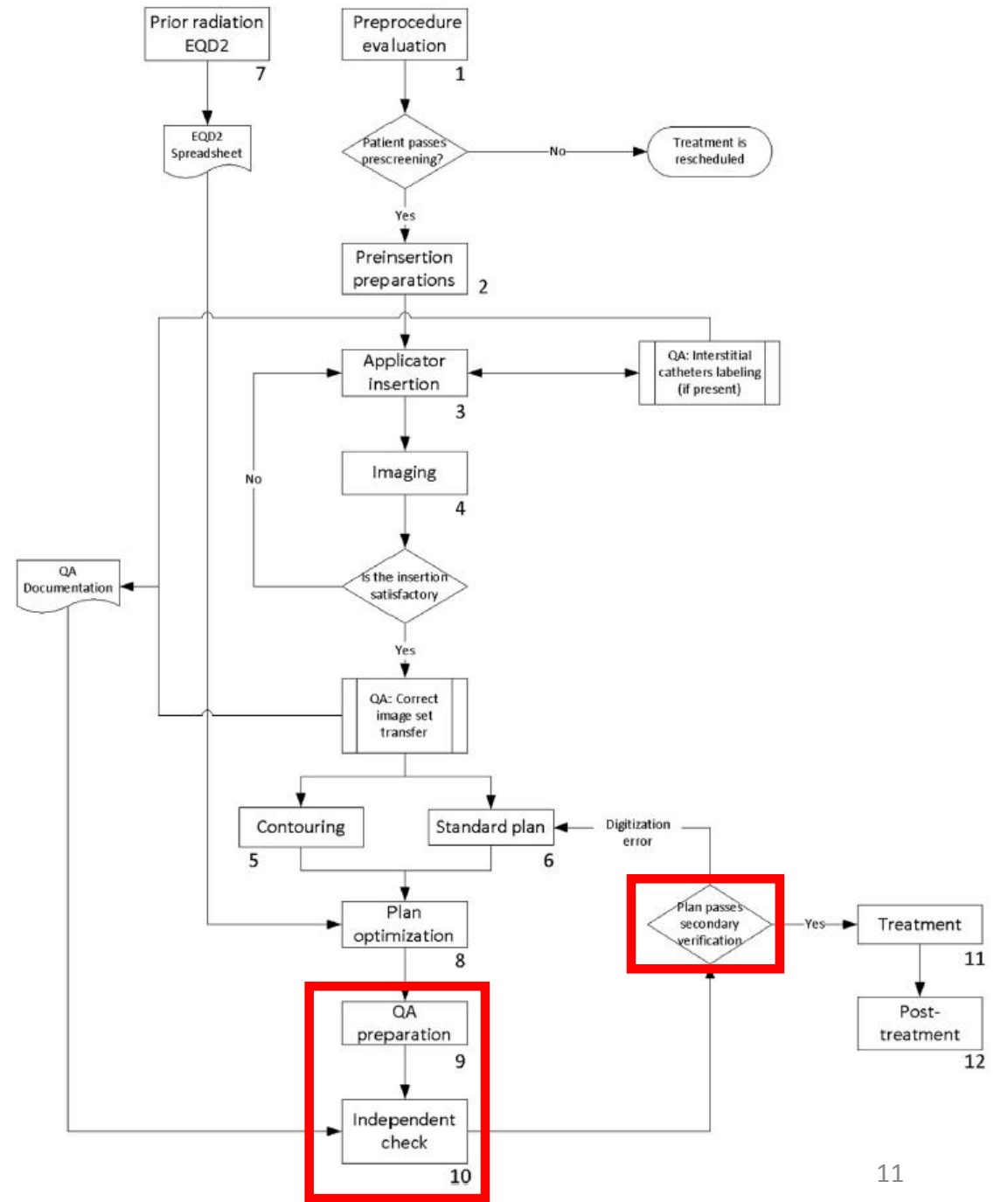
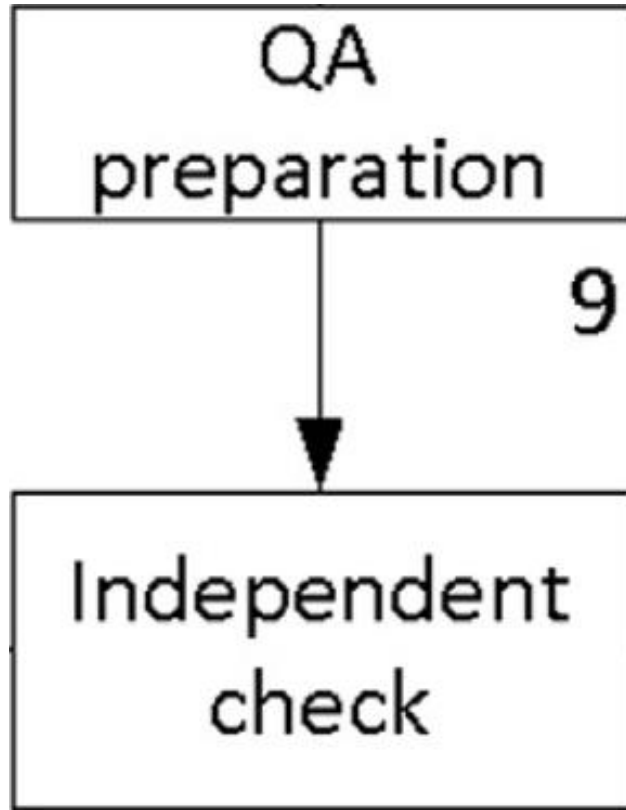
Contouring

