STPA of a New Radiation Oncology Procedure: CBCT only SRS

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STAMP Conference MIT
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UC San Diego
RADIATION ONCOLOGY

MIT ESD
Engineering
Systems Division

Outline

- Motivation

- Accidents and Hazards
- Control Structure
- STPA
  - Step 1
  - Step 2
- Requirements
  - Safety Constraints
- Conclusions and Further Work

SRS/SRT

- Stereotactic radiosurgery and radiotherapy

- Techniques to deliver high-dose radiation to an intracranial target(s) while minimizing radiation dose to adjacent normal tissues

Sample of Clinical Indications

Indication	Value
Functional	
• Trigeminal neuralgia	• Less numbness than rhizotomy
Vascular	
• AVM	
Benign tumors	
• Schwannoma, pituitary adenoma, meningioma, etc	• High tumor control, acceptable morbidity for selected small tumors
Brain metastases	• Control rates equal to or higher than those for surgery for small metastases
Primary malignant brain tumors	• Helpful for recurrent tumors, possibly initial pilocytic, neurocytoma

Adapted from: Flickinger, J. C., & Niranjan, A. (2013). Stereotactic Radiosurgery and Radiotherapy. In E. C. Halperin, D.E. Wazer, C. A. Perez & L. W. Brady (Eds.), Principles and Practice of Radiation Oncology 6th ed. (351-61). Philadelphia: Lippincott Williams & Wilkins.

Conventional SRS/SRT Procedure

MD, RN, MA [1 – 3 hrs] **Consultation**

↓

RTT, CMD, PhD [1 – 2 hrs] **Simulation**

↓

MD [1 – 3 hrs] **Prescription**

↓

CMD, PhD, MD [1 – 3 days] **Planning**

↓

RTT, PhD, MD [20 – 60 min/tx] **Treatment**

↓

MD, RN, MA [1 – 2 hrs] **Follow-up**

New SRS/SRT Procedure

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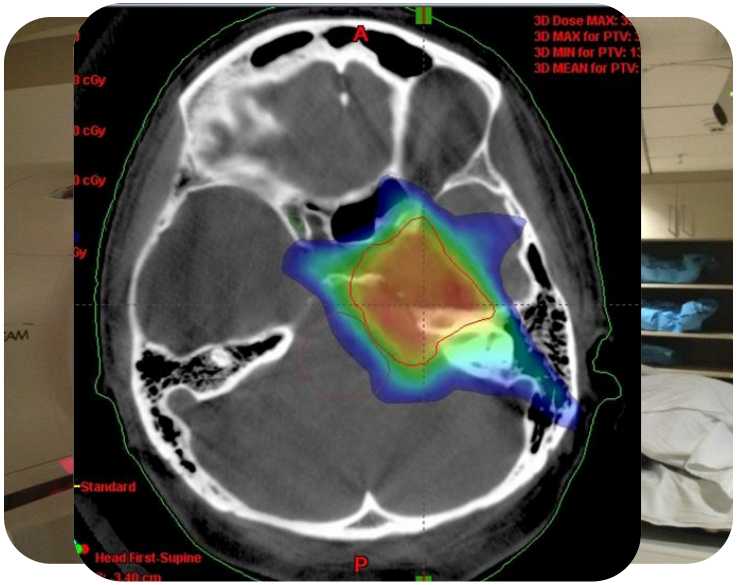


