STPA Analysis of Changes in the Process for Stereotactic Radiosurgery

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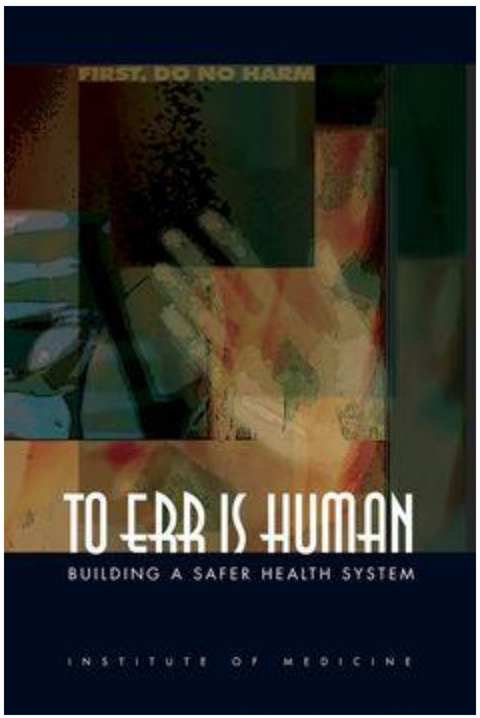
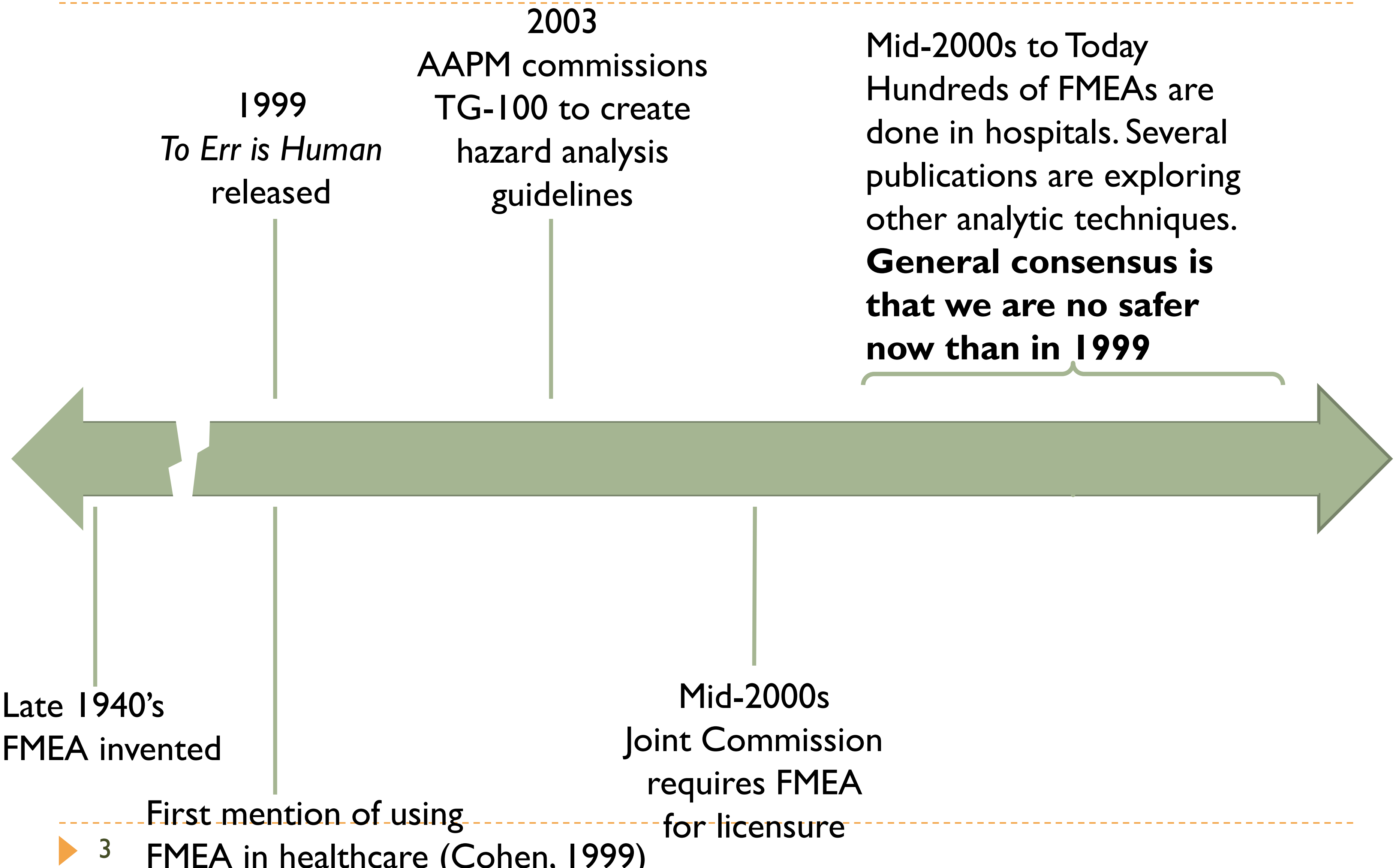
Patient Safety, or Why Should I Care?

- In 1999, IOM released a report, To Err is Human, saying that healthcare in the US killed 49,000-98,000 people per year



A 2013 meta-analysis, suggested that with improved measurement tools, we were actually contributing to the premature deaths of 210,000-400,000 people per year

Hazard Analysis in Healthcare



Healthcare FMEA Methodologies

- Wide variability in applications that fulfill the Joint Commission requirements
- Many organizations offer worksheets and guidance
  - Institute for Healthcare Improvement
    - Generic and classic FMEA, no adaptation for healthcare

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1–10)	Likelihood of Detection (1–10)	Severity (1–10)	Risk Priority Number (RPN)	Actions to Reduce Occurrence of Failure
1								
2								
3								

  - VA Healthcare FMEA
    - Copyrighted methodology, adapting FMEA to healthcare specific applications

Healthcare FMEA results

- Heterogeneous!
  - Partly due to the wide variety in available tools
  - Additionally, most hospitals do not have system engineering departments to provide engineers who specialize in doing these analyses

Laboratory Phlebotomy: Failure Modes and Effects Analysis (Wagar, 2006)

Process Step	Potential Failure Mode	Potential Failure Effects (on Patient)	SEV	Root Causes	OCC	Current Controls	DET	RPN	Strategies
1	Check patient's wrist-band (name and MR No.)	Specimen obtained from wrong patient; wrong blood in tube	7	Not checking wristband name spelling, and MR No.	4	Training; competencies	5	140*	Retrain to check patient name, correct spelling, and MR No.