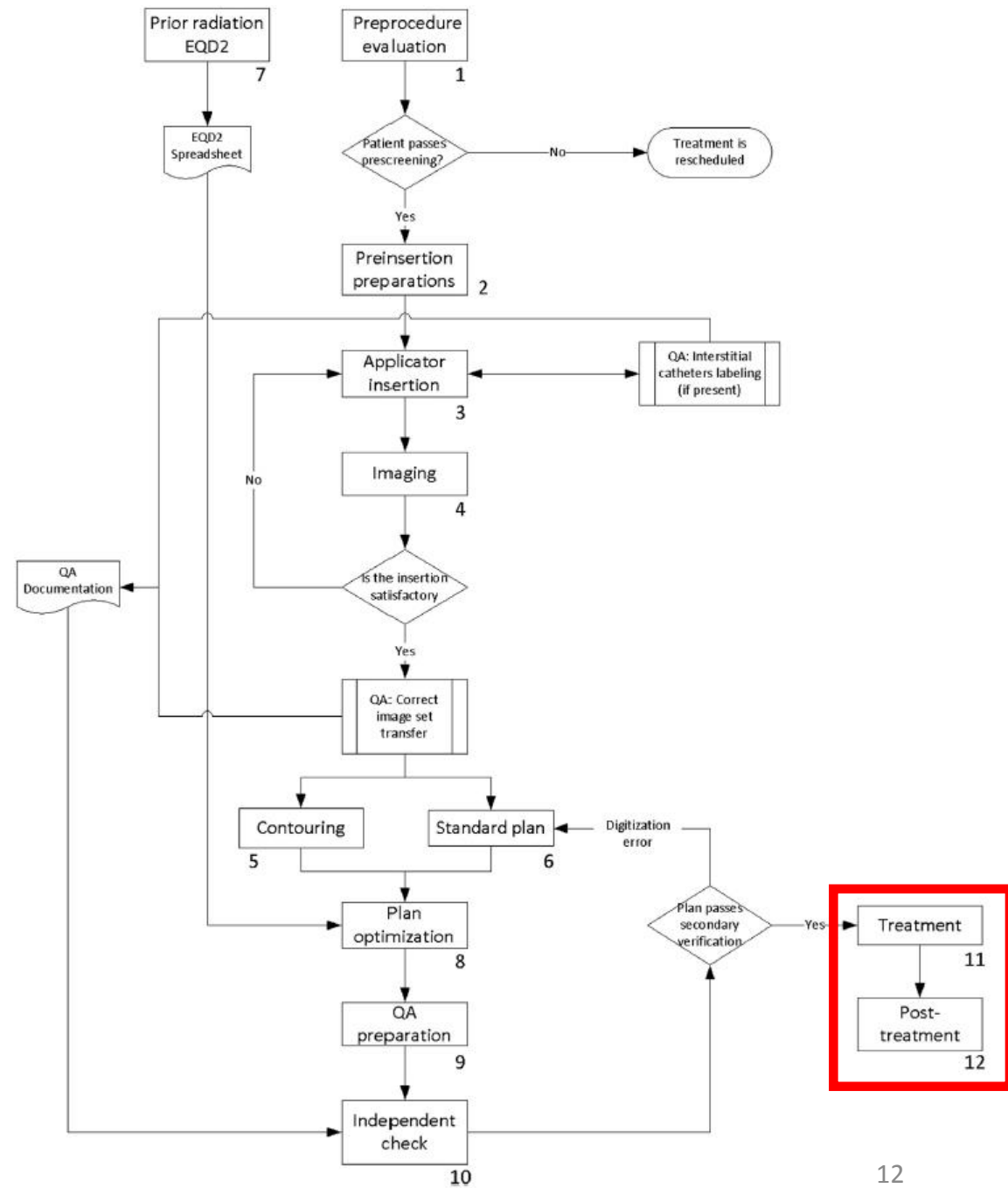
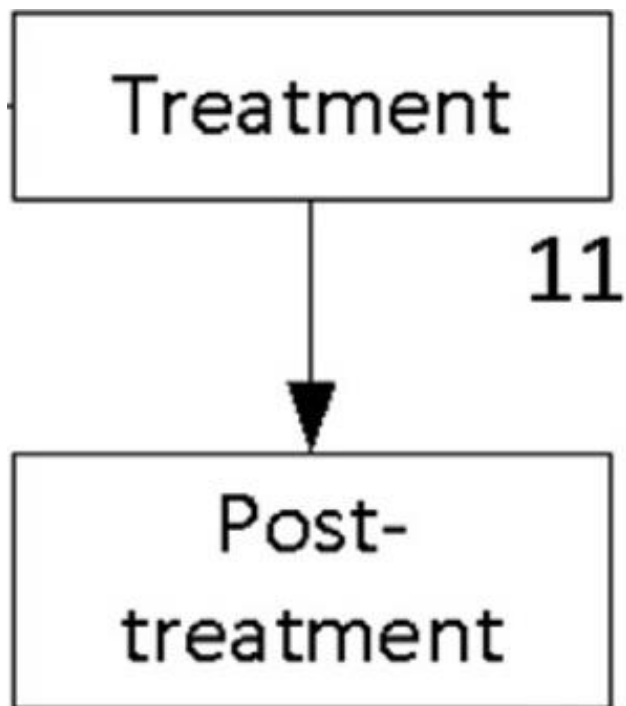
Standard plan