Accidents

A-1: Patient injured or killed from radiation exposure

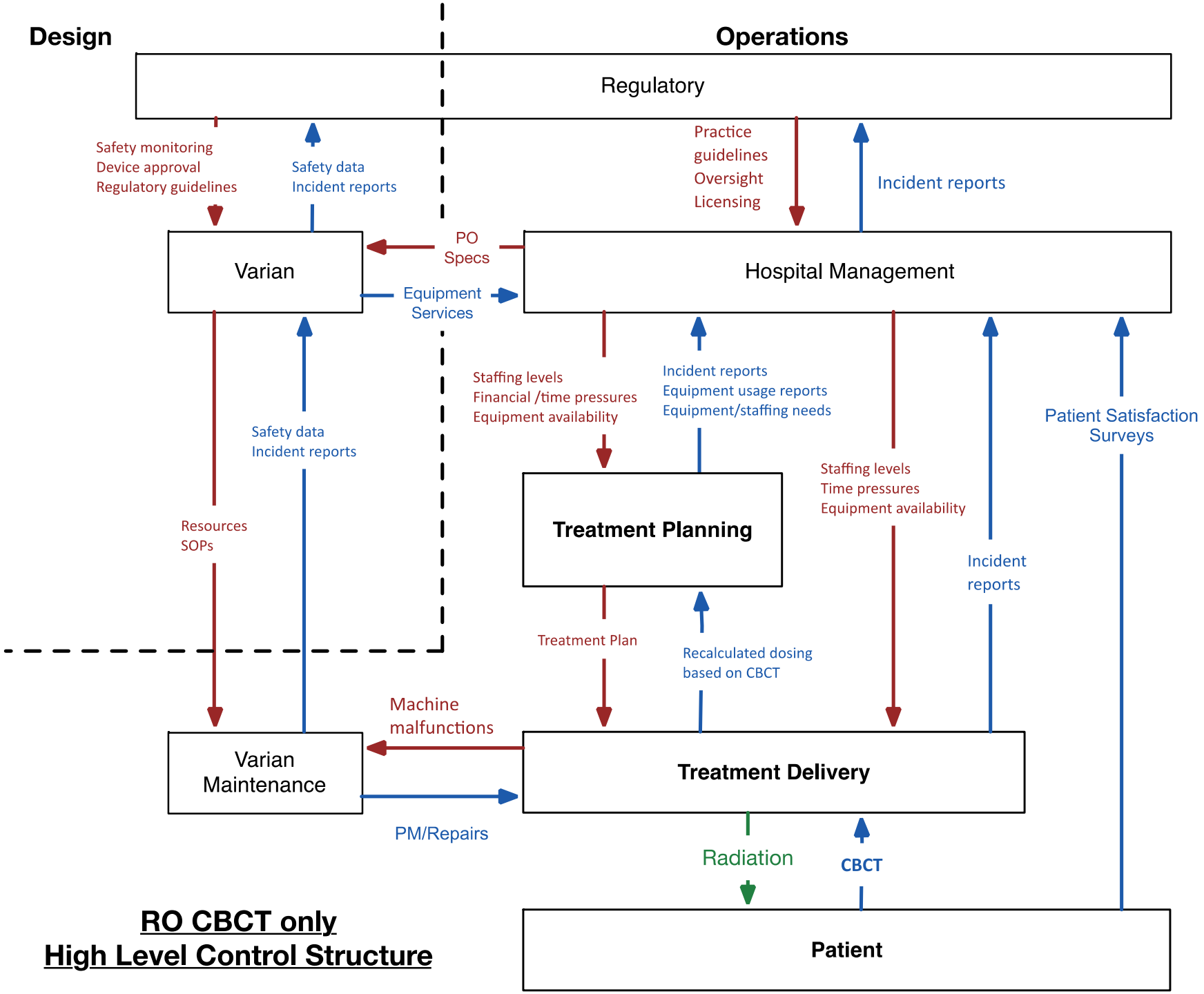
A-2: Non-patient injured or killed by radiation

