Radiation Oncology Safety
An Application of “Managerial” STPA

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STAMP Conference

3/28/13

Radiation Oncology

- A series of articles in NY Times[1] (2010) regarding accidents in radiology and radiation oncology
  - Deaths and injuries
  - Work flow issues, not just technical faults

- UCSD Radiation Oncology Department asked Prof. Leveson for assistance
  - Focusing on work processes above the linear accelerator
  - Two site visits in 2012

1 http://www.nytimes.com/2010/12/29/health/29radiation.html?pagewanted=all

“Managerial” STPA



PCA Peanut Butter Salmonella

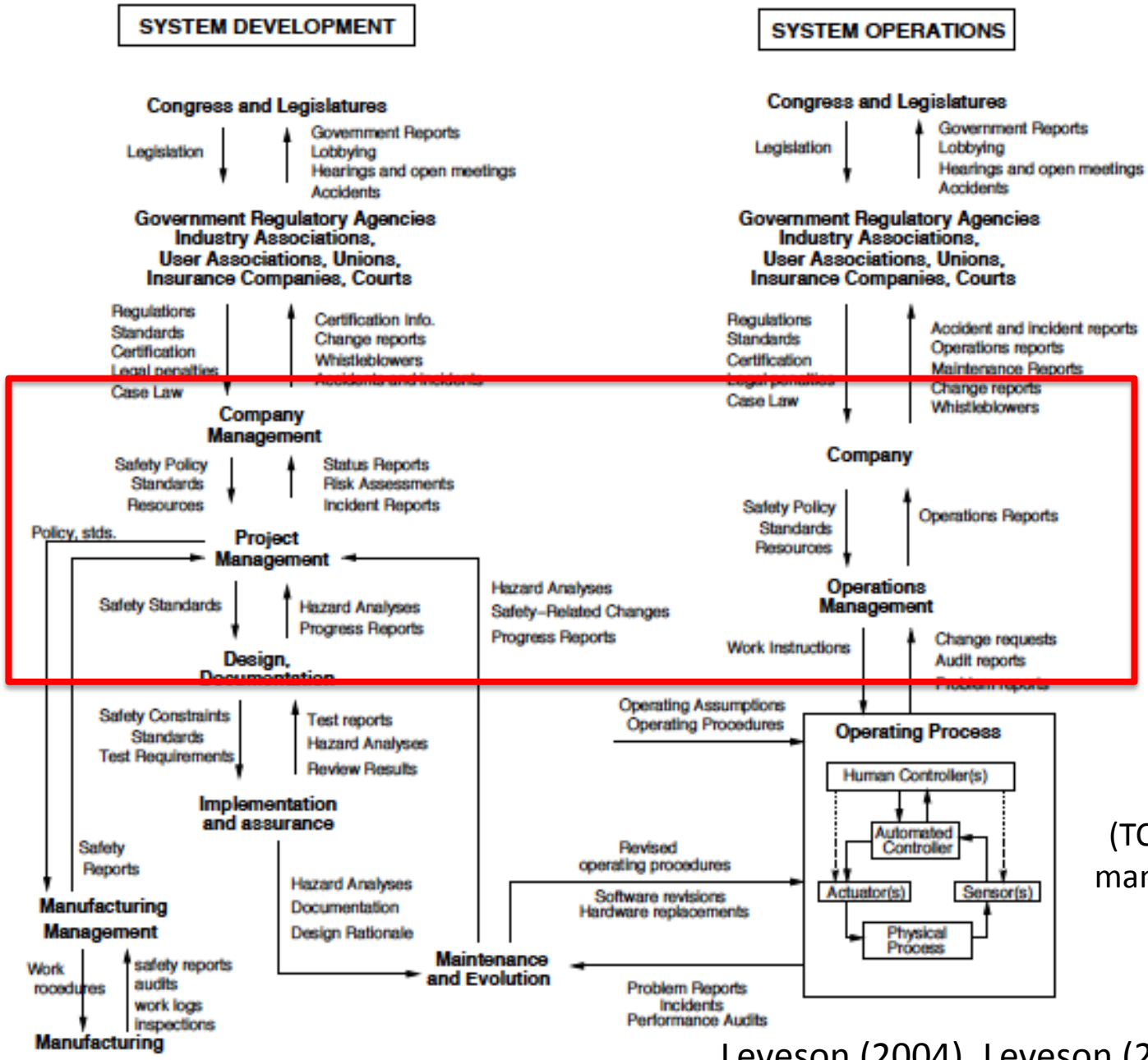

Radiation Oncology

- Managers’ decisions and actions contribute to safety risk in these systems
  - Leveson (2011), Perrow (1984)

- Few structured risk analysis methods have been developed for the managerial level in complex systems

- **The long term goal: Create a method to identify and mitigate safety risks in the managerial level of complex systems**

STAMP: Example Safety Control Structure



STPA
(TCAS, HTV, many others)[2]

Leveson (2004), Leveson (2011)

UC San Diego
RADIATION ONCOLOGY



LINAC



Control Room

Preliminary Risk Analysis

- System Hazards
- Safety Constraints
- System Requirements

Model Control Structure

- Roles and Responsibilities
- Feedback Mechanisms

Map Requirements to Responsibilities