Plan optimization

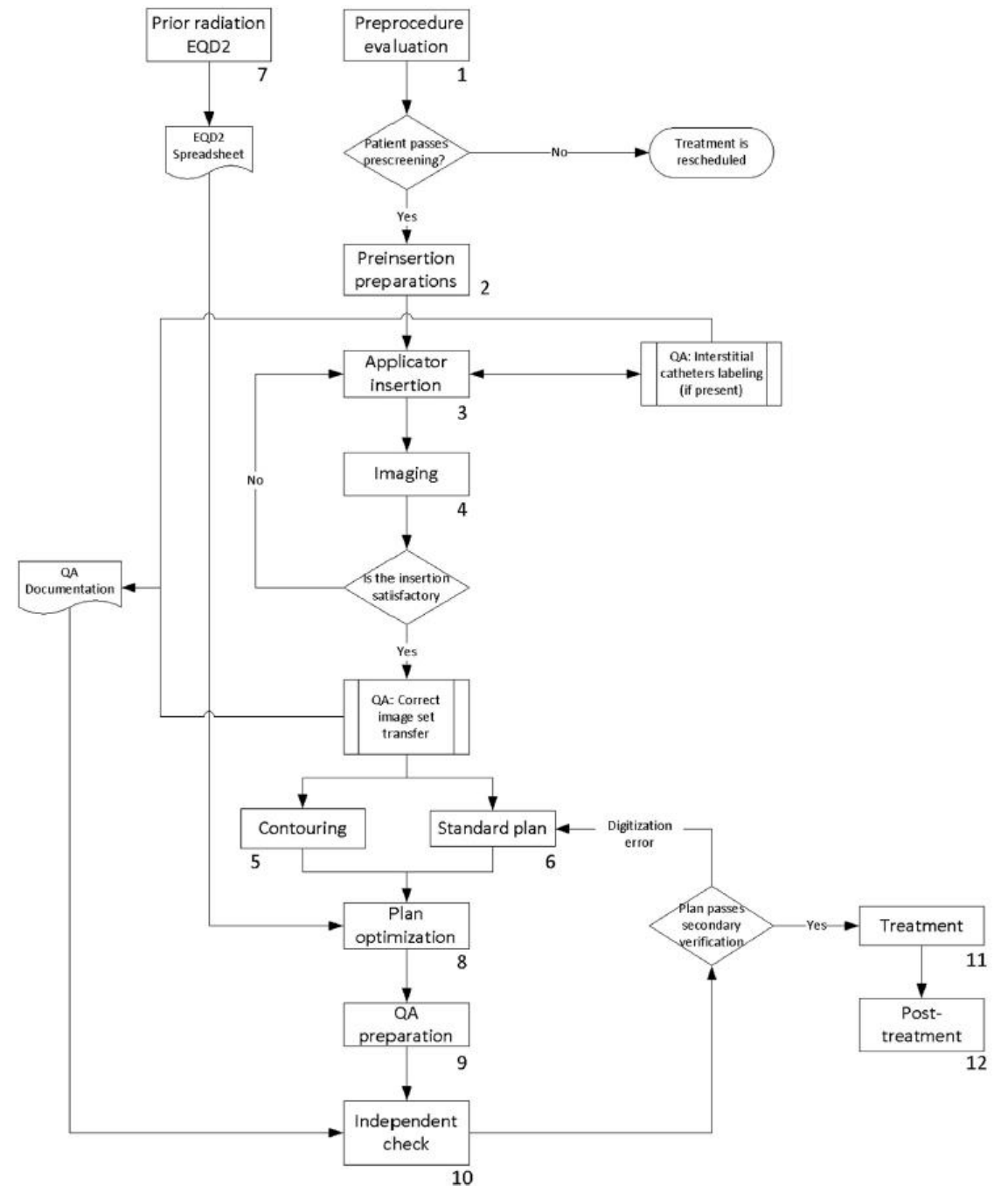


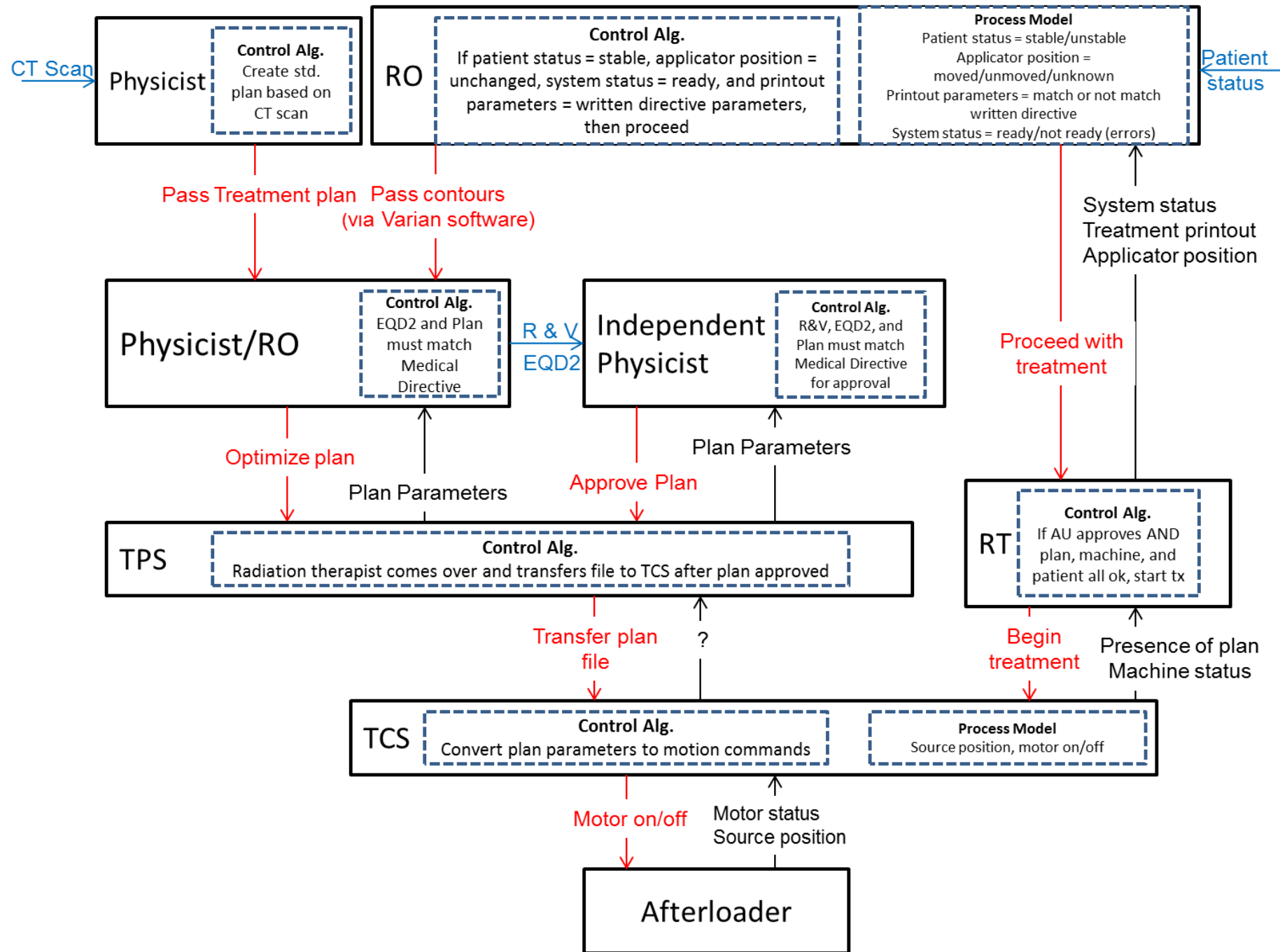


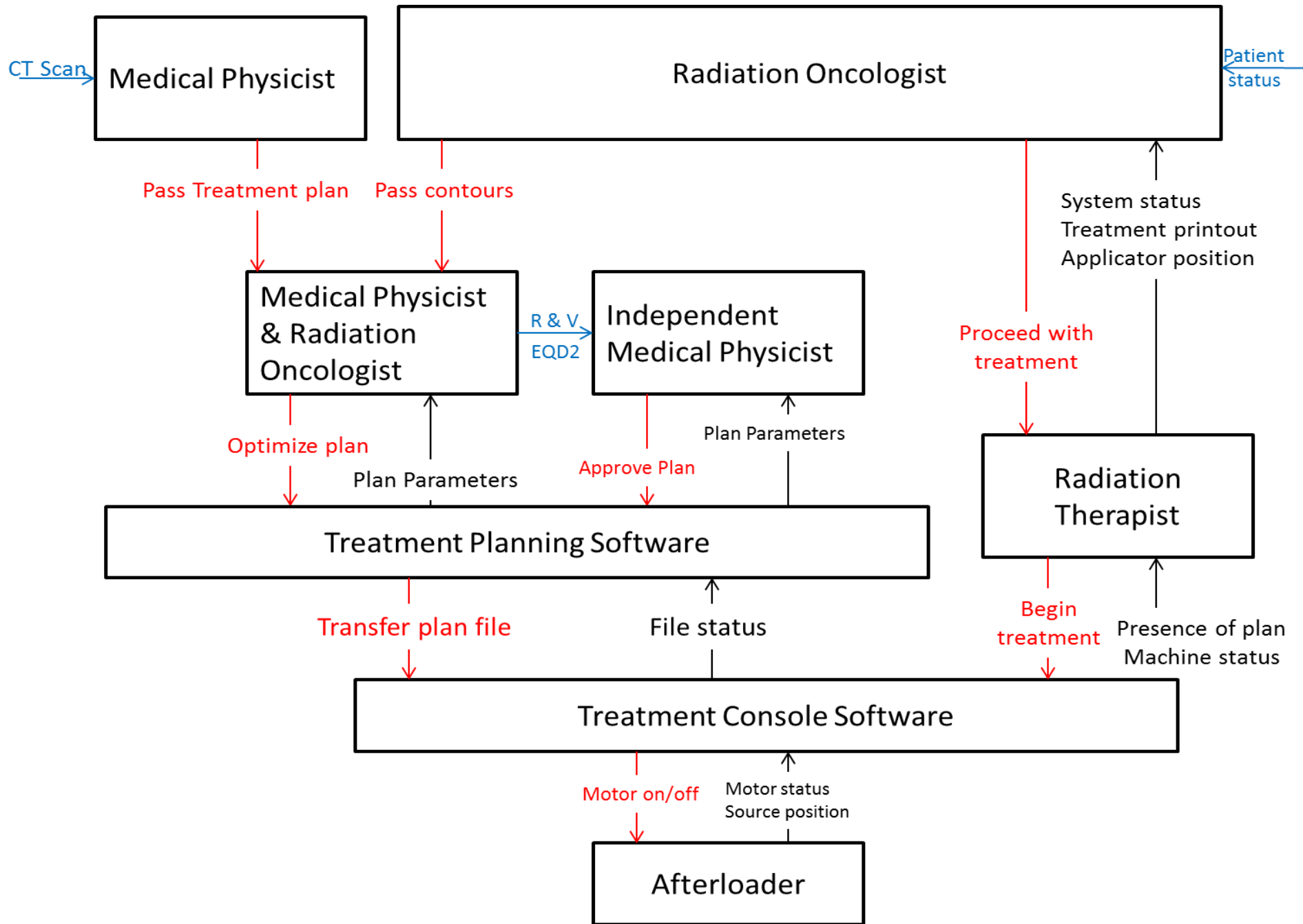


Summary of Steps:

