Radiation Oncology Safety
An Application of “Managerial” STPA

John Helferich
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

“Managerial” STPA

- Managers’ decisions and actions contribute to safety risk in these systems

- 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

Leveson (2004), Leveson (2011)
UC San Diego Radiation Oncology

LINAC

Control Room
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

<table>
<thead>
<tr>
<th>Set Goals and Direction</th>
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<tbody>
<tr>
<td>Establish Work Processes and Standards</td>
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<td>Staff, Schedule and Train</td>
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<td>Manage Facility and Equipment</td>
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<td>Monitor, evaluate performance</td>
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## Example of Radiation Oncology Safety Requirements

<table>
<thead>
<tr>
<th>Monitor, provide feedback and corrective action</th>
<th>Procedures must be in place to identify and investigate thoroughly all serious or potentially serious incidents.</th>
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<td>Recommendations must be implemented to eliminate or mitigate all identified factors contributing to the adverse events.</td>
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<td>Follow-up must be provided to ensure that recommendations have been implemented and are effective.</td>
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<td>Lessons learned must be documented and disseminated.</td>
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Control Structure for Radiation Oncology at UCSD

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
Control Structure for Radiation Oncology at UCSD

Chief of Radiation Oncologists

Chief of Medical Physicists

Chief RTT

Dosimetrist

Simulation RTTs

Radiation Therapist Team

Medical Physicists Team

Dose Planning

Technical Standards, Resources

Performance, Feedback

Policies, Standards, Resources

Performance, Feedback

Policies, Standards, Resources

Software (dosimetry, treatment plan, LINAC Control, scheduling, patient EMR)

Images, Physical Exam, Patient Experience

LINAC

Radiation Dose

Patient
Determining Unsafe Control Actions

- 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

**Preliminary Risk Analysis**
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**Findings and Recommendations**
- Policy
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### STPA Step 1 Current

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<th>A control action required for safety is not provided or is not followed</th>
<th>An unsafe control action is provided that leads to a risk</th>
<th>A potentially safe control action is provided too late, too early, or out of sequence</th>
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Management Control Actions

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

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<th>A control action required for safety is not provided or is not followed</th>
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Radiation Oncology Safety Requirements
## Example of Unsafe Control Actions

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<td>Implement procedures to identify and investigate all serious or potentially serious incidents.</td>
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<td>Incident investigation procedures are not implemented</td>
<td>An unsafe control action is provided that leads to a risk</td>
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<td>Incident investigation procedures implemented but not followed</td>
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<td>Incident investigation procedures are implemented before staff is trained</td>
<td>A safe control action is stopped too soon or applied too long</td>
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**Chief Physicist**  
UCSD Radiation Oncology

**Monitor, provide feedback and corrective action**

- 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

ASTRO, A.S.f.R.O., (2102) Safety is No Accident


