Implementing CAST in Health Care

An overview of the methodological and infrastructure development

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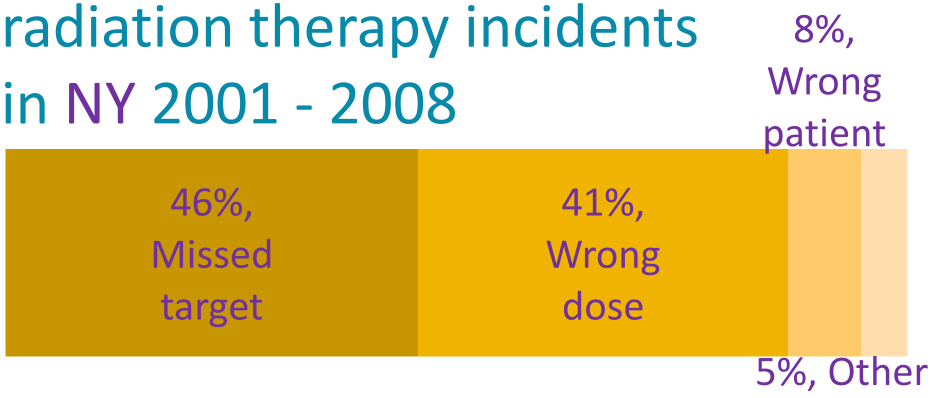
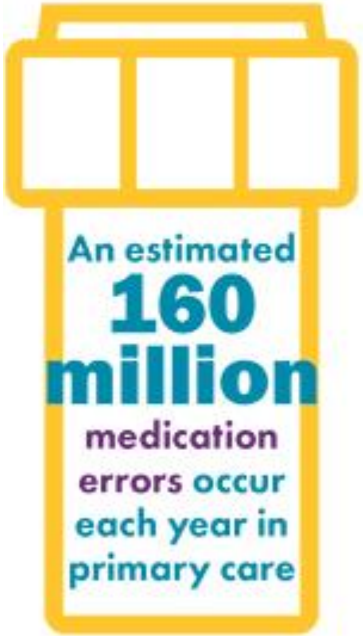
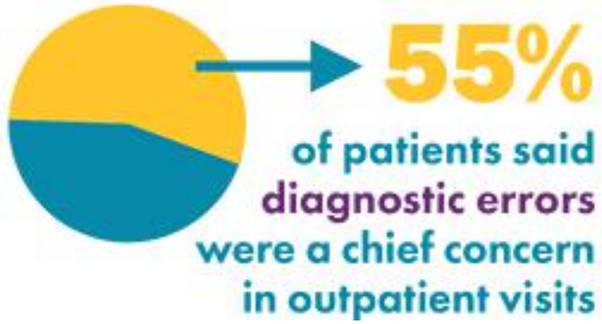
A concerning safety performance

621

radiation therapy incidents in NY 2001 - 2008







$617

million excess cost in MA in a year

Current approach to learning is not effective

More surgical items being left inside patients blamed on rushed operations

'I was in constant pain,' says woman who had glove, sponges still inside her

News

Survey of UK doctors highlights blame culture within the NHS

BMJ 2018 ; 362 doi: https://doi.org/10.1136/bmj.k4001 (Published 20 September 2018)

Root cause analyses (RCAs) are not generating the needed insights for safety improvement

Operational barriers to CAST application

Time

- 20-90 person-hours per RCA
- Little time for training

Knowledge

- No engineering/safety background
- Systems theory is foreign to most

How can we facilitate CAST application in health care?

Development to facilitate CAST application

CAST

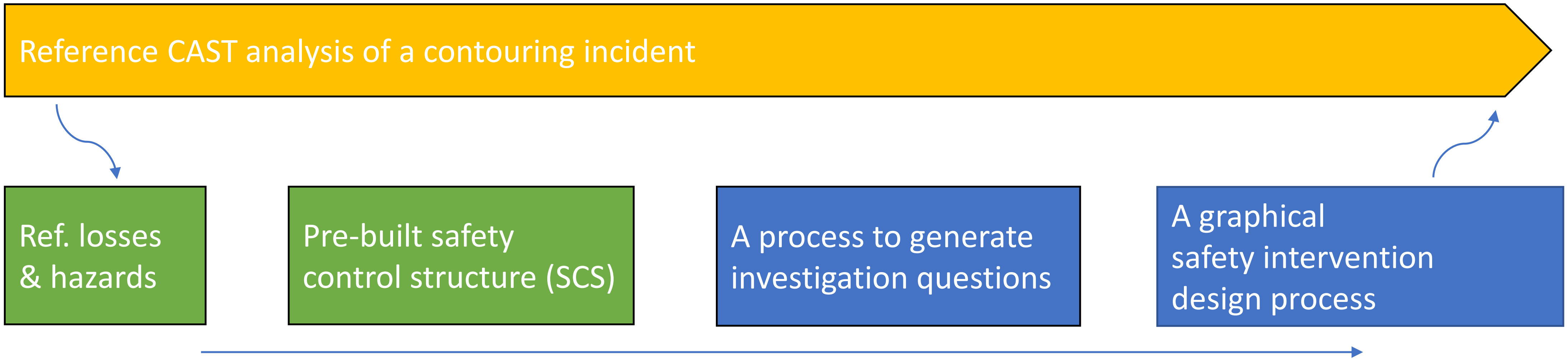
Assemble Basic Information → Model Safety Control Structure → Analyze Each Component in Loss → Identify Control Structure Flaws → Create Improvement Program

Methodological development
- A process to generate investigation questions
- A graphical safety intervention design process

Artifact dev.
- Ref. losses & hazards
- Pre-built safety control structure
- Reference controller responsibilities