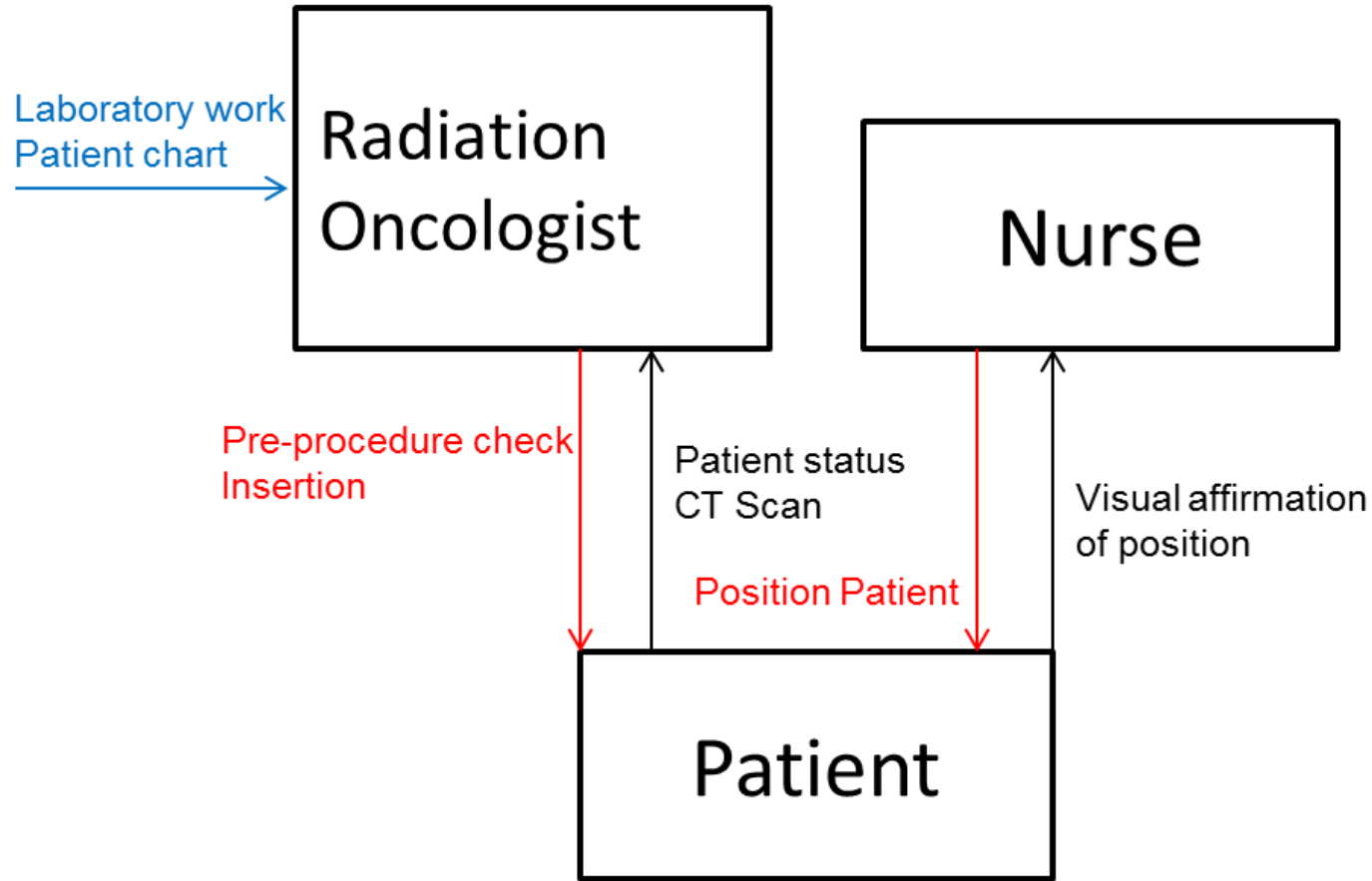
- 1. Patient is placed under general anesthesia.
- 2. Applicator is surgically inserted.
- 3. CT scan is taken to visualize the applicator and organs at risk.
- 4. A treatment plan and contour are created from the CT scan.
- 5. Plan is optimized to the patient's anatomy.
- 6. Radiation dosage is delivered.

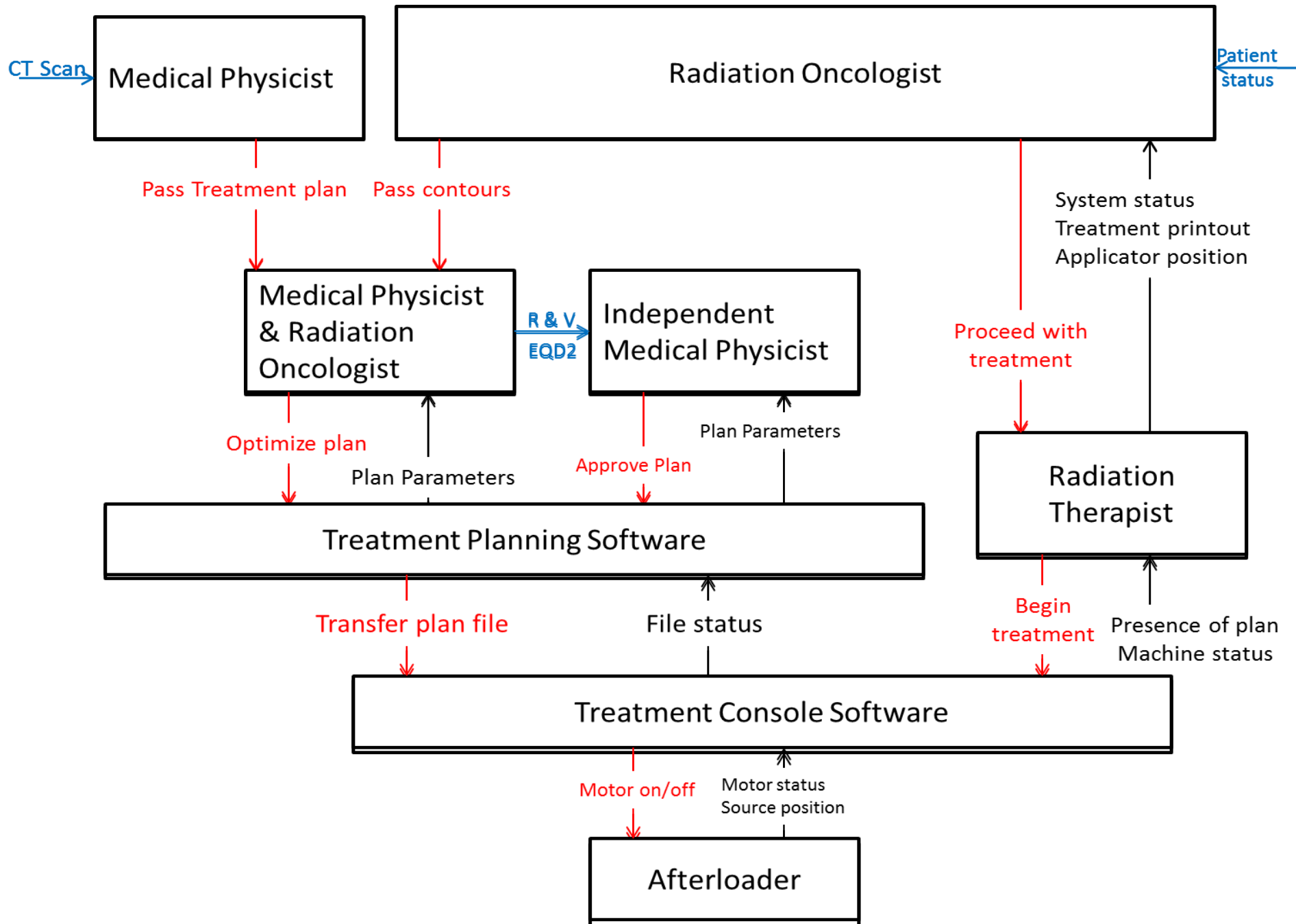






Treatment Preparation

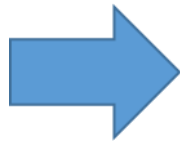




Outline:



What is brachytherapy and how do I derive the control structure?



Clinical workflow STPA Example: Analyzing a control action to develop a scenario.

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Accidents and Hazards

- A-1: Patient suffers radiological injury due to **over-radiation**.
 - A-2: Patient's cancer advances due to **under-radiation**.
 - A-3: Patient suffers **physical**, non-radiological injury.
 - A-4: **Staff** suffers injury (radiological or physical).
-
- H-1: Persons subject to non-radiological injuries.
 - H-2: Patient receives inappropriate treatment.
 - H-3: Patient does not receive treatment.
 - H-4: Non-patient receives radiation.