Process step	Failure mode	Hazard score	Causes	Recommendation
(1A) Chemotherapy treatment schedule in chart	(1) Old chemotherapy treatment schedule in chart	6	Pediatric oncologist did not update schedule in chart	(1) Design standard procedure for changes in chemotherapy treatment schedules
	(2) Chemotherapy treatment schedule misunderstood	4	Schedule in language other than Dutch or English	(2) Translate chemotherapy treatment schedules

(van Tilburg, 2006)

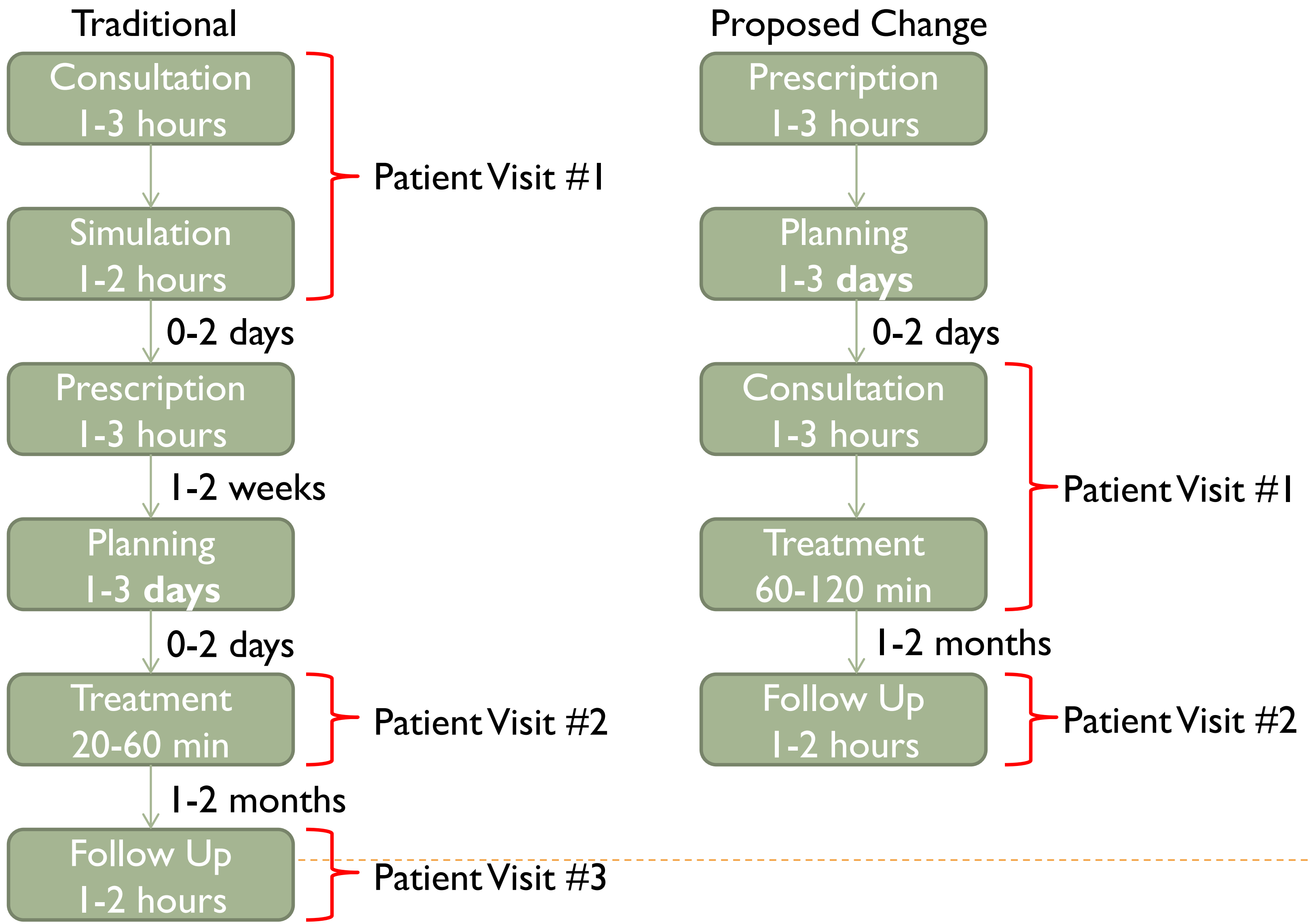
Project Objectives

- We believe that STPA can provide a conceptual framework that can consistently identify hazards and causal factors that can lead to strong systemic recommendations
  - Grounding in systems theory forces the analyst to consider the environment that the controller is operating within leading to solutions beyond merely re-training
- We propose a proof-of-concept case study showing that STPA can give meaningful results in healthcare applications
  - We chose to study a radiation oncology process

Why Radiation Oncology?

- Strong safety culture
  - After several negative media articles, the field has really begun to pay attention to safety in a way that other hospital areas have not yet
- Medical physicists
  - Radiation oncology is one of the few fields where technical faculty work in patient care applications
  - Bring an engineering perspective to a field otherwise dominated by clinicians with a focus on narrative description
- Device Precision
  - Radiation can be delivered with millimeter precision, which makes process errors and accidents a critical source of mistreatment

SRS Process


Traditional
Consultation
1-3 hours
Simulation
1-2 hours
Patient Visit #1
0-2 days
Prescription
1-3 hours
1-2 weeks
Planning
1-3 **days**
0-2 days
Treatment
20-60 min
Patient Visit #2
1-2 months
Follow Up
1-2 hours
Patient Visit #3
Proposed Change
Prescription
1-3 hours
Planning
1-3 **days**
0-2 days
Consultation
1-3 hours
Treatment
60-120 min
Patient Visit #1
1-2 months
Follow Up
1-2 hours
Patient Visit #2