Template & training dev.
- Cases illustrating systemic factors
- Reference CAST analysis of a contouring incident

Presentation Road Map



Not covered in the interest of time

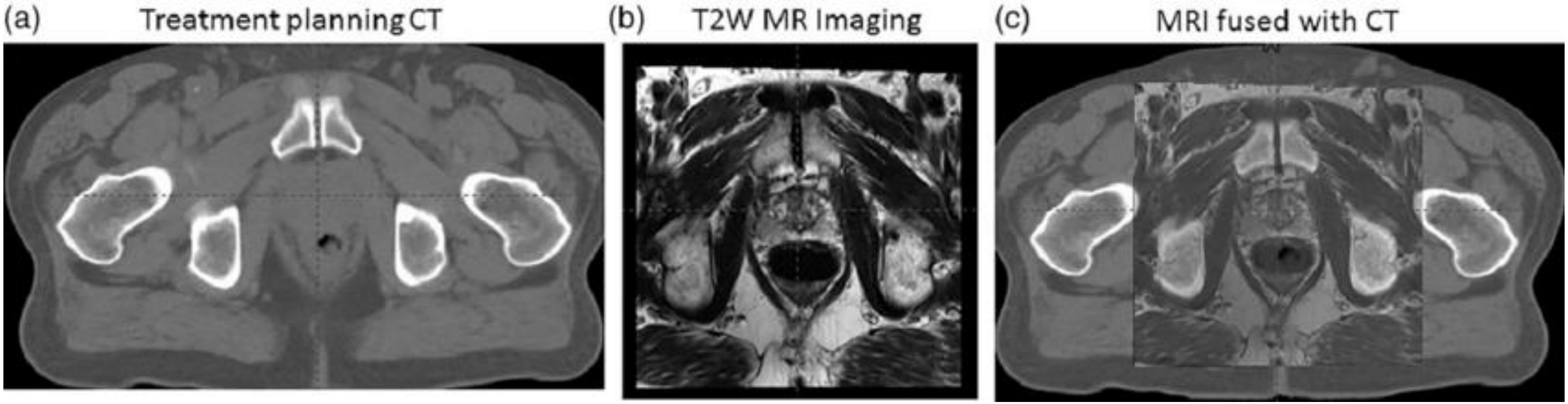
- Reference controller responsibilities
- Cases illustrating systemic factors
- Template & training

A Reference CAST Analysis – Case Background

- Radiation oncology – provide radiation therapy for cancer

A Reference CAST Analysis – Case Background (2)