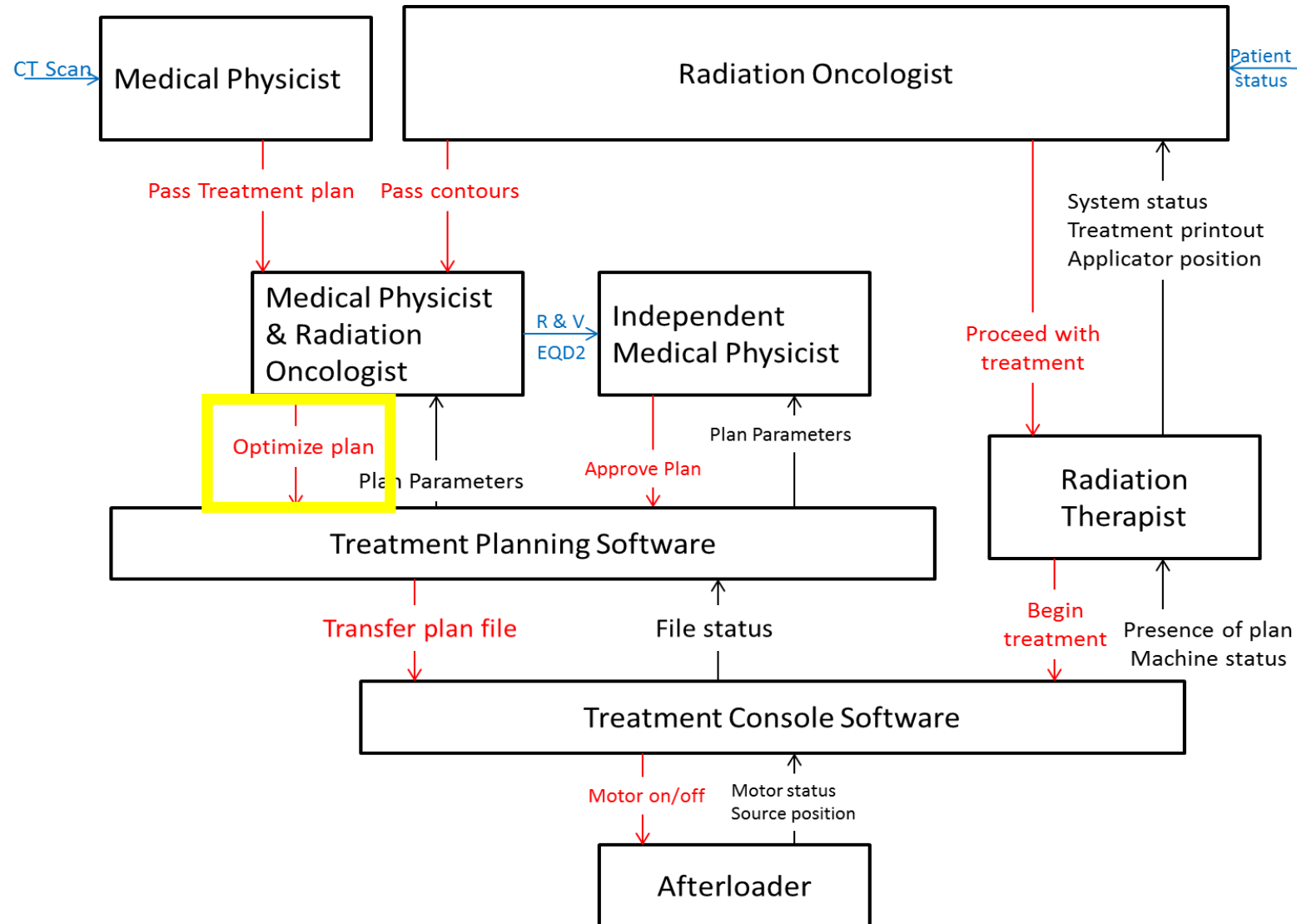
What are the safety implications?

- We analyzed the **11** control actions.
- STPA step 1 was performed, and **26** Unsafe Control Actions (UCA) were identified.
- STPA step 2 is ongoing with **100+** causal factors identified.

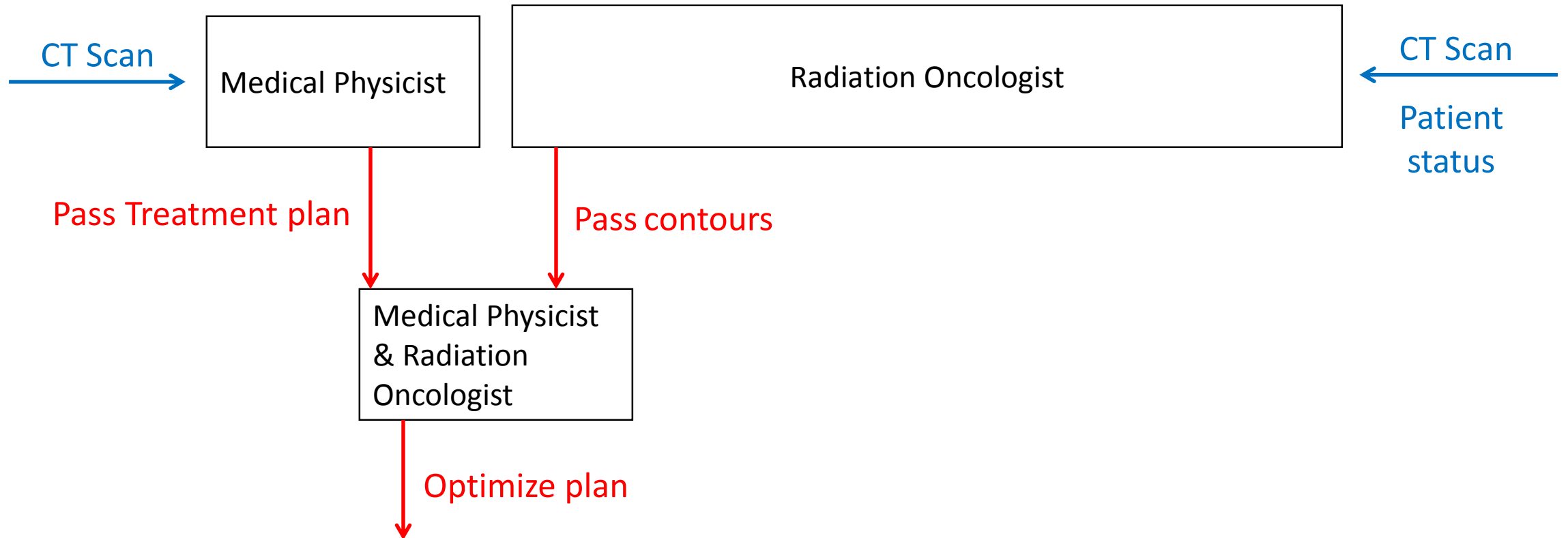
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

Control Action:	Not Providing Causes Hazard:	Providing Causes Hazard:	Wrong Timing or Order Causes Hazard:	Stopped Too Soon or Applied Too Long
Optimize Plan	Physicist/RO does not optimize Tx. Plan that is appropriate. (H-3)	Physicist/RO optimizes Tx. Plan that is incorrect. (H-2)	N/A	N/A

UCA: Physicist/RO optimizes a treatment plan that is incorrect.



What went wrong?





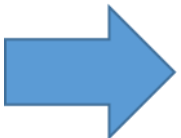
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