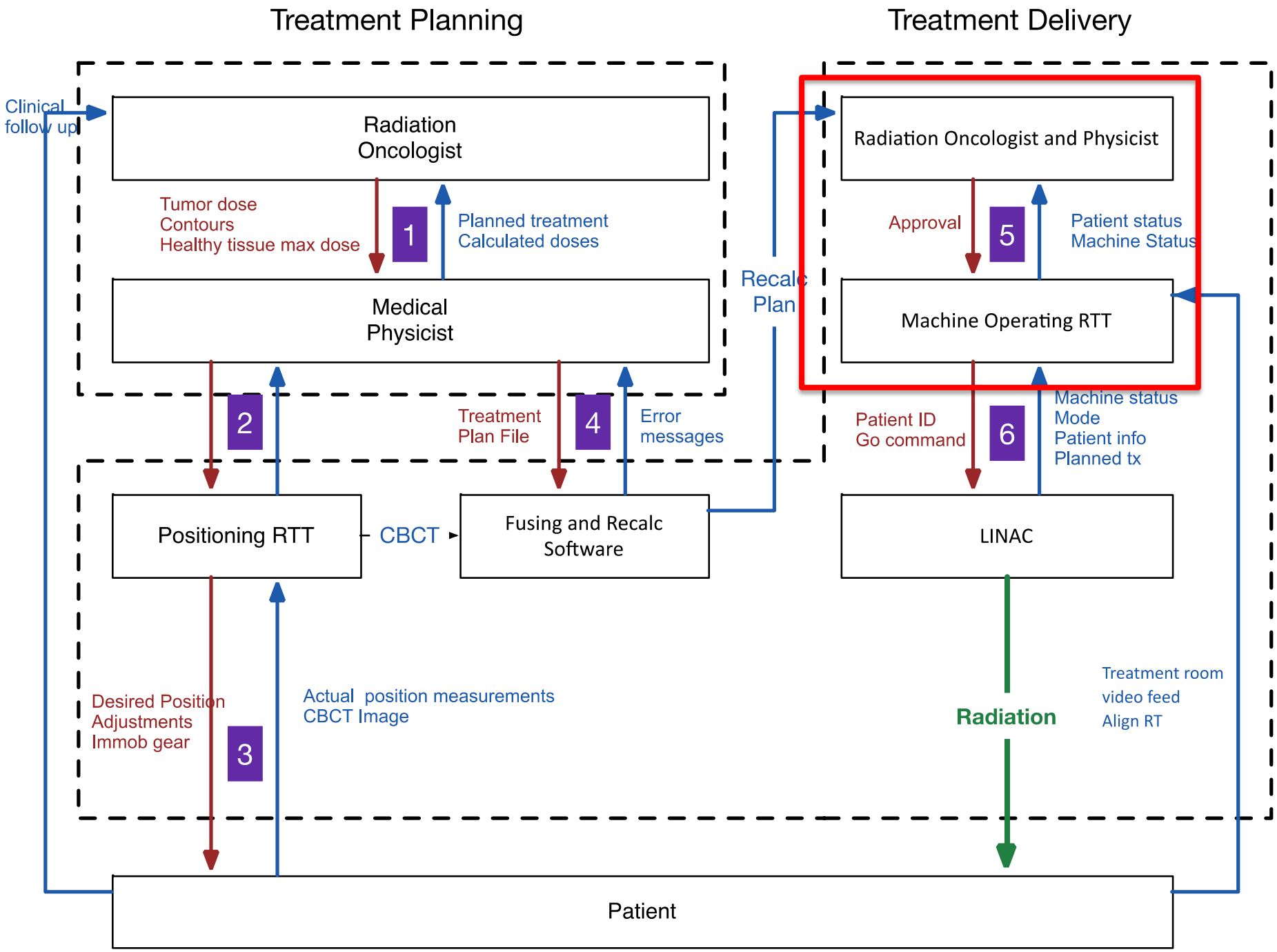
A-3: Damage or loss of equipment

A-4: Physical injury to patient or non-patient during treatment

High Level Hazards

- H1. WRONG DOSE: Dose delivered to patient is wrong in either amount, location, or timing.
  - H1.1 - Right Patient, Right Dose, Wrong Location
  - H1.2 - Right Patient, Wrong dose, Right Location
  - H1.3 - Right Patient, Wrong dose, Wrong Location
  - H1.4 - Wrong Patient
- H2. NON-PATIENT IS UNNECESSARILY EXPOSED TO RADIATION
- H3. EQUIPMENT IS SUBJECT TO UNNECESSARY STRESS
- H4. PERSONS ARE SUBJECTED TO THE POSSIBILITY OF NON-RADIOLOGICAL INJURY


Design
Operations
Regulatory
Safety monitoring
Device approval
Regulatory guidelines
Safety data
Incident reports
Practice
guidelines
Oversight
Licensing
Incident reports
Varian
PO
Specs
Equipment
Services
Hospital Management
Staffing levels
Financial /time pressures
Equipment availability
Incident reports
Equipment usage reports
Equipment/staffing needs
Patient Satisfaction
Surveys
Safety data
Incident reports
Resources
SOPs
Treatment Planning
Staffing levels
Time pressures
Equipment availability
Incident
reports
Treatment Plan
Recalculated dosing
based on CBCT
Machine
malfunctions
Varian
Maintenance
Treatment Delivery
PM/Repairs
Radiation
CBCT
Patient
RO CBCT only
High Level Control Structure


Treatment Planning
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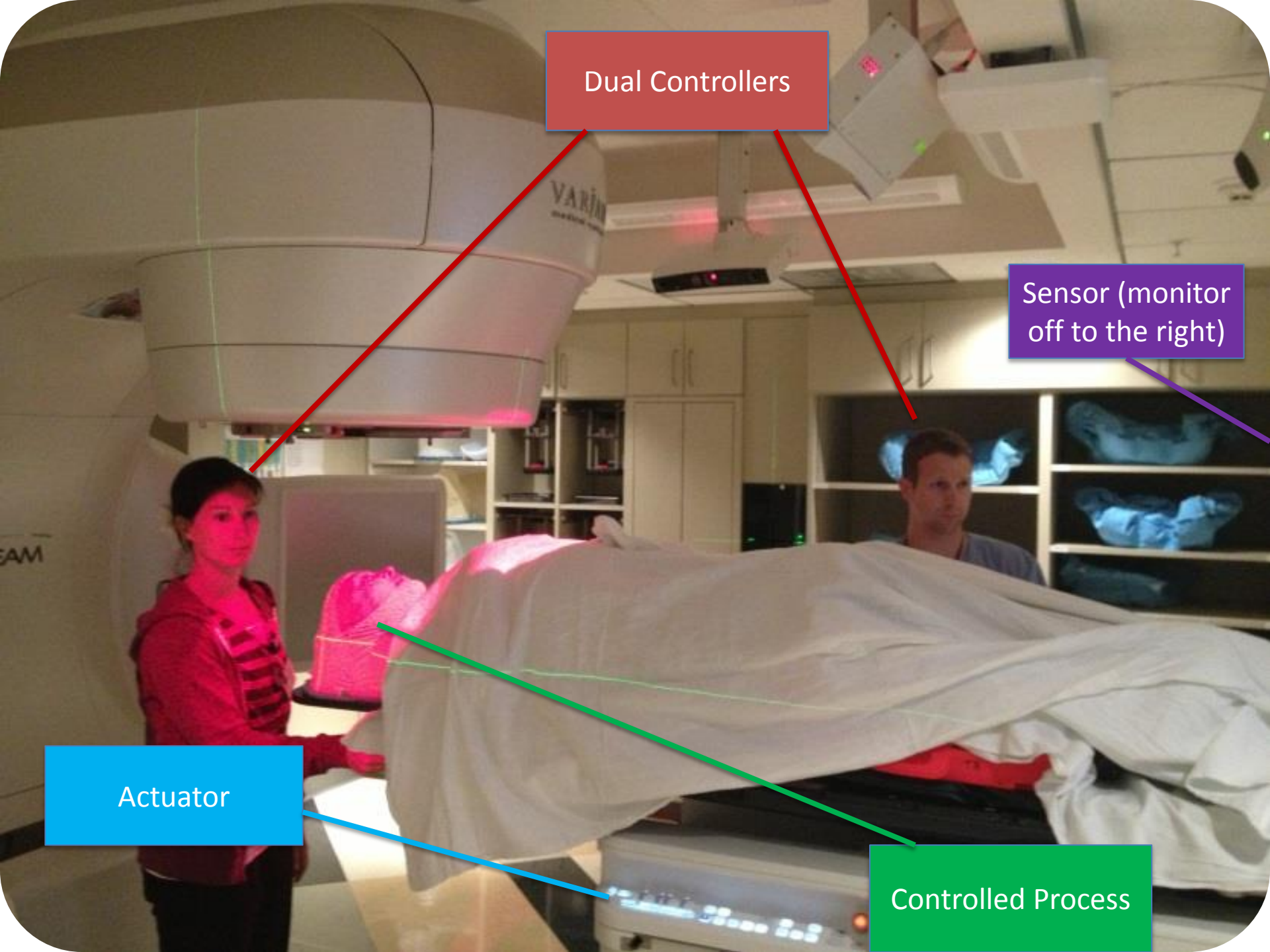
Healthy tissue max dose
1
Planned treatment
Calculated doses
Medical Physicist
Recalc Plan
Radiation Oncologist and Physicist
Approval
5
Patient status
Machine Status
Machine Operating RTT
2
Treatment Plan File
4
Error messages
Patient ID
Go command
6
Machine status
Mode
Patient info
Planned tx
Positioning RTT
CBCT
Fusing and Recalc Software
LINAC
Desired Position
Adjustments
Immob gear
3
Actual position measurements
CBCT Image
Radiation
Treatment room
video feed
Align RT
Patient