- Magnetic resonance imaging (MRI) improves treatment planning accuracy

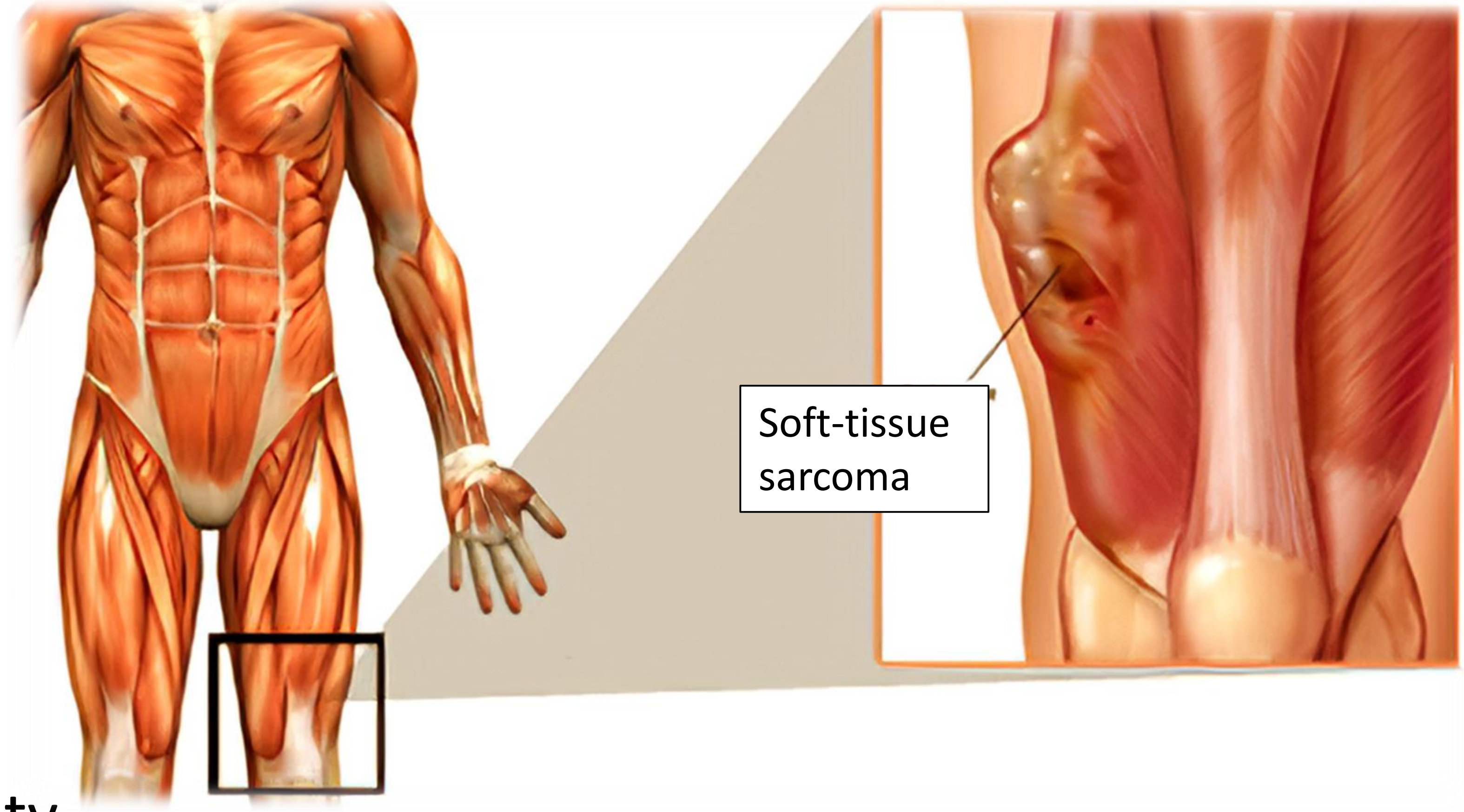


A Reference CAST Analysis – A Contouring Incident

- 6-year-old
- Right-thigh sarcoma
- MRI fusion missed in treatment planning

Impact

- Target volume 30% larger than necessary
- Increased risk of growth delay & infertility



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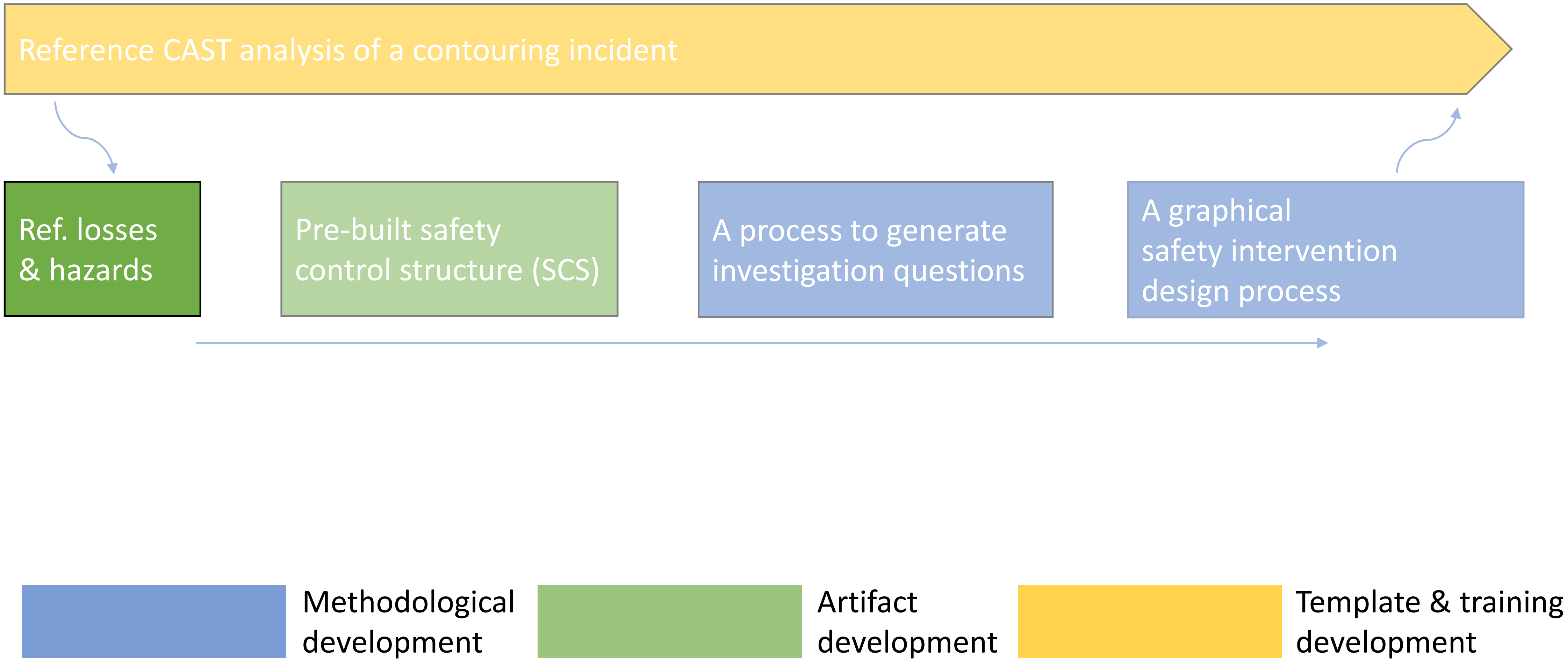

Reference losses and hazards

- 5 losses and 5 hazards

Losses	Hazards
1. Patient is (potentially or actually; same hereafter) injured or killed from radiation overexposure or under-treatment	1. Radiation is delivered in the wrong dose (amount, location, or timing), or to the wrong patient. [L1,L5]
2. Nonpatient is injured or killed by radiation	2. Nonpatient is unexpectedly exposed to radiation. [L2,L5]
3. Physical injury to a patient or nonpatient not from radiation	3. Any person is exposed to nonradiation materials and energies (e.g., cryogen, noise) at hazardous levels. [L3,L5]
4. Damage or loss of equipment	4. Equipment is subject to stress beyond design. [L4, L5]
5. Damage to patient and staff satisfaction or hospital reputation	5. Patient or staff is subject to unexpected stress, delays, or urgencies [L5]

Using the reference losses and hazards

Case description

Increased risk of growth delay & infertility; target volume 30% larger than necessary