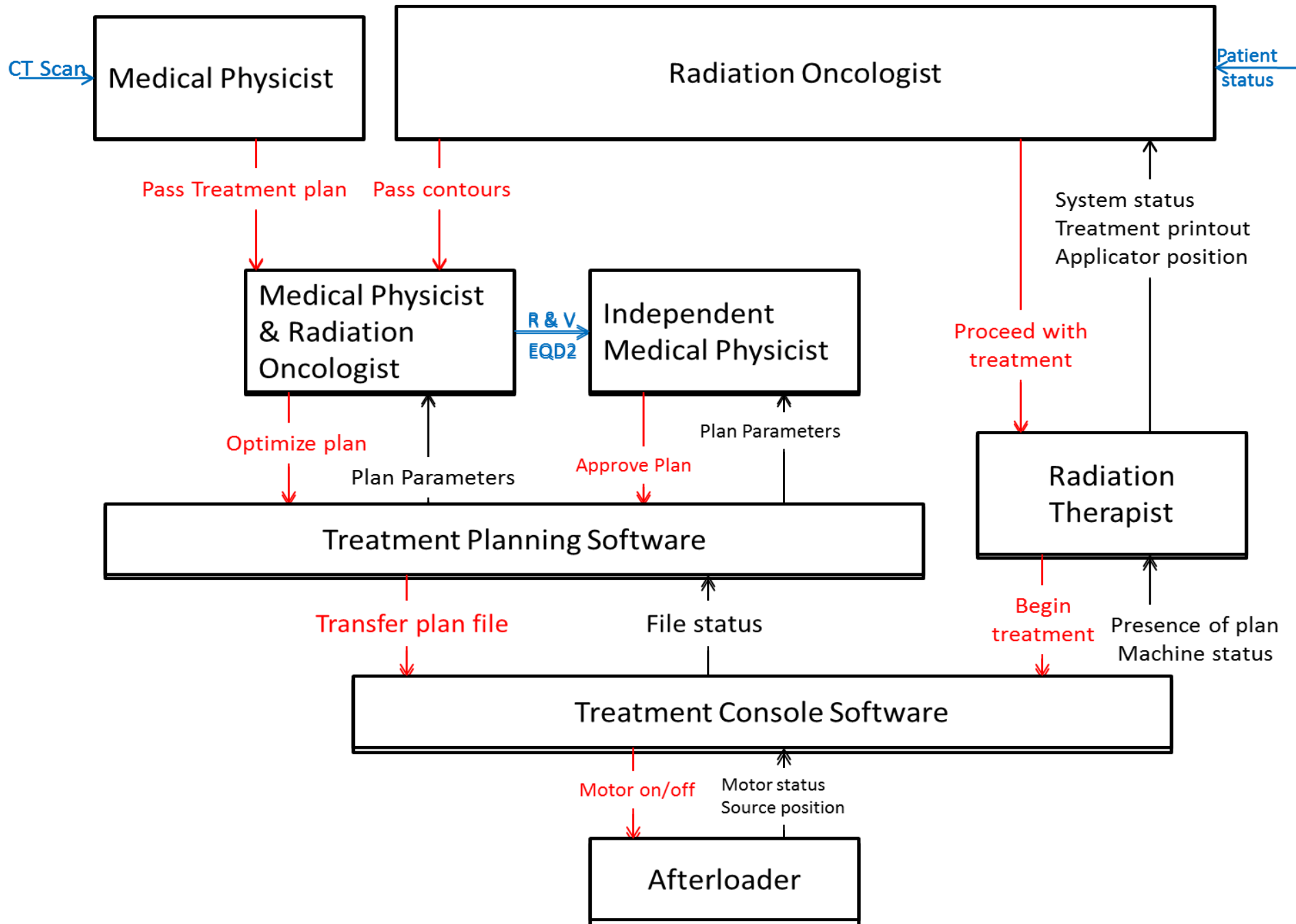
- Scenario:
 - Rad Onc finishes applicator insertion, takes CT scan, and tells the physicist to start the Treatment Plan.
 - Now consider the Rad Onc wants to reposition applicator and take another CT scan.
 - Extra causal factor: The physicist is already in another room finishing up the Treatment Plan.
- Working on different CT scans?
- Working on the same **old** one?

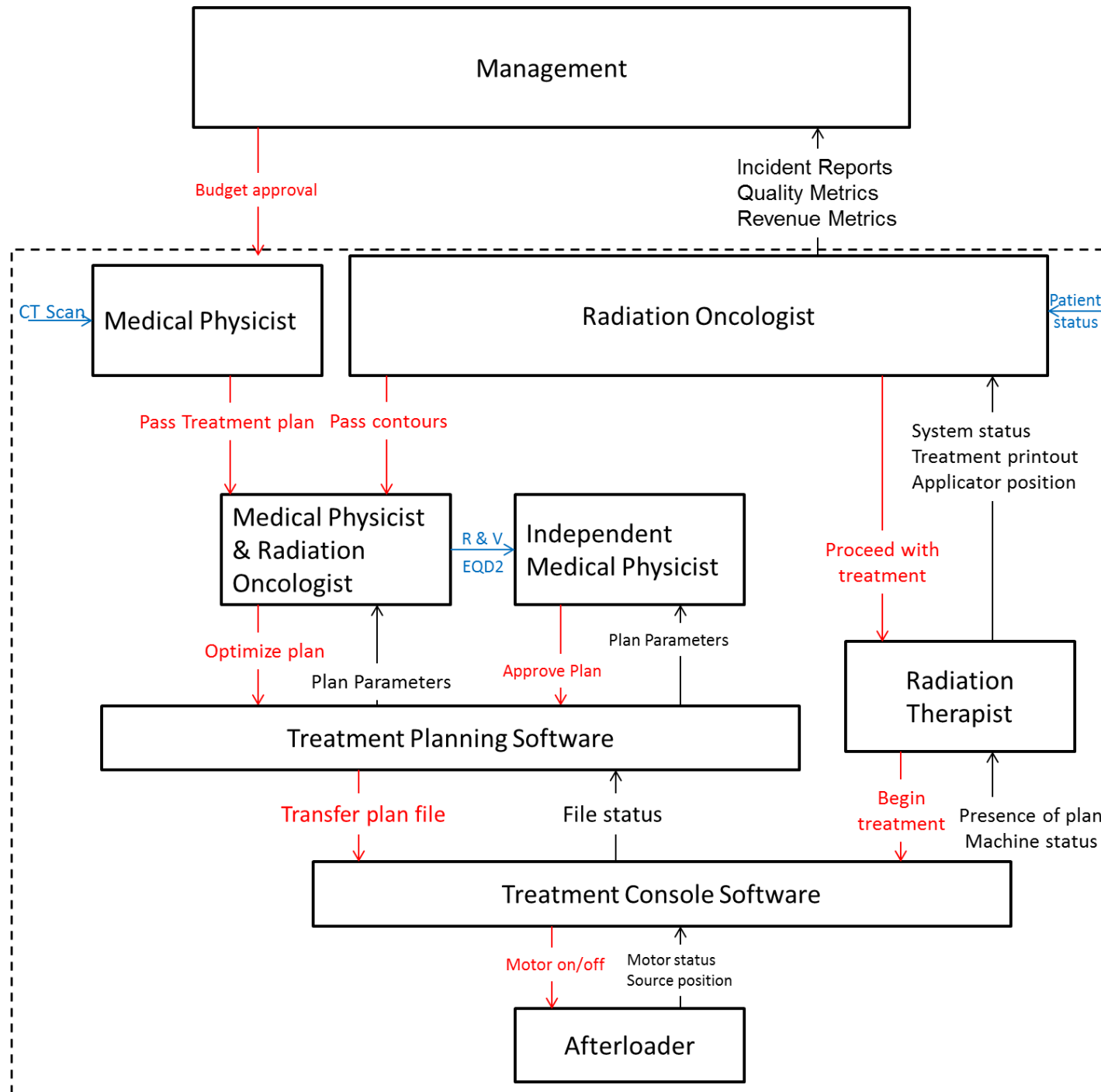
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

- Summary:
 - Two CT Scans that look similar and are taken minutes apart.
 - Communication issues could lead to inadequate feedback. The physicist may not have even known there was a new CT Scan.
 - Radiation Oncologist chooses a CT scan to contour off of and chooses the old one.
 - Both Medical Physicist and Radiation Oncologist mistakenly work on the old CT which passed through the software. This is where the UCA will come from.