- Gap Analysis

Risk Analysis (STPA – Step 1)

- Basic Risks
- Coordination Risks

Categorize Risks

- Intermediate and Longer Term

Causal Analysis (STPA - Step 2)

- Potential Causes of Risks

Findings and Recommendations

- Policy
- Structural
- Risk Mitigation Strategies

Identification of Radiation Oncology Hazards

- Dose delivered to patient is wrong in either amount, location, or timing.
- Non-patient is unnecessarily exposed to radiation
- Persons are subjected to the possibility of non-radiological injury

Identification of High Level Safety Requirements

- 27 safety requirements identified from
  - Site visits to UCSD
  - Past cases (Leveson)
  - "Safety is No Accident" ASTRO (2012)

Managerial Requirements Categories

Set Goals and Direction
Establish Work Processes and Standards
Staff, Schedule and Train
Manage Facility and Equipment
Allocate Resources
Monitor, evaluate performance

Example of Radiation Oncology Safety Requirements

Monitor, provide feedback and corrective action	Procedures must be in place to identify and investigate thoroughly all serious or potentially serious incidents.
	Recommendations must be implemented to eliminate or mitigate all identified factors contributing to the adverse events.
	Follow-up must be provided to ensure that recommendations have been implemented and are effective.
	Lessons learned must be documented and disseminated.