Losses	Hazards
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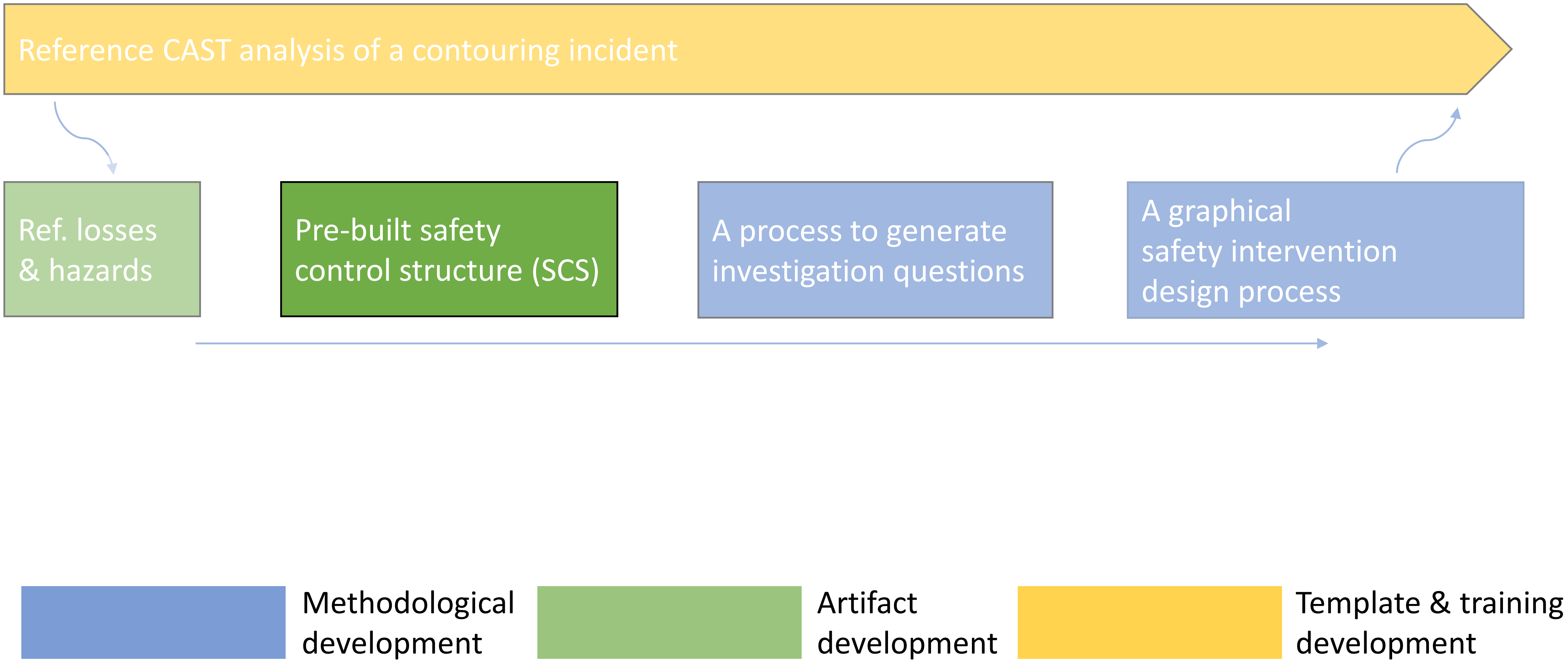
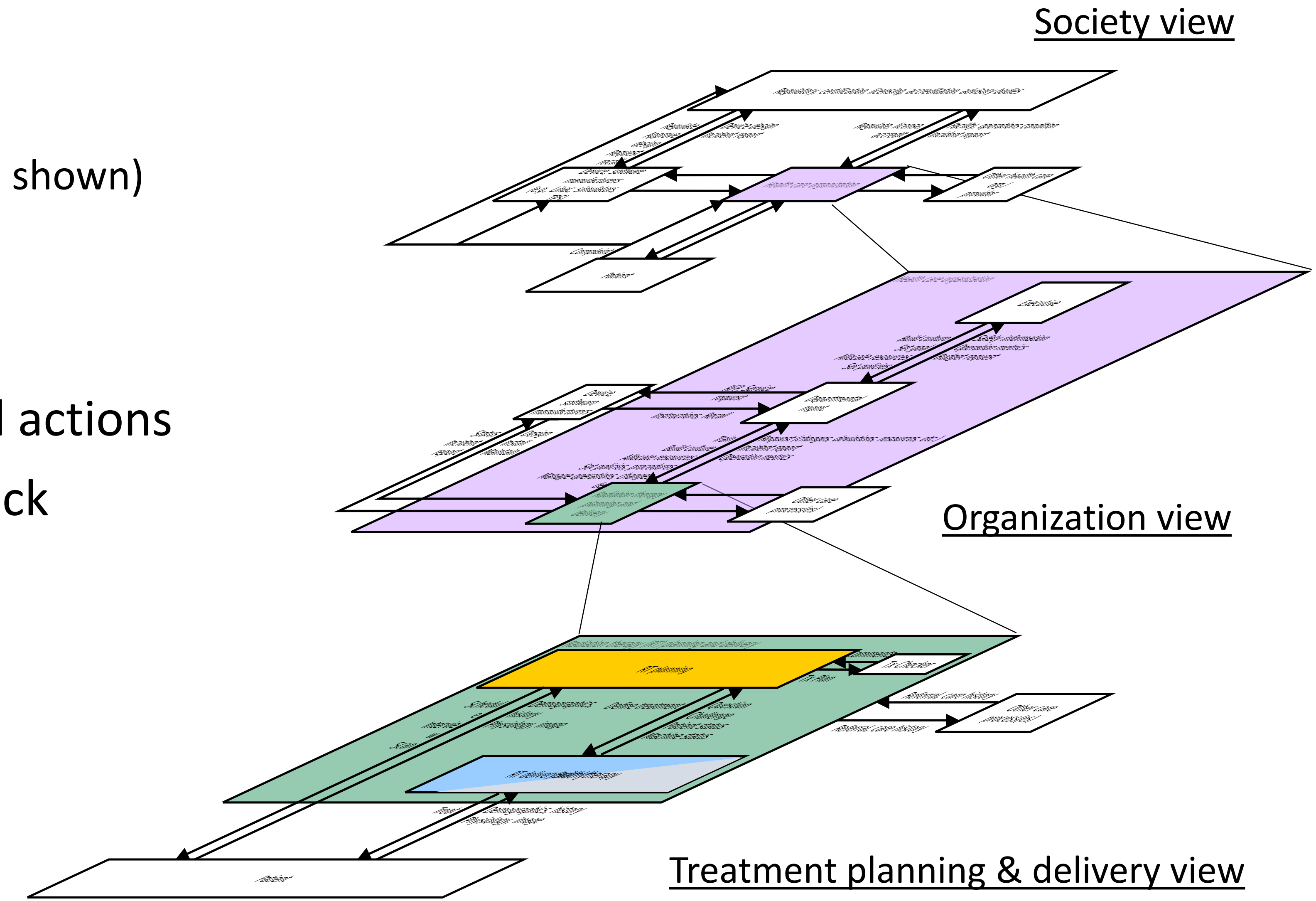