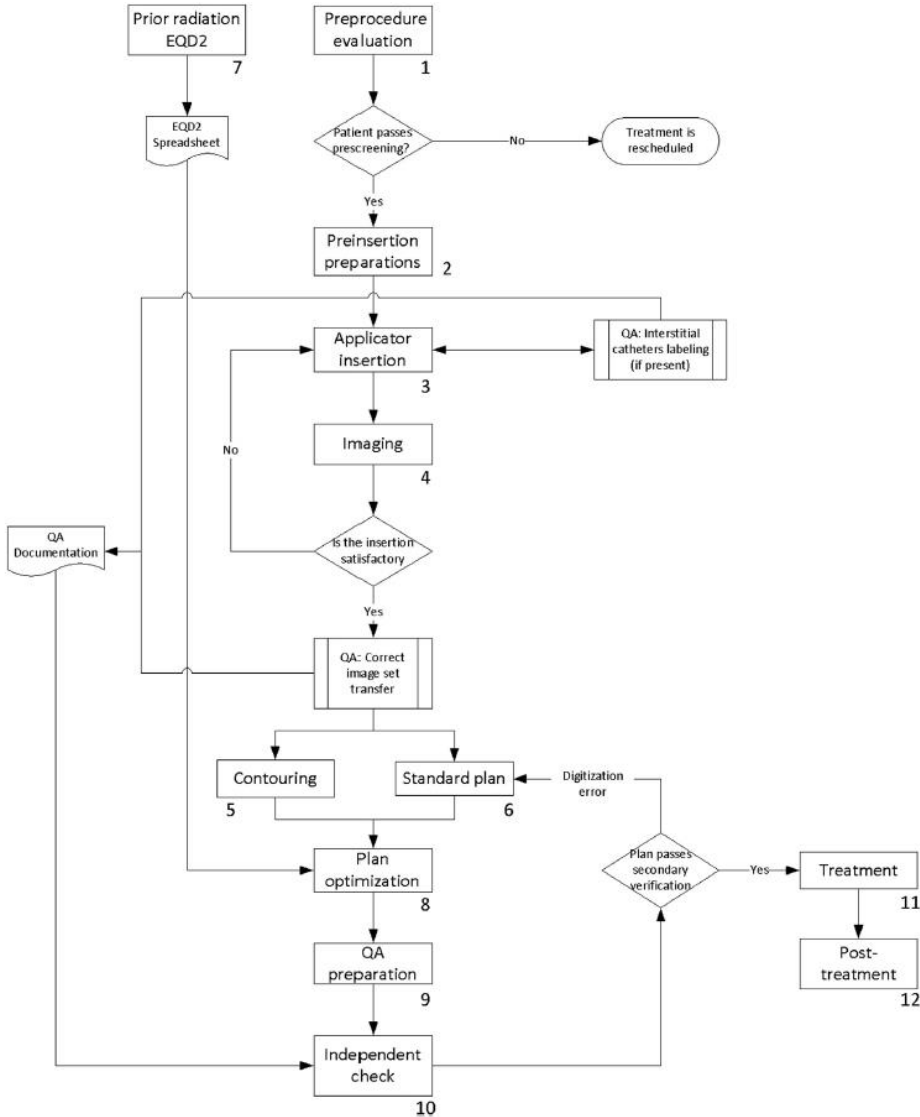
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Management



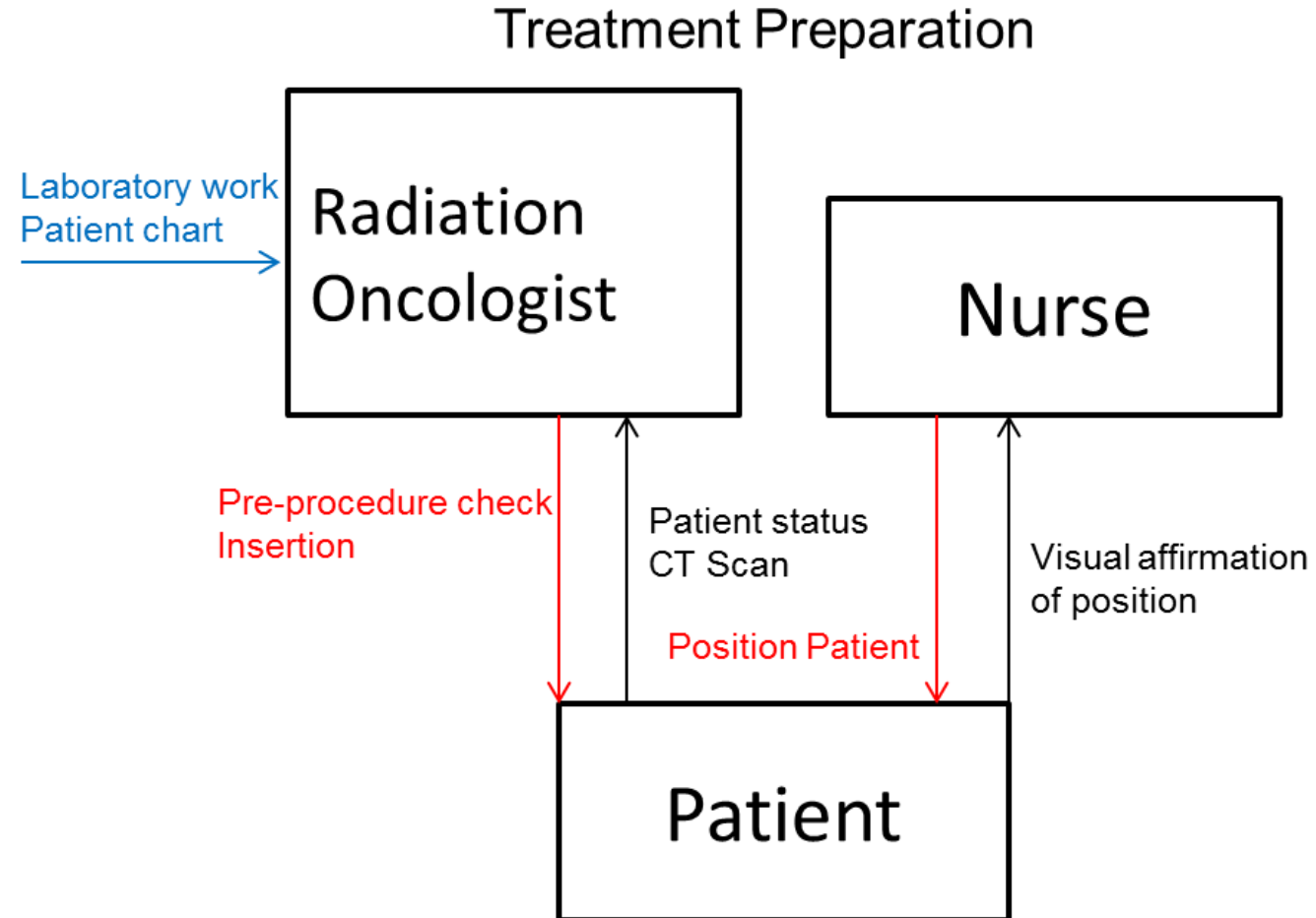
How does management influence contribute to hazard analysis?

Leadership & Management



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A different example:



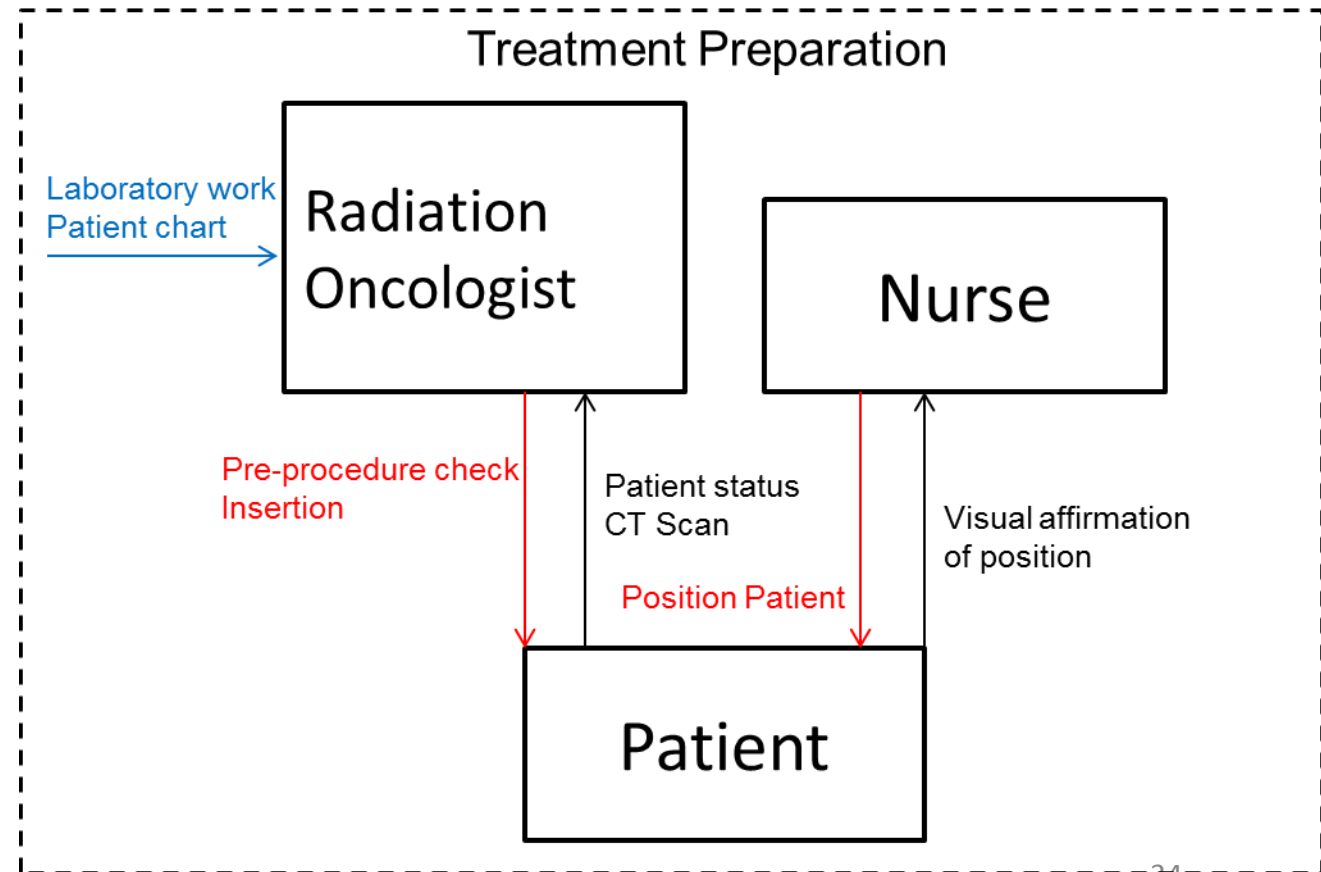


UCA: Nurse moves patient into a sub-optimal position.

- This ties to one of the hazards we identified being physical harm to the patient and/or staff.
 - When people think of hazard analysis in radiation oncology, this is a hazard that tends to be ignored.
- Causal factor: Moving the patient with too few people.

Why too few people?

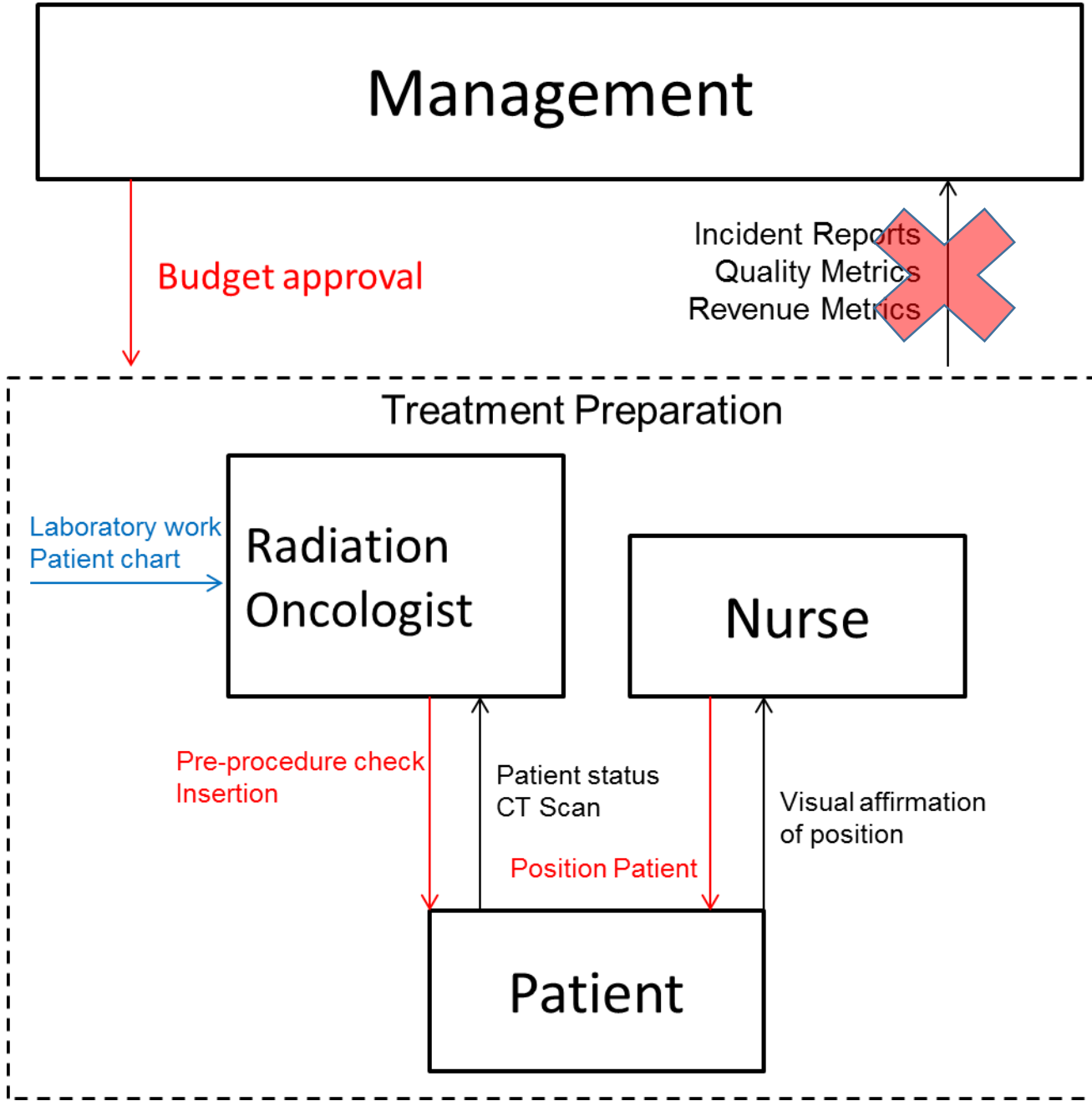
- Management UCA:
Provides inadequate budget.



Step 2 Analysis:

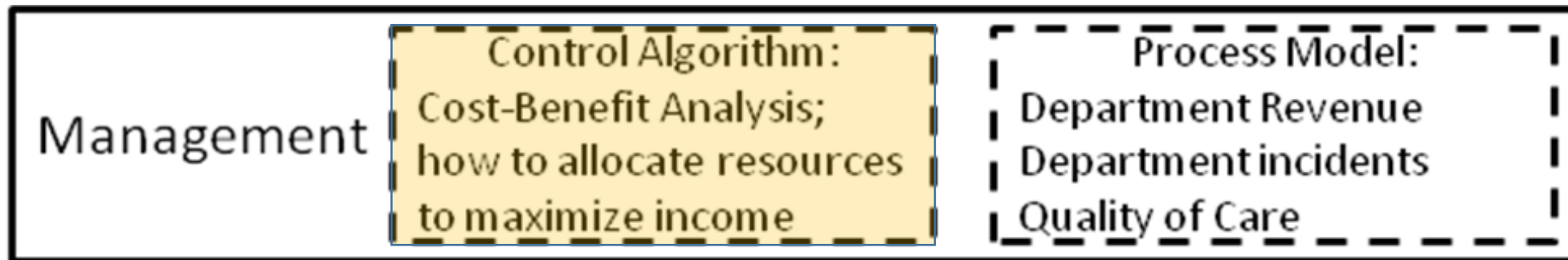
- Easy answer: Hire more staff.
 - Why might an inadequate budget get approved?
 - Look at the Process Model.








Step 2 Analysis:

- Other things to consider: Control Algorithm
- MBA vs MD
 - Roles, Responsibility, and Training
- Interesting power dynamic.



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Conclusion:

- STPA can be used to analyze a brachytherapy process.
- The ability to analyze management is unique feature to STPA that FMEA lacks.
- The tension between management and clinical controllers appears to be important and warrants more research.

Questions?

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