Dual Controllers
Sensor (monitor off to the right)
Actuator
Controlled Process

STPA Step 1

- Strategy:
  - We analyzed the system from a differential perspective
    - i.e. What is different in this new workflow compared to the existing workflow?
  - This helped focus us on particular pieces of the system that were most relevant to UCSD
  - We completed typical Step 1 tables for each loop in the structure

Process Map

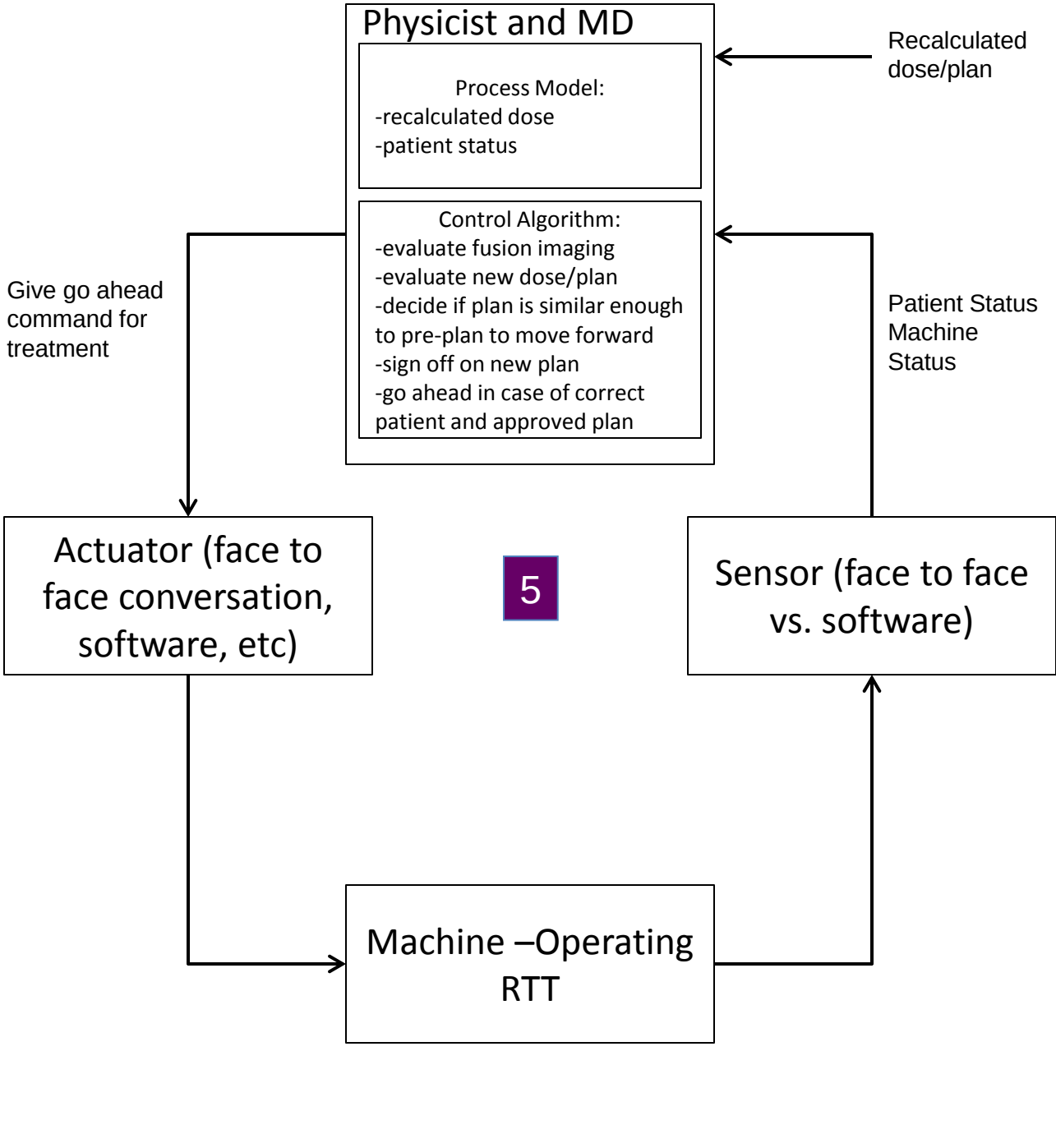
1. Physicist sends command to recalculate plan to software