Pre-built safety control structure

- 8 views in total
  (from the top down, first 3 views shown)

- 39 controllers
- On the order of 100 control actions
- On the order of 100 feedback



Using the pre-built safety control structure

Case description
The treatment plan was created and approved without leveraging the available MR images
…

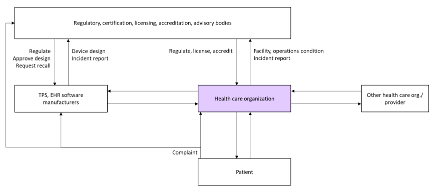
&

Loss, hazard statements

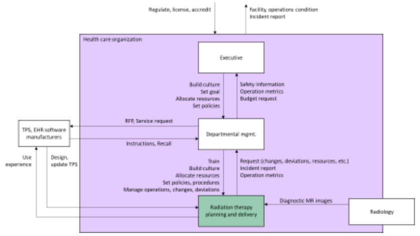
Selecting the relevant SCS views and edit

(rather than building SCS from scratch)

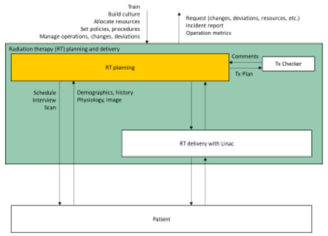
3 views incorporated with little modifications