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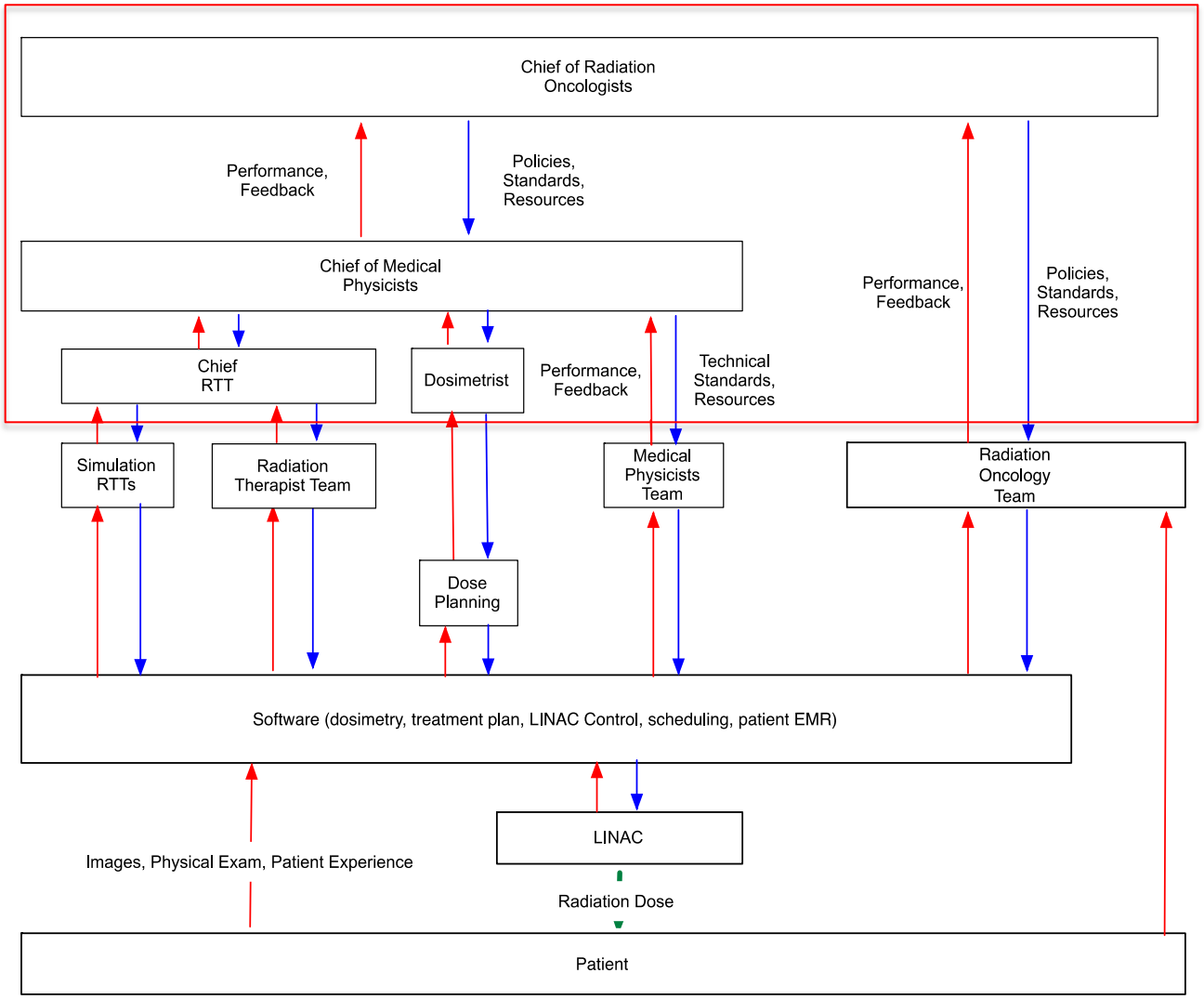
Control Structure for Radiation Oncology at UCSD