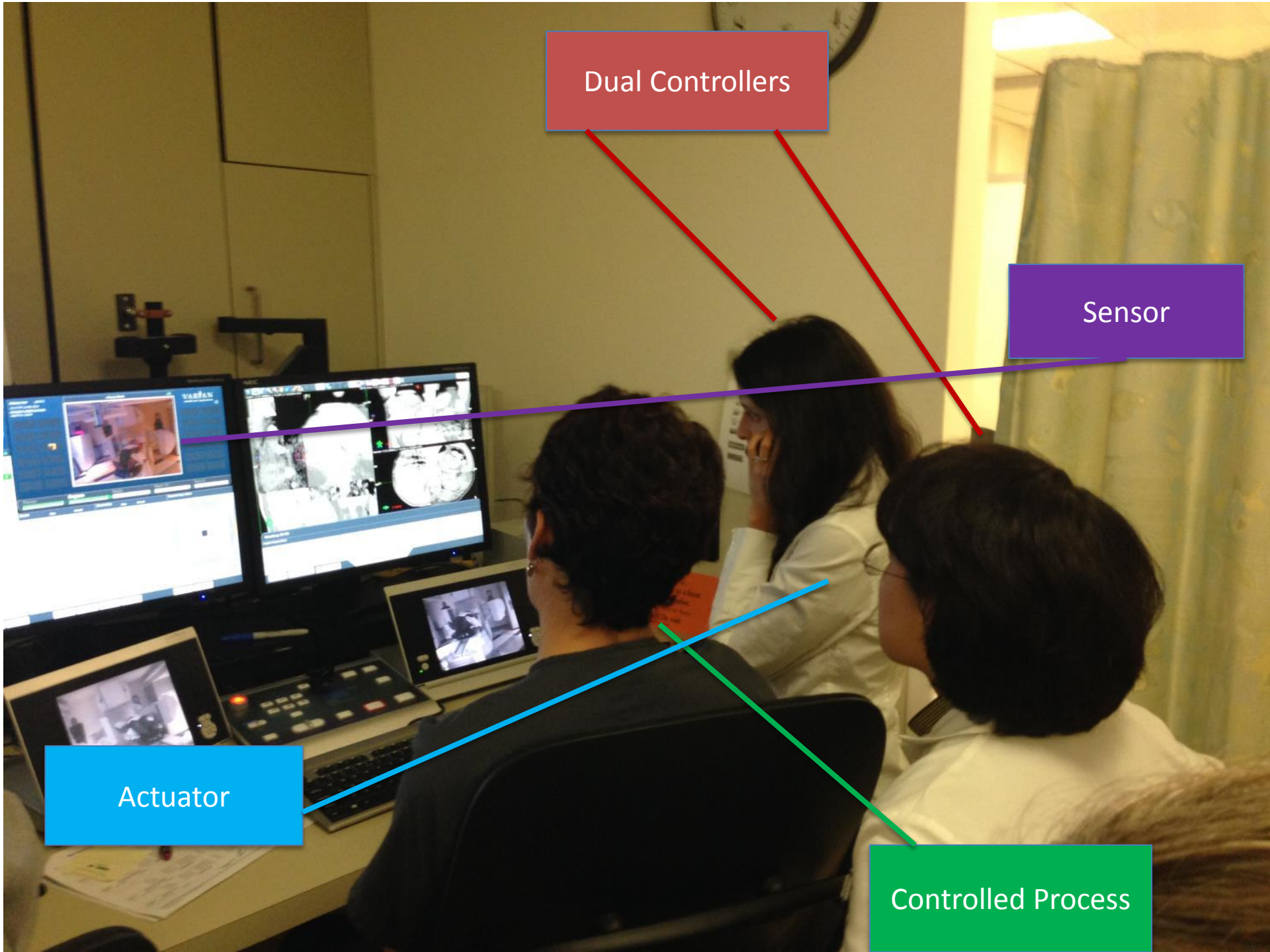
2. Software fuses MR to CBCT and imports contours onto CBCT

3. Software uses fused images to optimize (if necessary) and recalculate dose

4. Software outputs fused image and new plan and dose

5. Physicist and MD evaluate new dose and decide to accept or reject

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STPA Step 1

Control Action	Not Providing Causes Hazard	Providing Causes Hazard	Wrong Timing/Order Causes Hazard	Stopped Too Soon or Applied Too Long
Give "go ahead command" for treatment based on "recalc"		**Provides a" go ahead command" for an "incorrect recalc" (H1.1-3)**	Providing "recalc" approval late results in patient moving (H1.1,3) Provide "go ahead command" before "recalc approved" (H1.1-3)	Incomplete recalc plan issued (H1.1-3)