Society View

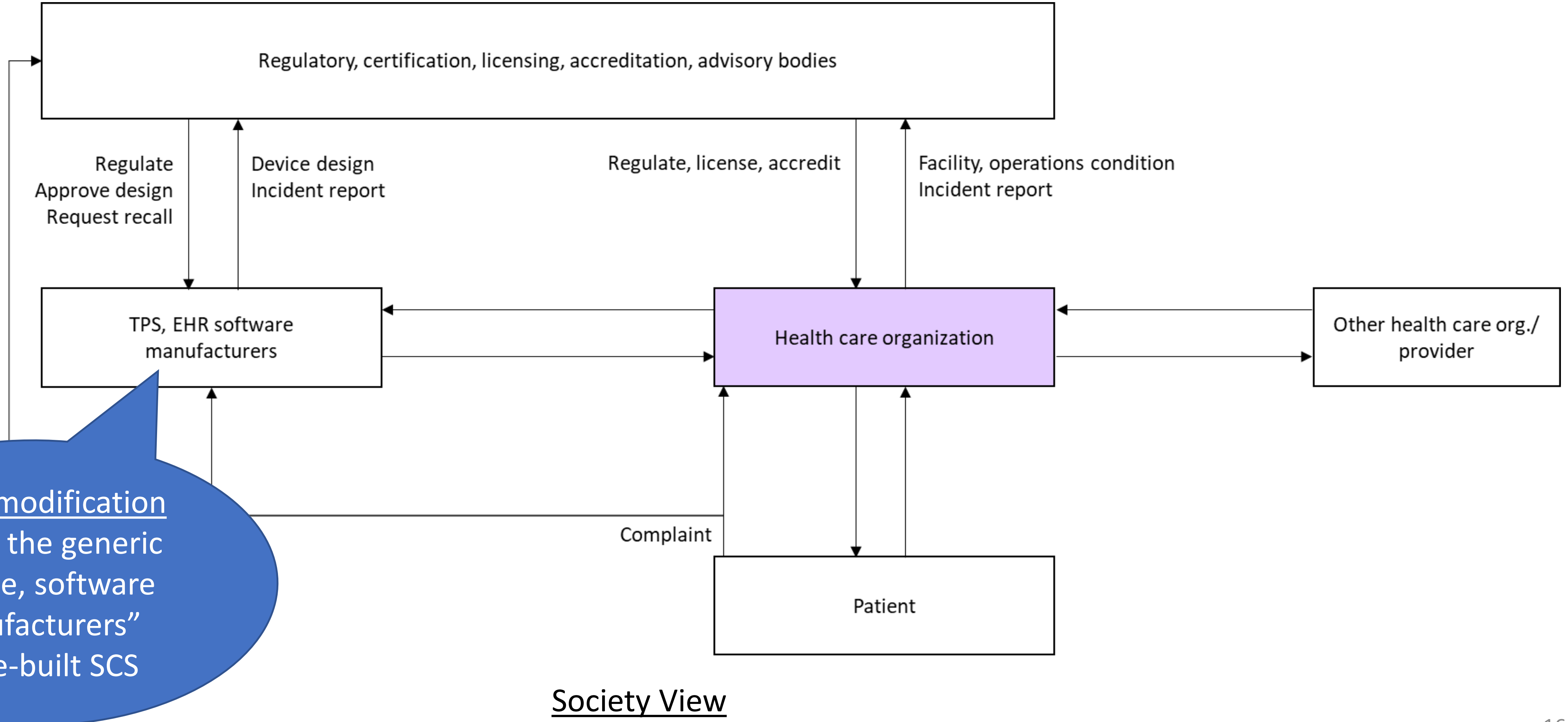


Organization View



RT Planning and Delivery View

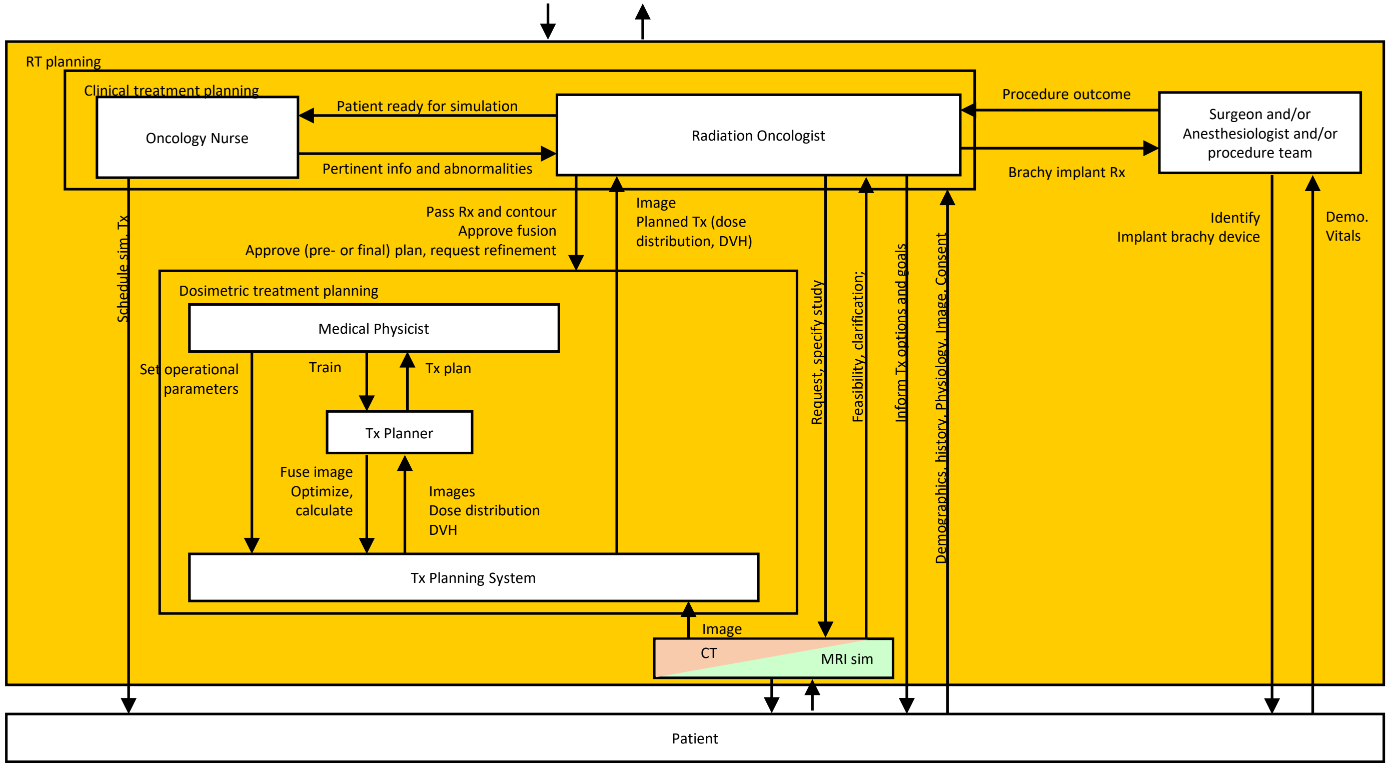
Using the pre-built safety control structure (2)



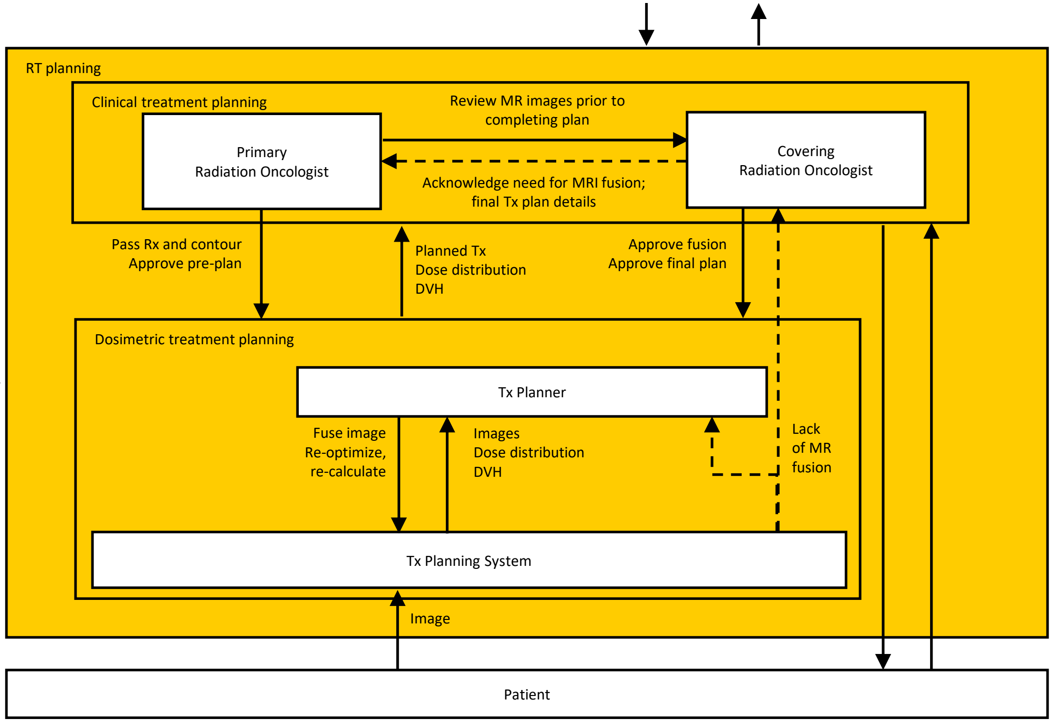
Minor modification
Editing the generic "Device, software manufacturers" In pre-built SCS