Accidents

A-1. Patient injured or killed due to radiation

A-2. Non-patient injured or killed due to radiation

A-3. Damage to equipment

A-4. Death or injury of patient or non-patient not due to radiation

Hazards

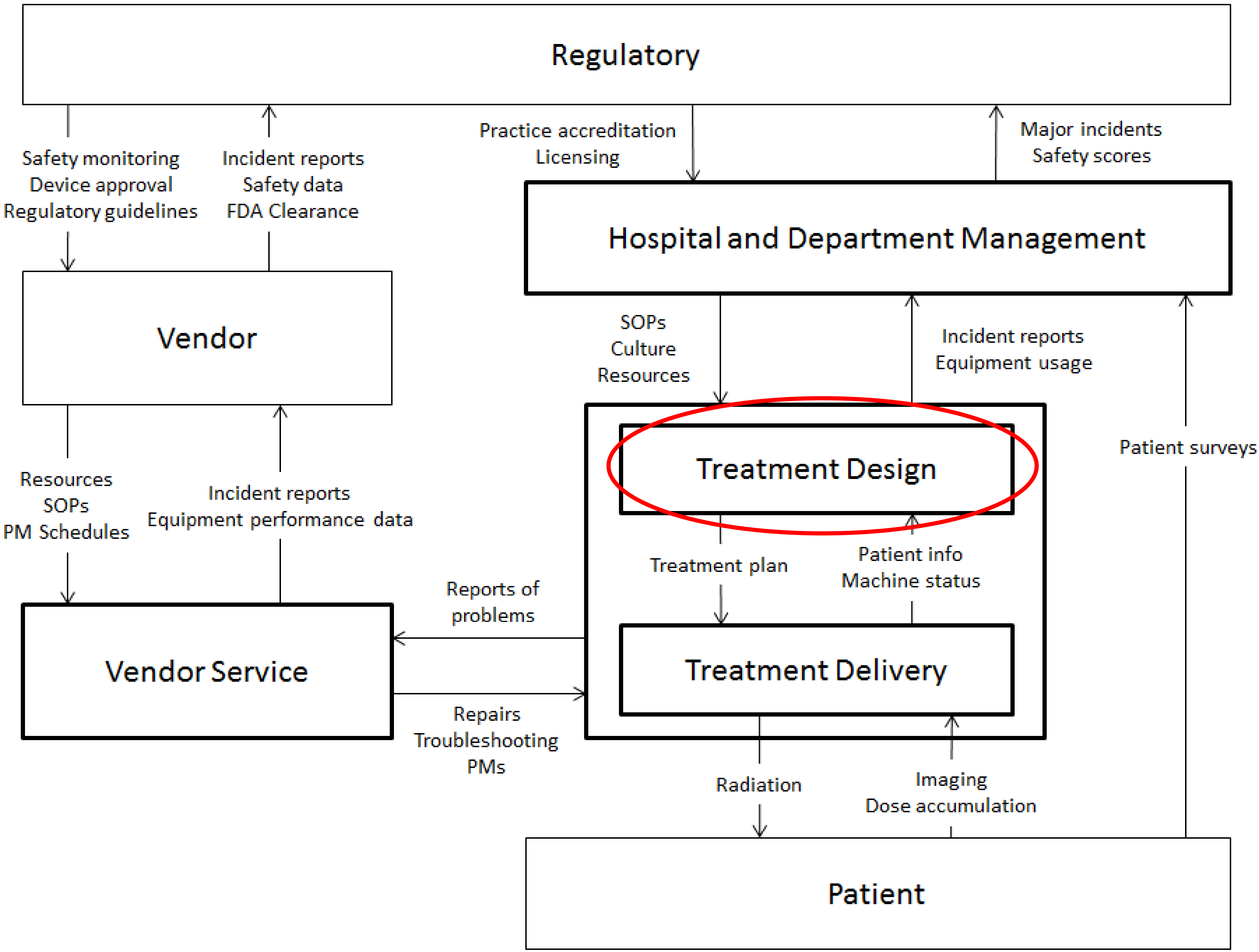
H1. Wrong radiation delivered

- **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

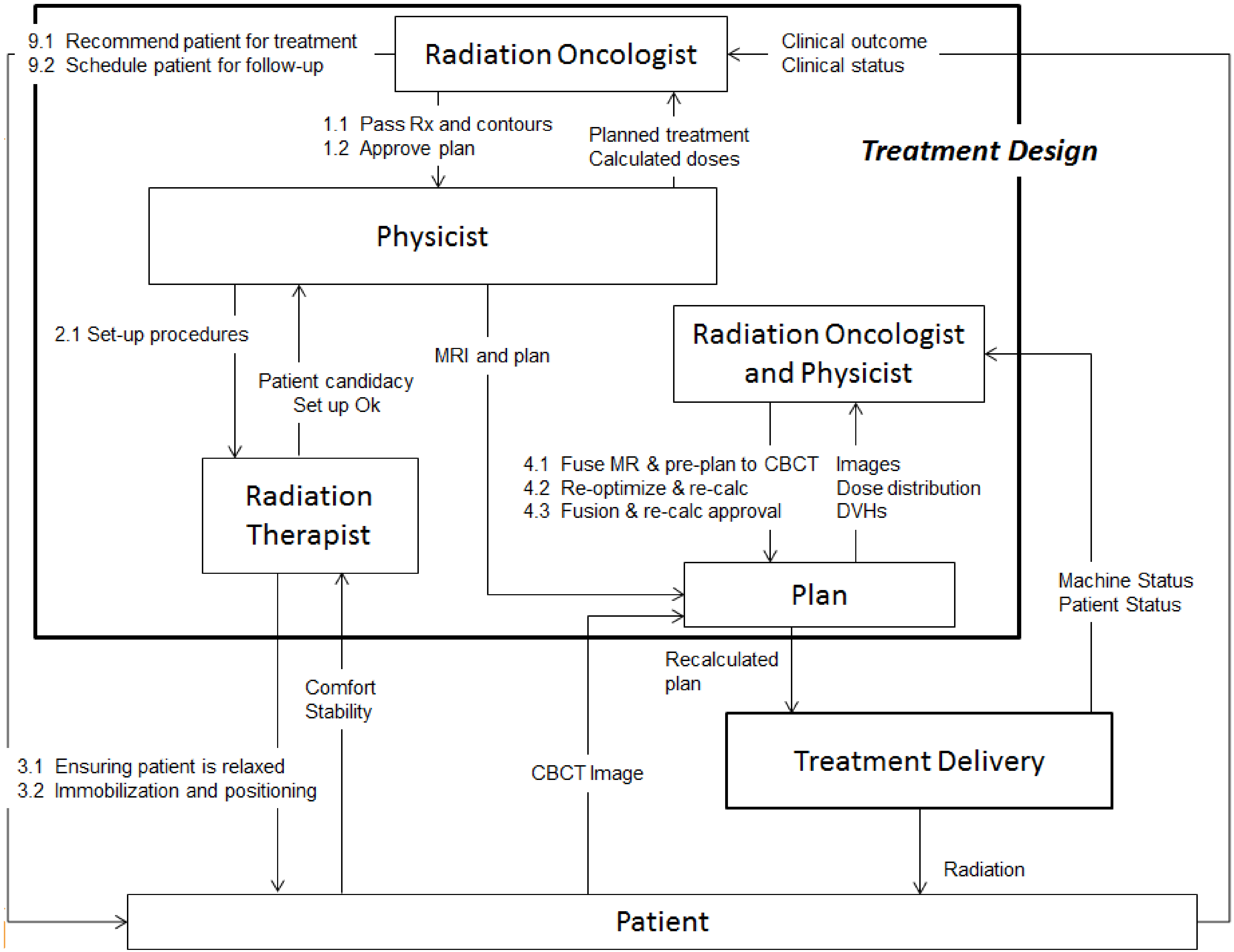
H2. Staff is unnecessarily exposed to radiation