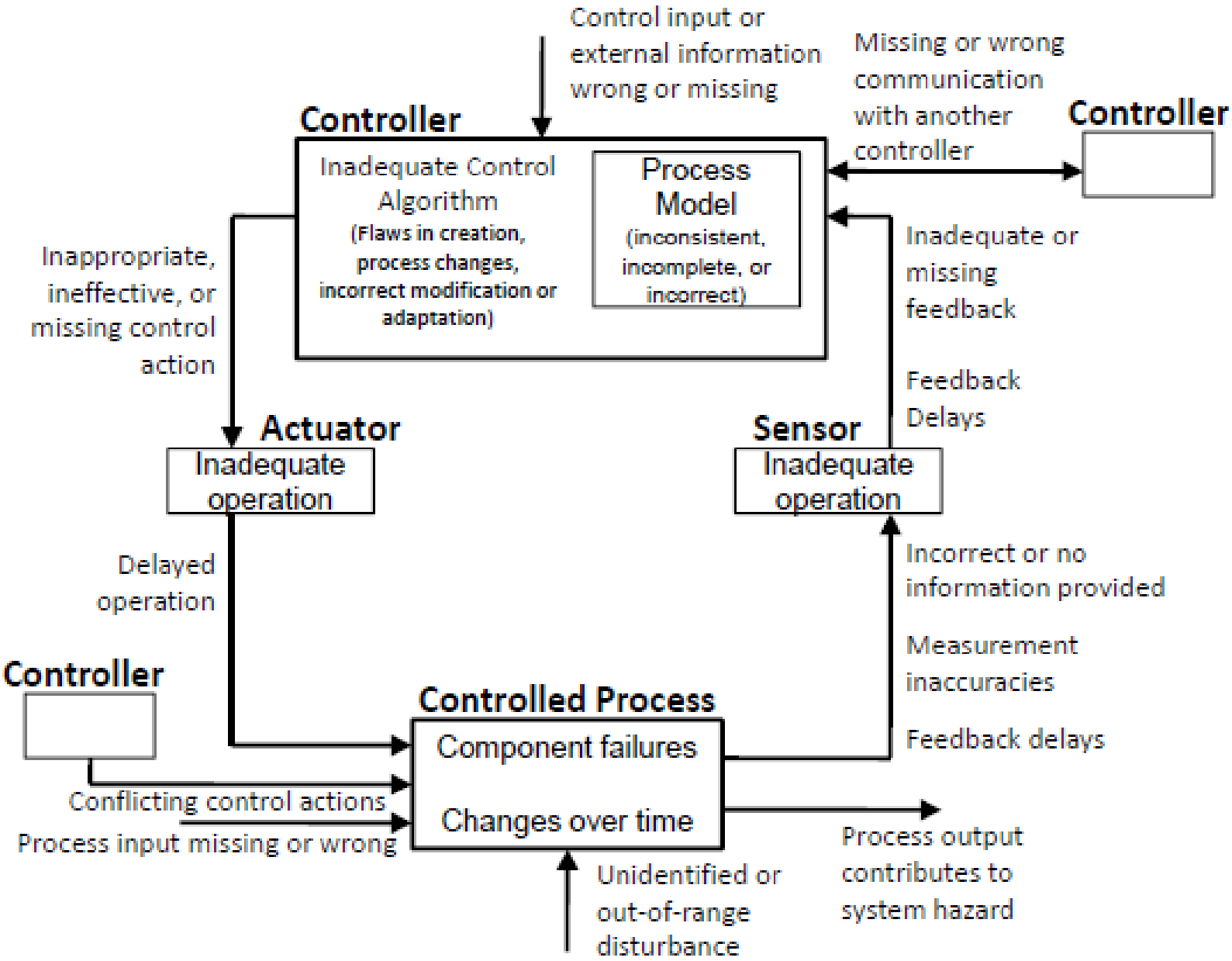
STPA Step 1 - Results

- Found 40 Unsafe Control Actions out of 9 control actions analyzed
- Some interesting and unexpected UCAs:
  - Incomplete file transfer: implicated in prior overdoses during treatment
  - Recalculated plan approval takes too long: this balances time pressure in making this decision with the constraint that the patient simply cannot remain motionless that long
- Analyzed 5 of the more interesting ones to complete a preliminary Step 2 analysis

STPA Step 2 - Process

- MIT served as facilitators to walk UCSD through the control loop
- Loops completed in random order to focus the scenarios to the UCA being analyzed
- Created spreadsheets linking the scenarios to the UCA, the position in the control loop, and the hazard
  - Helpful for translating these into safety constraints for each role in the system

Step 2: Identifying How UCAs Could Occur



UCA: Wrong Recalc Plan Approved

Radiation Oncologist and Physicist

Algorithm

MD looks at wrong patient description
Data corrupted during analysis
Head sides "flipped" during analysis
Image is corrupted
Wrong patient
Wrong patient as multiple cases are worked on simultaneously
Reviewed plan inadequately (comprehensive review not done)
Mistakes caused by time pressure to get analysis done before patient moves
MD/PhD interaction: MD says go, PhD has reservations but feels Phd cannot speak up
MD and PhD in different locations have low quality discussion about approving recalc plan
Review MR fusion to CBCT, decides it is close enough and it isn't

Process Model

Assumed patient hasn't moved, but patient has moved
Patient monitoring fails or is inattentive
Align RT gives bad position info due to crashes, or other cause
Assumes dose calculated correctly when it hasn't been calculated correctly
MD/PhD have excellent rapport - may not examine each other's work critically