Using the pre-built safety control structure (3)

RT Planning View – modified with mostly deletion

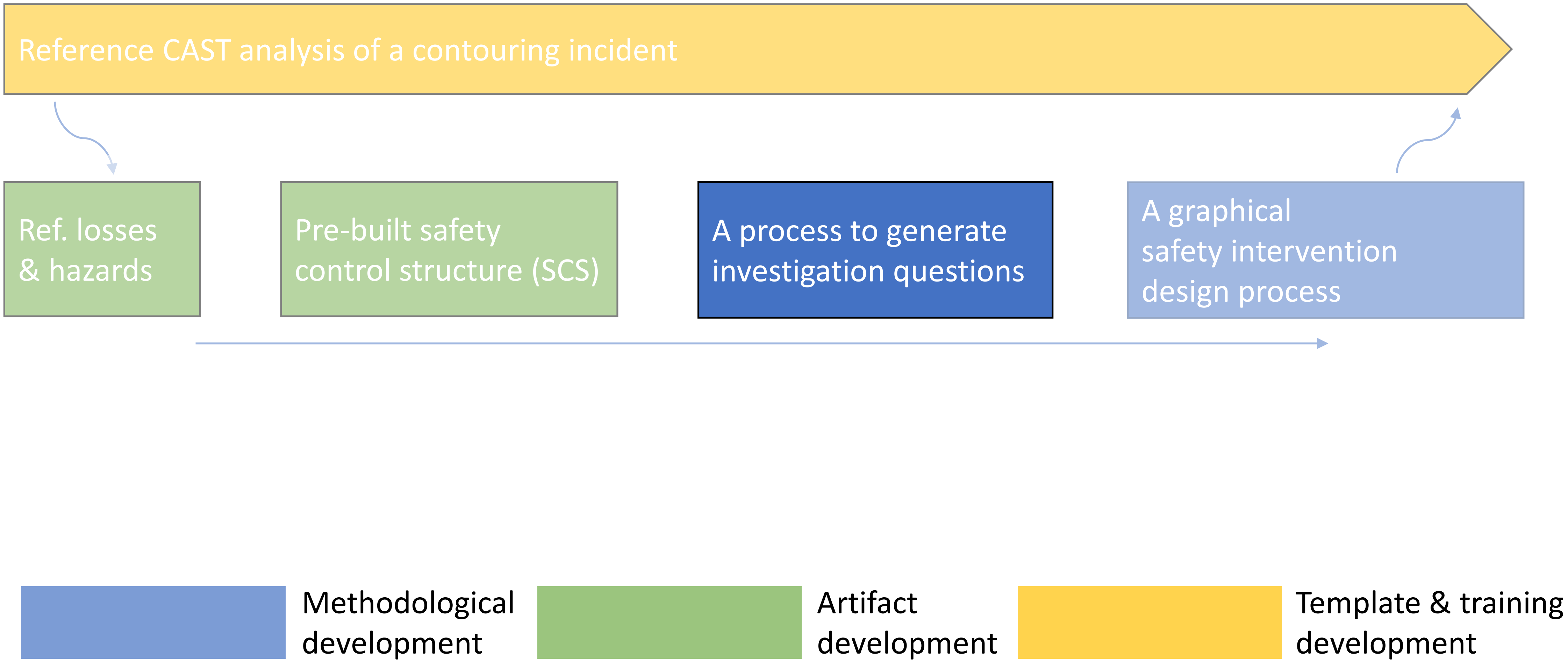


Version from Pre-built Safety Control Structure



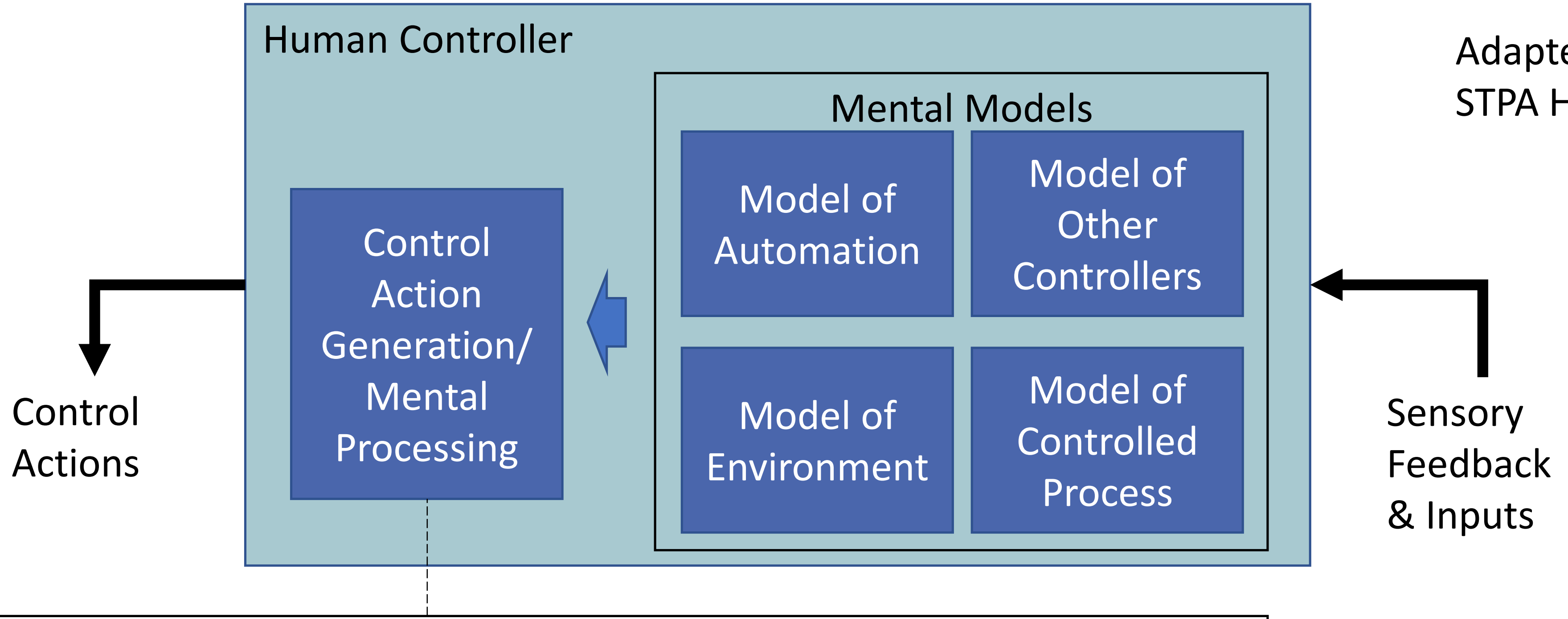
Version for analysis

Presentation Road Map



A process to generate investigation questions

- Controller-specific questions generated mostly by substitution



Adapted from Fig. G-2, STPA Handbook