H3. Equipment subject to unnecessary stress

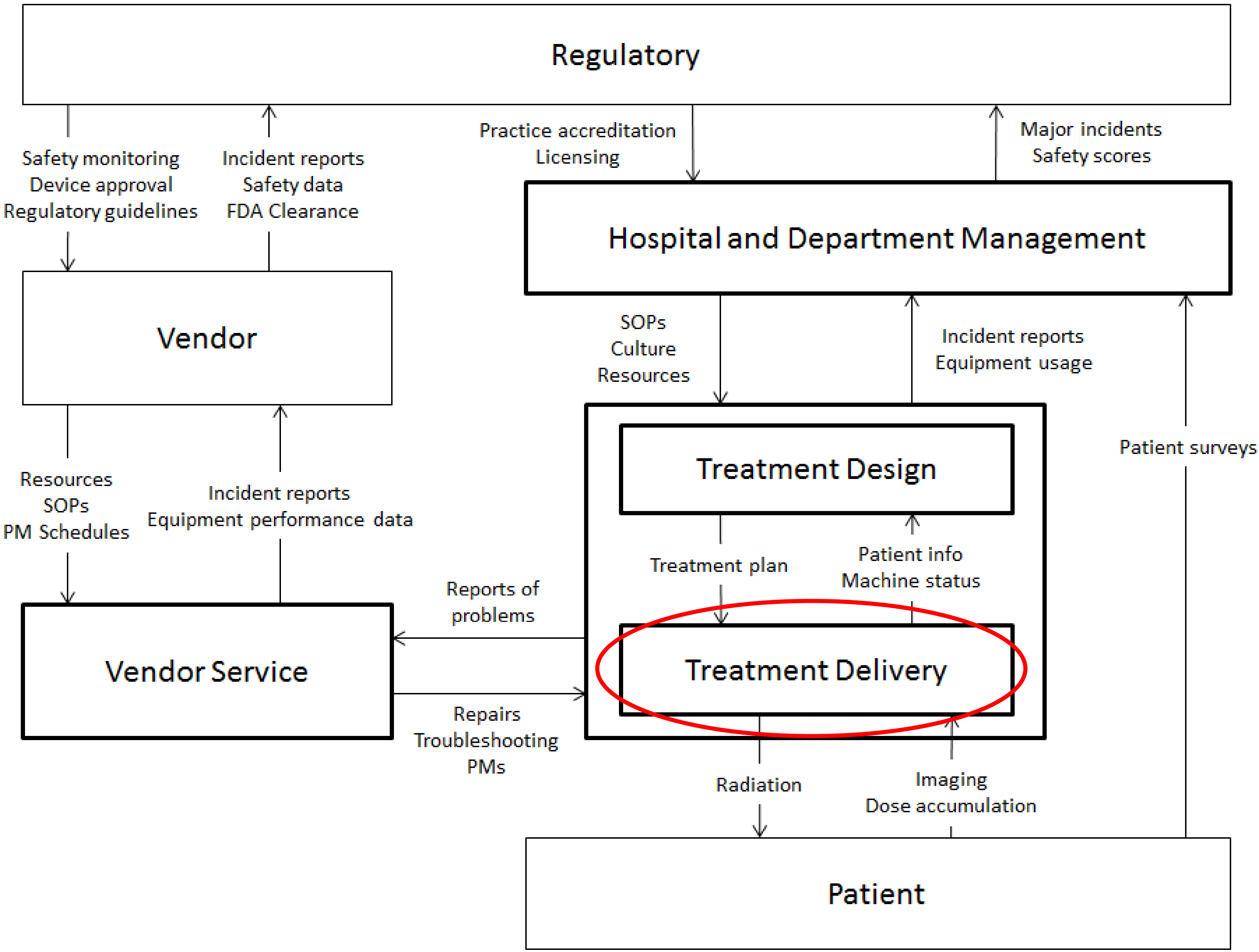
H4. Persons subjected to the possibility of non-radiation injury



Regulatory
Safety monitoring
Device approval
Regulatory guidelines
Incident reports
Safety data
FDA Clearance
Practice accreditation
Licensing
Major incidents
Safety scores
Hospital and Department Management
Vendor
SOPs
Culture
Resources
Incident reports
Equipment usage
Treatment Design
Patient surveys
Resources
SOPs
PM Schedules
Incident reports
Equipment performance data
Treatment plan
Patient info
Machine status
Reports of
problems
Vendor Service
Treatment Delivery
Repairs
Troubleshooting
PMs
Radiation
Imaging
Dose accumulation
Patient



9.1 Recommend patient for treatment
9.2 Schedule patient for follow-up
Radiation Oncologist
Clinical outcome
Clinical status
1.1 Pass Rx and contours
1.2 Approve plan
Planned treatment
Calculated doses
Treatment Design
Physicist
2.1 Set-up procedures
Patient candidacy
Set up Ok
MRI and plan
Radiation Oncologist and Physicist
Radiation Therapist
4.1 Fuse MR & pre-plan to CBCT
4.2 Re-optimize & re-calc
4.3 Fusion & re-calc approval
Images
Dose distribution
DVHs
Plan
Machine Status
Patient Status
Recalculated plan
Comfort
Stability
3.1 Ensuring patient is relaxed
3.2 Immobilization and positioning
CBCT Image
Treatment Delivery
Radiation
Patient