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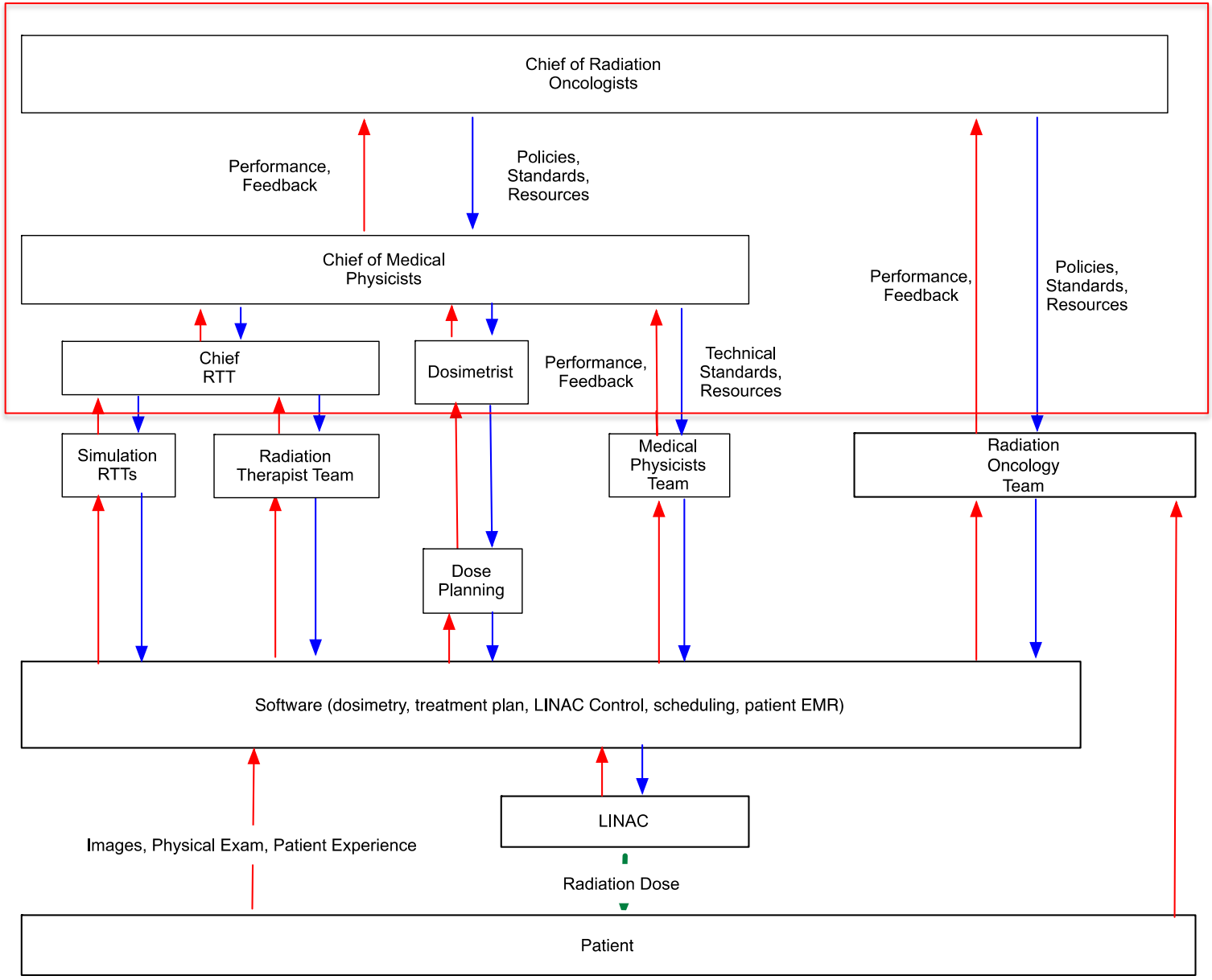

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Determining Unsafe Control Actions

Review of Accidents with Large Managerial Component

Management Responsibility Literature



Developed Classes of Managerial Control Actions with examples



Conducted STPA Step 1 for 2 Managerial Controllers in the USCD Radiation Oncology Control Structure



Guides added to STPA Step 1

STPA Step 1 Current

	A control action required for safety is not provided or is not followed	An unsafe control action is provided that leads to a risk	A potentially safe control action is provided too late, too early, or out of sequence	A safe control action is stopped too soon or applied too long
Control Actions				
Control Actions				
Control Actions				
Control Actions				
Control Actions				
Control Actions				