Software File Transfer and Verbal Approval

Software doesn't pass on file correctly
Software crashes in a not easily recoverable manner
Software changes something that is not easily detectable
Software imports data incorrectly
Varian software self check fails

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Verbal Confirmation

RTT not communicating critical info to PhD and MD

Machine Operating RTT

Poor RTT machine interface results in input error
Long queue of patients could result in wrong patient file being pushed to varian machine software
RTT does not shut off beam if patient moves
Too many "eyes" on process results in RTT hesitation while waiting for "other" eyes to detect error

Example Step 2 Table

	UCA Scenario	Hazard
Algorithm		
Process Model		
Controller		
Actuator		
Controlled Process		
Sensor		

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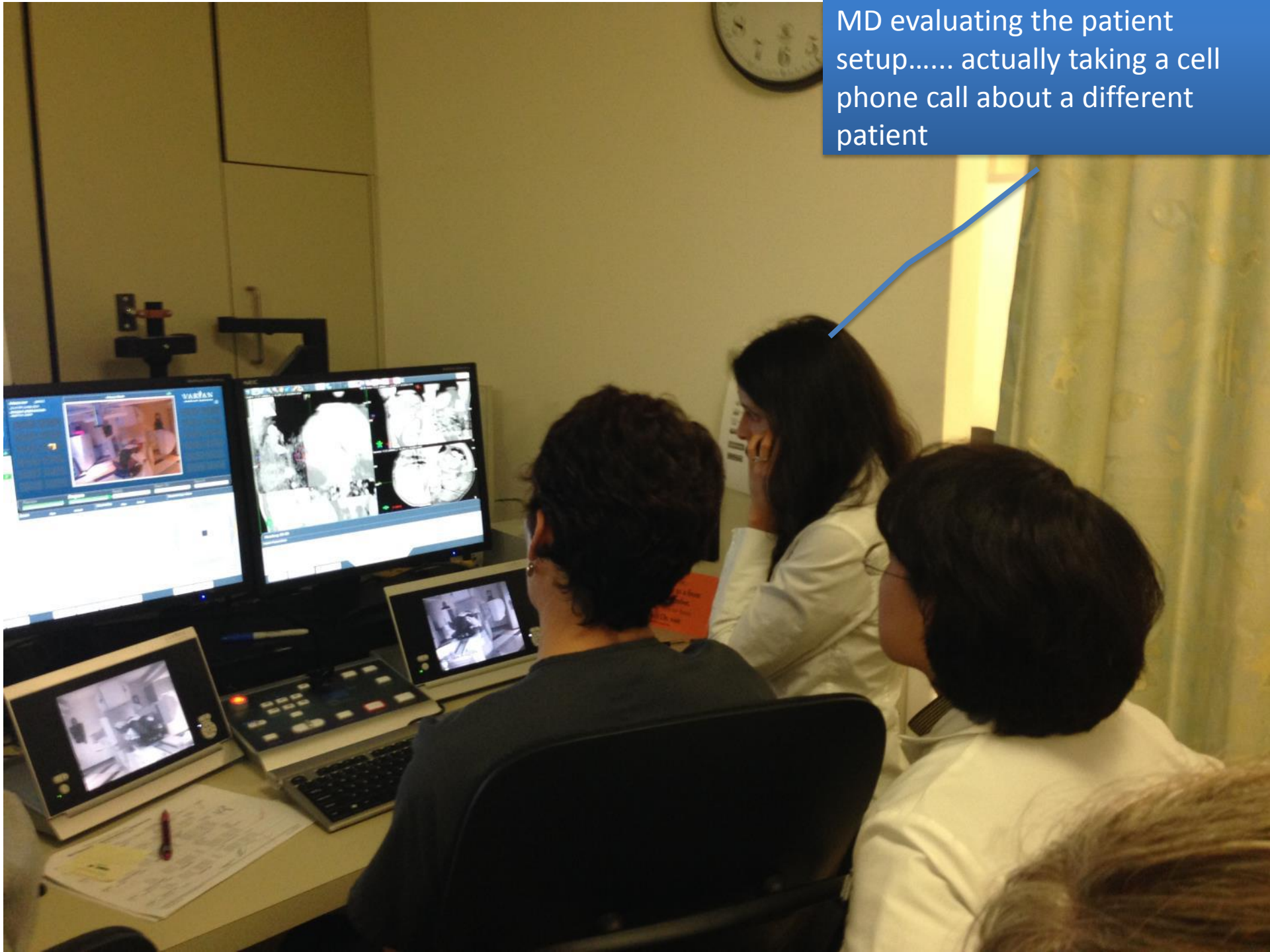
STPA Step 2 Results

UCA: Wrong recalc plan issued

Scenario for Algorithm	*Associated Hazard*
MD looks at wrong patient description	1.3
Data corrupted during analysis	1.1
Head sides "flipped" during analysis	1.2
Image is corrupted	1.1
Wrong patient	1.3
Wrong patient as multiple cases are worked on simultaneously	1.3
Reviewed plan inadequately (comprehensive review not done)	1.1
Mistakes caused by time pressure to get analysis done before patient moves	1.1
MD/PhD interaction: MD says go, PhD has reservations but feels PhD cannot speak up	1.1
MD and PhD in different locations and **have low quality discussion about approving recalc plan**	1.1
Review MR fusion to CBCT, decides it is close enough and it isn't	1.1