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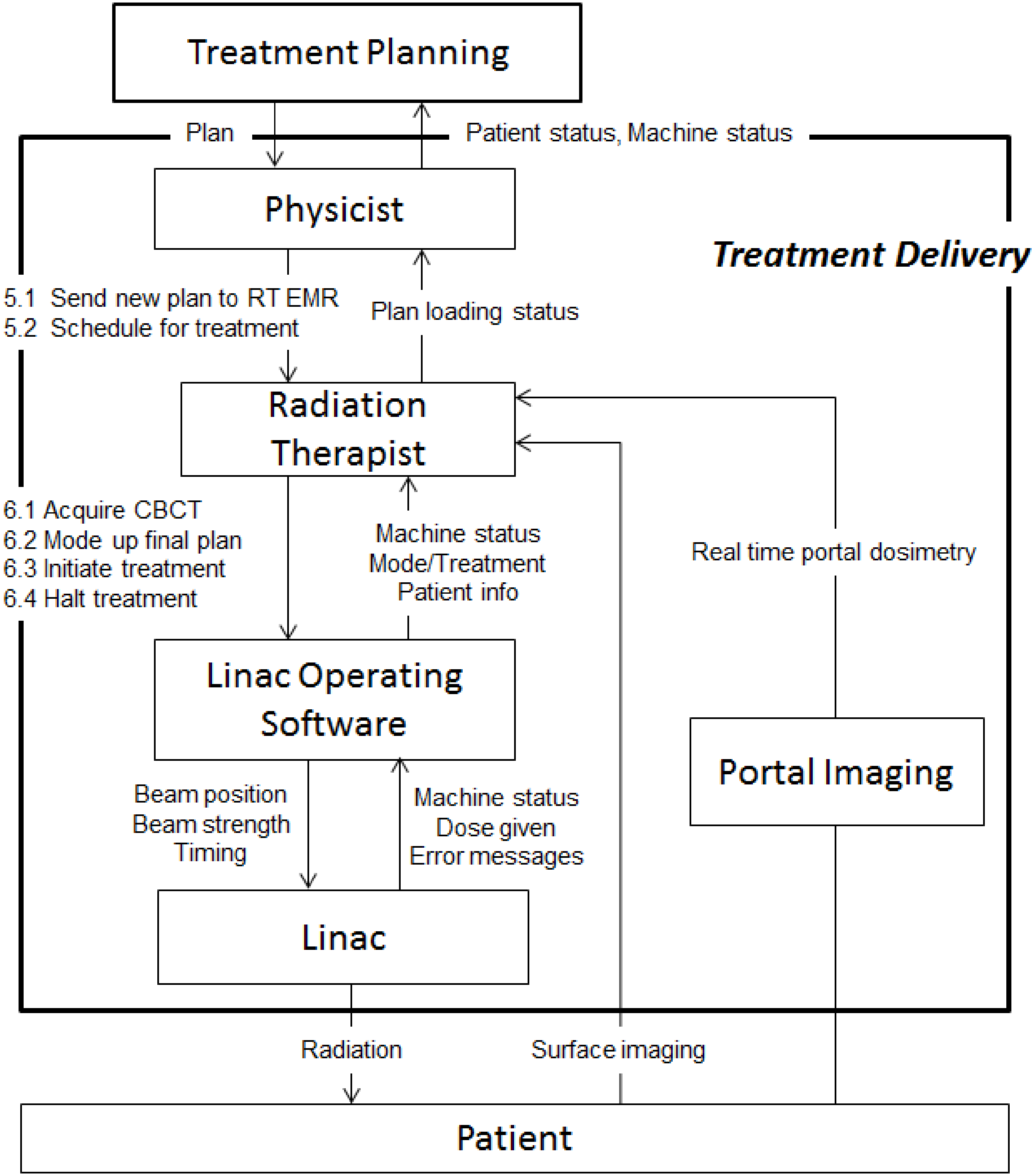
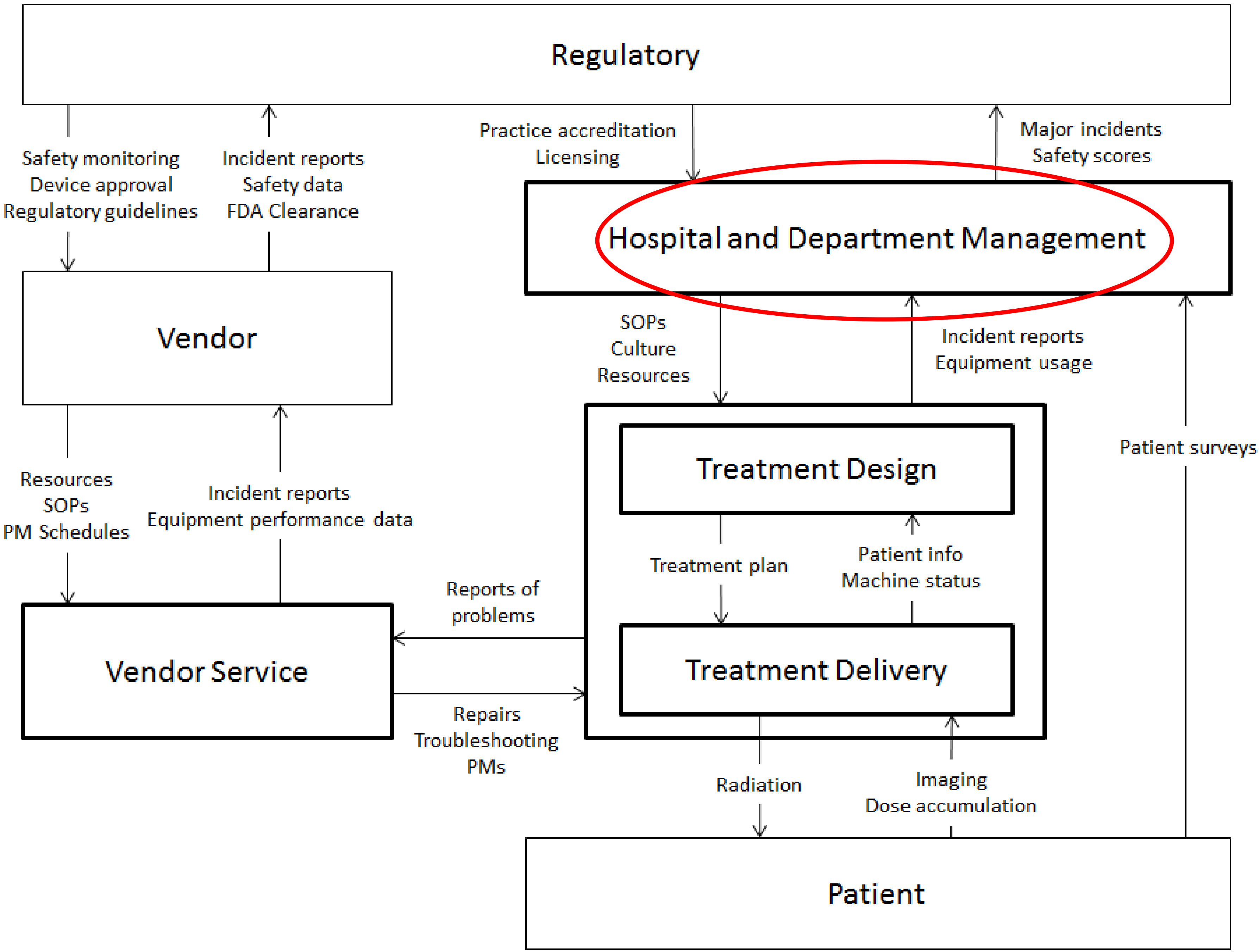
PMs
Radiation
Imaging
Dose accumulation
Patient