Management Control Actions

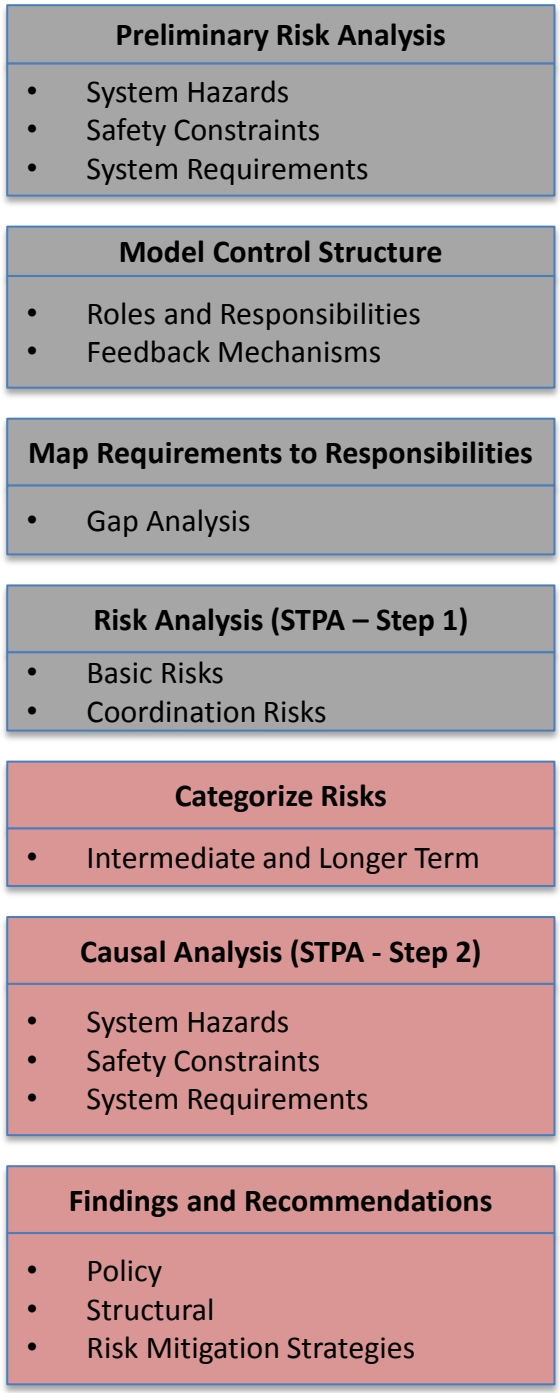
For example:
Classic: Drucker 1974
System Based: Wilson 1994

Classes of Managerial Control Actions		A control action required for safety is not provided or is not followed	An unsafe control action is provided that leads to a risk	A potentially safe control action is provided too late, too early, or out of sequence	A safe control action is stopped too soon or applied too long	Examples
Set Goals and Direction	Specific Control Actions					
Establish Work Processes and Standards	Specific Control Actions					
Staff, Schedule and Train	Specific Control Actions					
Manage Facility and Equipment	Specific Control Actions					
Allocate Resources	Specific Control Actions					
Monitor, evaluate performance	Specific Control Actions					

Radiation Oncology Safety Requirements

Example of Unsafe Control Actions

		Chief Physicist UCSD Radiation Oncology	Classes of Unsafe Control Actions			
			A control action required for safety is not provided or is not followed	**An unsafe control action is provided that leads to a risk**	**A potentially safe control action is provided too late, too early, or out of sequence**	**A safe control action is stopped too soon or applied too long**
Manager Control Actions	**Monitor, provide feedback and corrective action**	**Implement procedures to identify and investigate all serious or potentially serious incidents.**	**Incident investigation procedures are not implemented** **Incident investigation procedures implemented but not followed**	**Poorly designed incident investigation procedures are implemented**	**Incident investigation procedures are implemented before staff is trained**	**Incident investigation procedures are initiated but are not supported and procedures cease to be followed**
		Eliminate or mitigate…				
		Provide Follow-up				
		Disseminate lessons learned …				



Further Research

- STPA Step 2
  - Methods to determine the causes of UCAs
  - Incorporate cultural and political aspects
    - Carroll (2006)
    - Schein (2010)

European STAMP Conference

- May 23 –

- Braunschweig Univ

Thank You

Questions?

References

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