MD evaluating the patient setup…… actually taking a cell phone call about a different patient

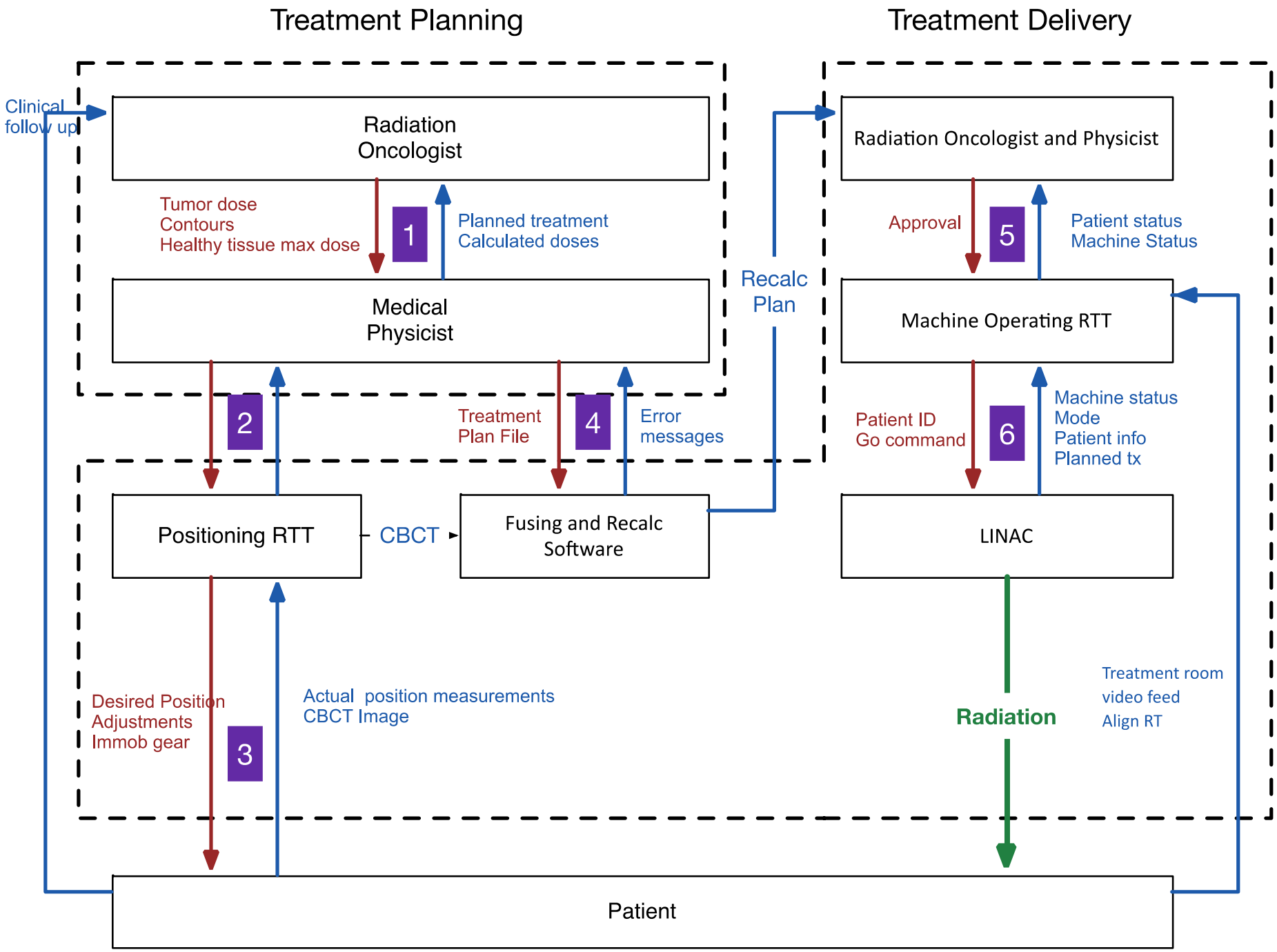
Requirements and Constraints

- Step 2 scenarios translated into either requirements or constraints
- General principle:
  - Write constraints for each person or piece of equipment
  - Break it down by function
  - Include the intention behind the constraint

Software Constraints - Example

[R-8] Software must complete calculations within 2 minutes

Intent: Patients cannot stay completely still forever on the treatment table. There are no good studies out there looking at how long patients can remain in one position, but anecdotally adding on about two minutes to the total procedure time is about the maximum reasonable time.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Treatment room
video feed
Align RT
Patient

Future Directions for UCSD

- Complete STPA Analysis
  - Share with vendor for input
  - Discuss with MDs, RTTs, etc
- Create software required
  - Design from scratch vs. patchwork of existing
  - Possibly use STPA to evaluate the designs
- Apply for Varian funding
- Test the new procedure

Conclusions

- STPA is useful in a healthcare setting to assist with early process design
  - Identified high level requirements and constraints
  - Highlighted design decisions
- Lessons learned in facilitating STPA
  - Difficult to transition from thinking of linear processes to control loops
  - Concept of control actions and unsafe control actions in an early design can be difficult to grasp