Treatment Planning
Plan
Patient status, Machine status
Physicist
Treatment Delivery
5.1 Send new plan to RT EMR
5.2 Schedule for treatment
Plan loading status
Radiation Therapist
6.1 Acquire CBCT
6.2 Mode up final plan
6.3 Initiate treatment
6.4 Halt treatment
Machine status
Mode/Treatment
Patient info
Real time portal dosimetry
Linac Operating Software
Portal Imaging
Beam position
Beam strength
Timing
Machine status
Dose given
Error messages
Linac
Radiation
Surface imaging
Patient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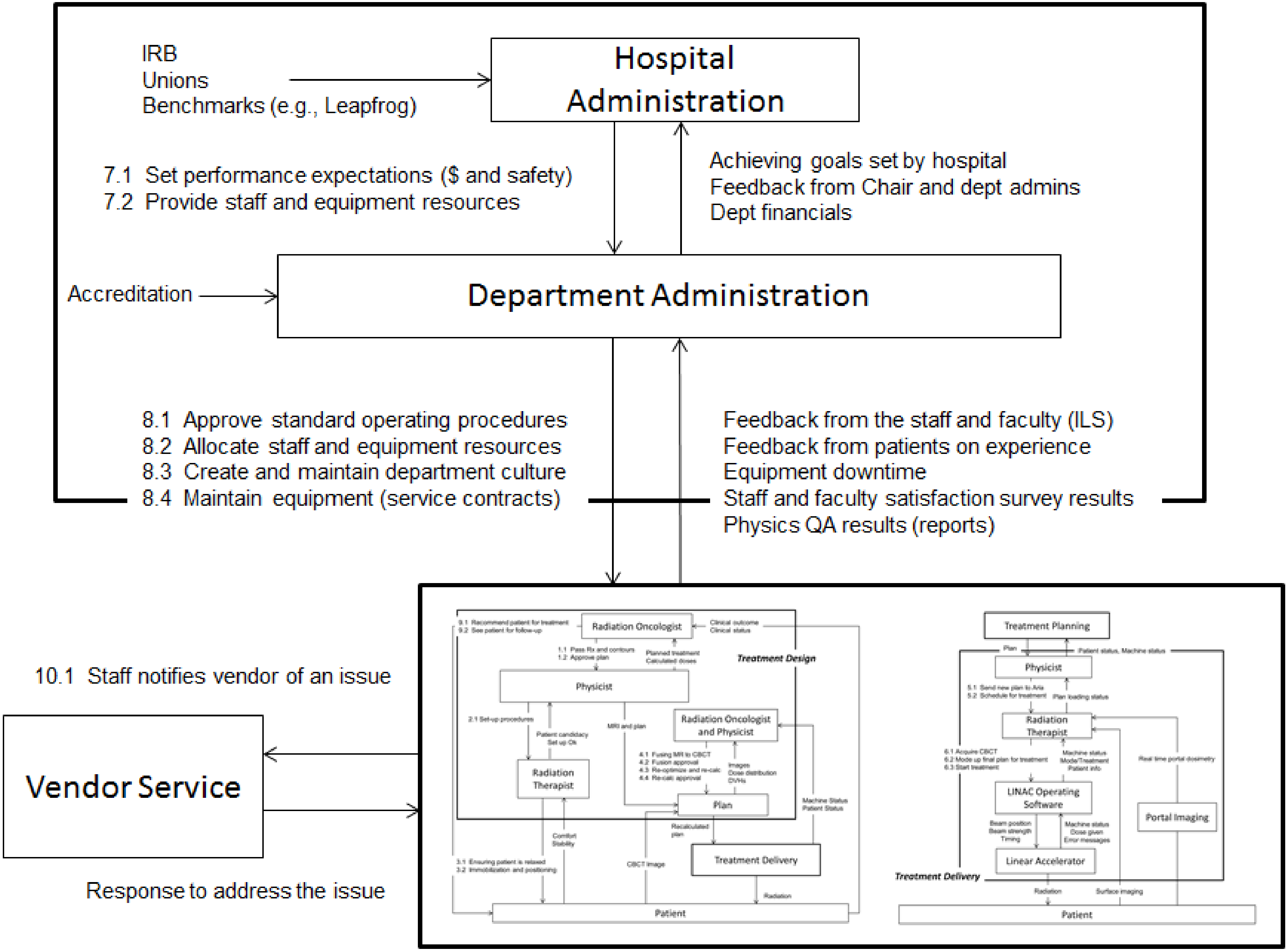


IRB
Unions
Benchmarks (e.g., Leapfrog)
Hospital Administration
7.1 Set performance expectations ($ and safety)
7.2 Provide staff and equipment resources
Achieving goals set by hospital
Feedback from Chair and dept admins
Dept financials
Accreditation
Department Administration
8.1 Approve standard operating procedures
8.2 Allocate staff and equipment resources
8.3 Create and maintain department culture
8.4 Maintain equipment (service contracts)
Feedback from the staff and faculty (ILS)
Feedback from patients on experience
Equipment downtime
Staff and faculty satisfaction survey results
Physics QA results (reports)
10.1 Staff notifies vendor of an issue
Vendor Service
Response to address the issue
Radiation Oncologist
Treatment Design
Physicist
Radiation Oncologist and Physicist
Radiation Therapist
Plan
Treatment Delivery
Patient
Treatment Planning
Physicist
Radiation Therapist
LINAC Operating Software
Portal Imaging
Linear Accelerator
Treatment Delivery
Patient

Step 1

- Analyzed 21 control actions using classic Step 1 Tables
- Identified 85 unsafe control actions

Step 1 Tables for Medical Physicist – Radiation Oncologist Hybrid Controller

Control Action	Not providing causes hazard	Providing leads to hazard	Wrong timing leads to hazard	Applied too long or too short leads to hazard
4.1 Fuse MR and pre-plan to CBCT	UCA 4.1.1: The physicist does not perform the fusion when the images and pre-plan are ready. [H1]	UCA 4.1.2: The physicist fuses the images and pre-plan incorrectly when using the fusion software. [H1]	UCA 4.1.3: The images are fused before the final or most recent CBCT is acquired and transferred for fusion. [H1]	UCA 4.1.4: The fusion takes too long when transferring images or using the fusion software. [H1]
4.2 Re-optimize and re-calculate	UCA 4.2.1: Suboptimal treatment occurs when a suboptimal pre-plan is scheduled for treatment. [H1]	UCA 4.2.2: An inaccurate dose calculation is provided when the physicist uses the software to perform the re-calc. [H1]	UCA 4.2.3: Re-optimize and re-calculate before fusion is complete [H1.1-3]	UCA 4.2.4: Re-optimization or re-calculation takes too long when using the treatment planning software. [H1] UCA 4.2.5: Re-optimization ends before completed after the physicist initiates the optimization. [H1]
4.3 Fusion and final plan approval	UCA 4.3.1: The fusion is not checked by the radiation oncologist when it is suboptimal. [H1] UCA 4.3.2: The final plan is not checked by the radiation oncologist when it is suboptimal. [H1.1-3]	UCA 4.3.3: The radiation oncologist approves the fusion when it is suboptimal. [H1] UCA 4.3.4: The radiation oncologist approves the final plan when it is suboptimal. [H1.1-3]	UCA 4.3.5: The fusion is approved after the plan has been scheduled for treatment. [H1] UCA 4.3.6: The radiation oncologists approves a plan before the final plan is completed. [H1]	UCA 4.3.7: The fusion and final plan approval are delayed when they are ready to be checked. [H1]

Step 2- The physicist/oncologist does not perform the fusion when the images and pre-plan are ready.

- Controller is unaware that they need to complete the fusion at this time
  - Missing input: If the CBCT is not uploaded into the computer in the normal file location then the physicist may not realize that it is time to complete the fusion. They may also not have received a page or other communication that it is time to proceed.
  - Falsely believe that the patient has moved and therefore the CBCT is not valid to use for the fusion
    - False alarm from the surface imaging
    - Poor quality video feed from the room makes it appear that patient moved
- Controller does not have the files to proceed
  - Missing input: CBCT or MRI with contours and plan not loaded into computer.
  - Missing input: Images are loaded into the computer but in the wrong location
  - Missing input: Images are loaded in the improper file format
- Implementation of control actions is flawed (i.e. scenarios where the controller knows to run the fusion, but somehow the fusion is not created)
  - Fusion software does not create a fusion, but does not give an error message that is obvious to the physicist. The physicist therefore assumes that the fusion proceeded as planned.
  - Physicist does not know how to use the fusion software. This is a likely problem to run into at the start of using this new process or when a new physicist is hired.

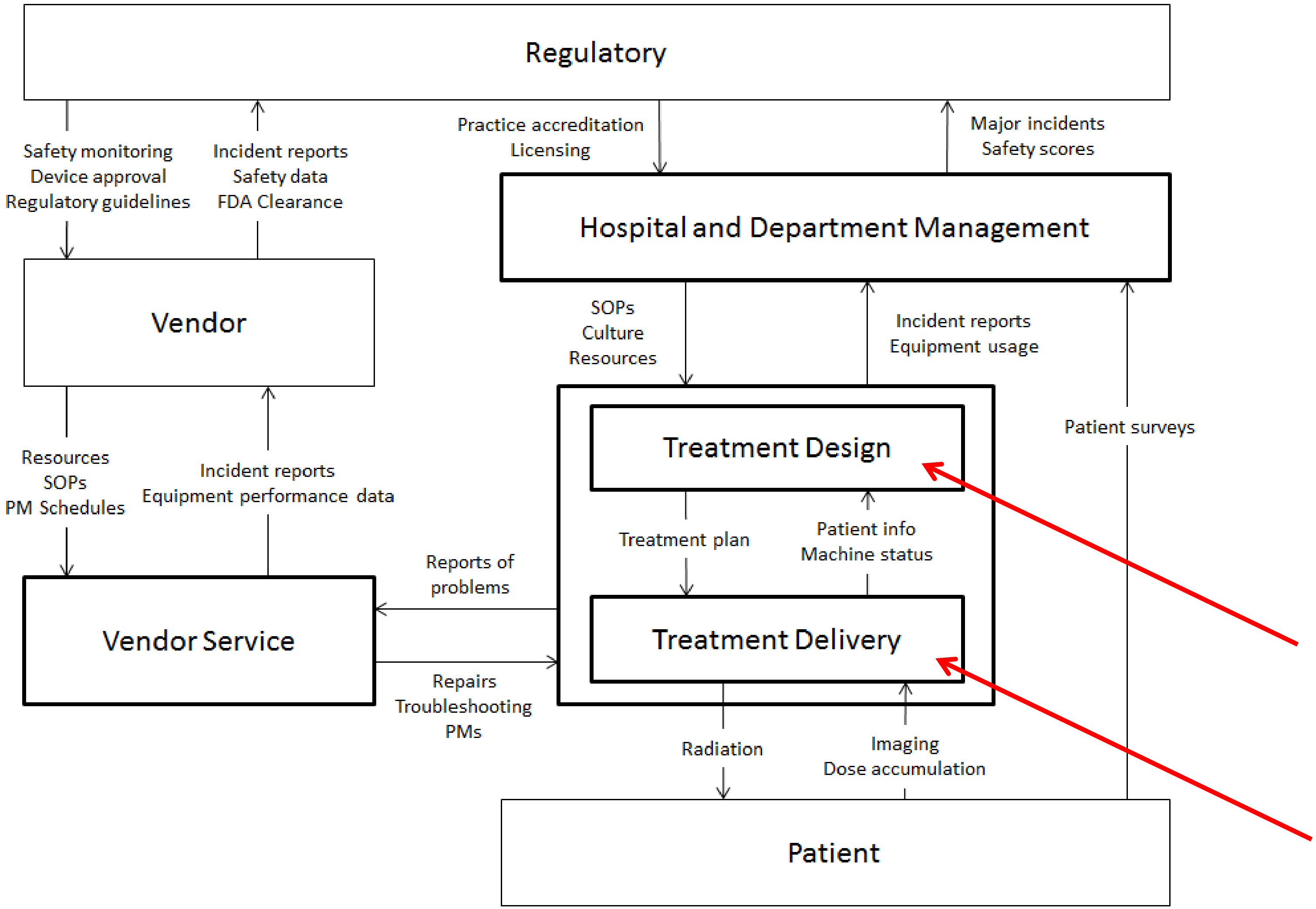
Requirements

- Our ultimate goal in this project is to deliver a set of “requirements” for clinicians’ new roles and for the new software
  - These are not traditional requirements in the software engineering sense
  - Rather our goal is to determine what type of behavior each controller, actuator, and sensor needs to ensure that every controller can take the correct and safe control action
- What might this look like?
  - What do we give to a software developer to assist in defining the specifications for this software?
  - What could we give to clinicians to help them best understand their roles in ensuring safe practice as we roll out this new process?

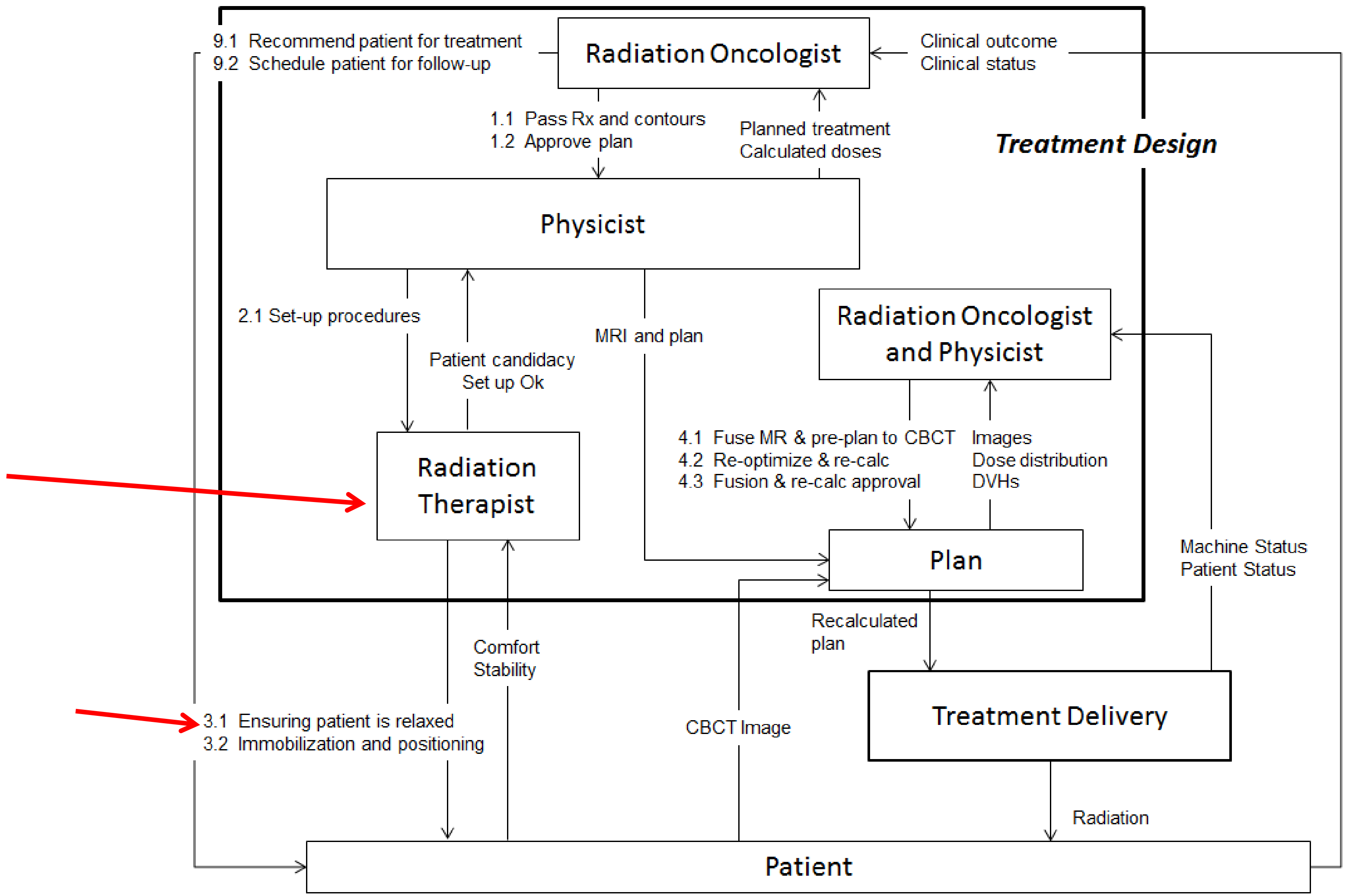
Requirements – Fusion Software

- Behaves as an actuator and a sensor for the medical physicist/radiation oncologist controller
  - Use step 2 results from analyzing the UCAs associated with that controller to place behavioral requirements on the software
- Sample requirements:
  - Software must check both MRI and CBCT image for completeness (UCA 4.1.2)
  - Software must not run fusion if either MRI or CBCT is missing (UCA 4.1.1)
  - Software must complete fusion within X minutes (UCA 4.1.4)
  - Software must output a high quality image, by radiology standards, for fusion evaluation (UCA 4.1.2)

Requirements – Radiation Therapist



Requirements – Radiation Therapist



Requirements – Radiation Therapist

- Safety Responsibility: Positioning the patient
- Safety Constraints: adapted from the UCAs
  - Therapist must position the patient according to the SOPs for this new process
  - Therapist must not take too long positioning the patient
  - Therapist must securely immobilize the patient to prevent motion
- Other System Requirements: adapted from Step 2 causal factors
  - Adequate pillows, restraints, and foam pieces must be available
  - Patient must be able and willing to tell therapist that they are uncomfortable
  - Positioning SOPs must be clear and unambiguous for therapists. If there is any confusion, therapist must clarify with medical physicist

Strengths of STPA in Process Analysis

- Clear framework for considering safety and the role of the environment in allowing clinicians to make safe control decisions
- Creates a model that can be shared by the entire team involved in the process
  - Shared mental model helps with clarity of communication
  - Just seeing the system and your role in it changes your perspective to consider how your actions impact people beyond your local area
- Create clear requirements for clinician behavior and environmental constraints to promote safety

Conclusions

- STPA works well with healthcare processes for identifying safety concerns
- Next step would be to compare results to findings using FMEA and other techniques promoted by TG-100 working group
  - Potential metrics:
    - Number of causal factors
    - Quality of causal factors
    - Time/effort to complete analysis
- More future work would be in utilizing these requirements and working with social scientists to explore the best way to present these requirements

References

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