E.g., How did the **<controller>** choose to perform **<control action; or between control action options>**?

A process to generate investigation questions (2)

<u>Treatment Planner</u>

Responsibility relevant to this safety incident

- Fusion and registration (primary)

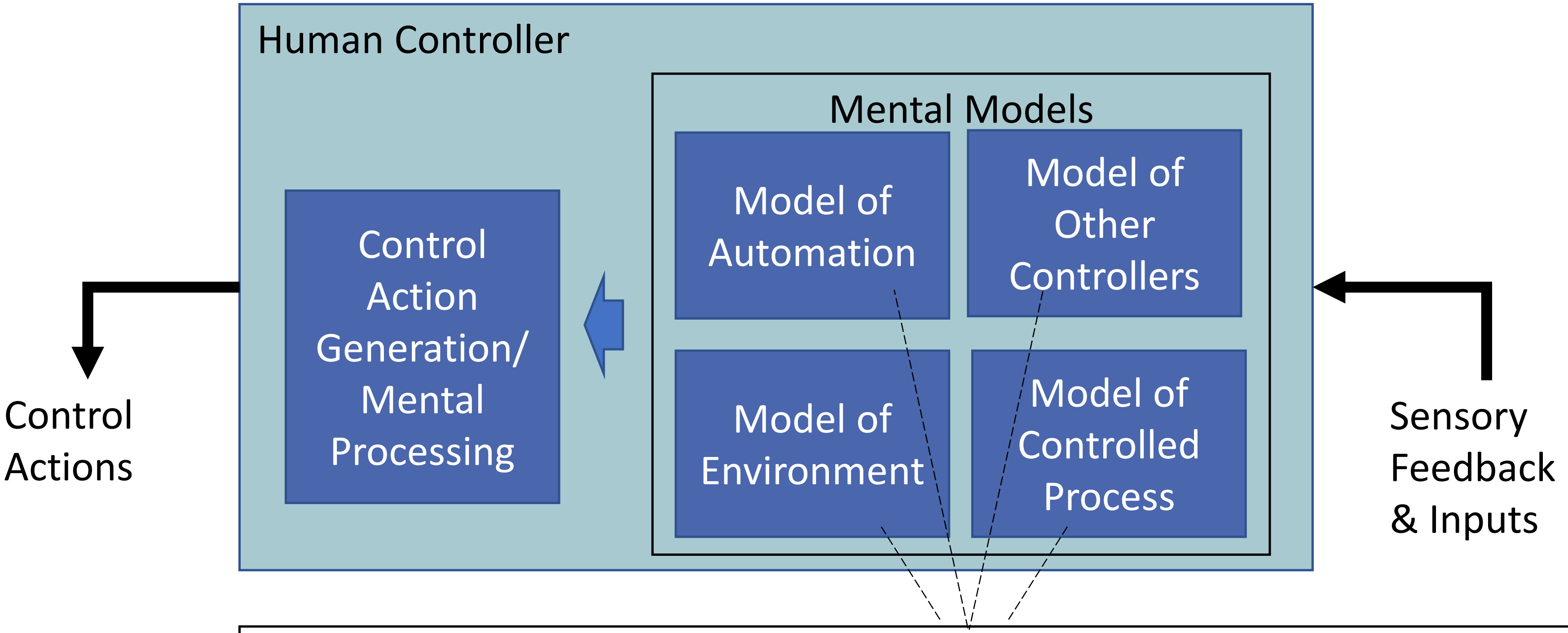
Contribution to the hazardous state

- Did not fuse MR image to CT for contouring

Investigation question:
How did the Treatment Planner choose to perform MR image fusion or not?

A process to generate investigation questions (3)

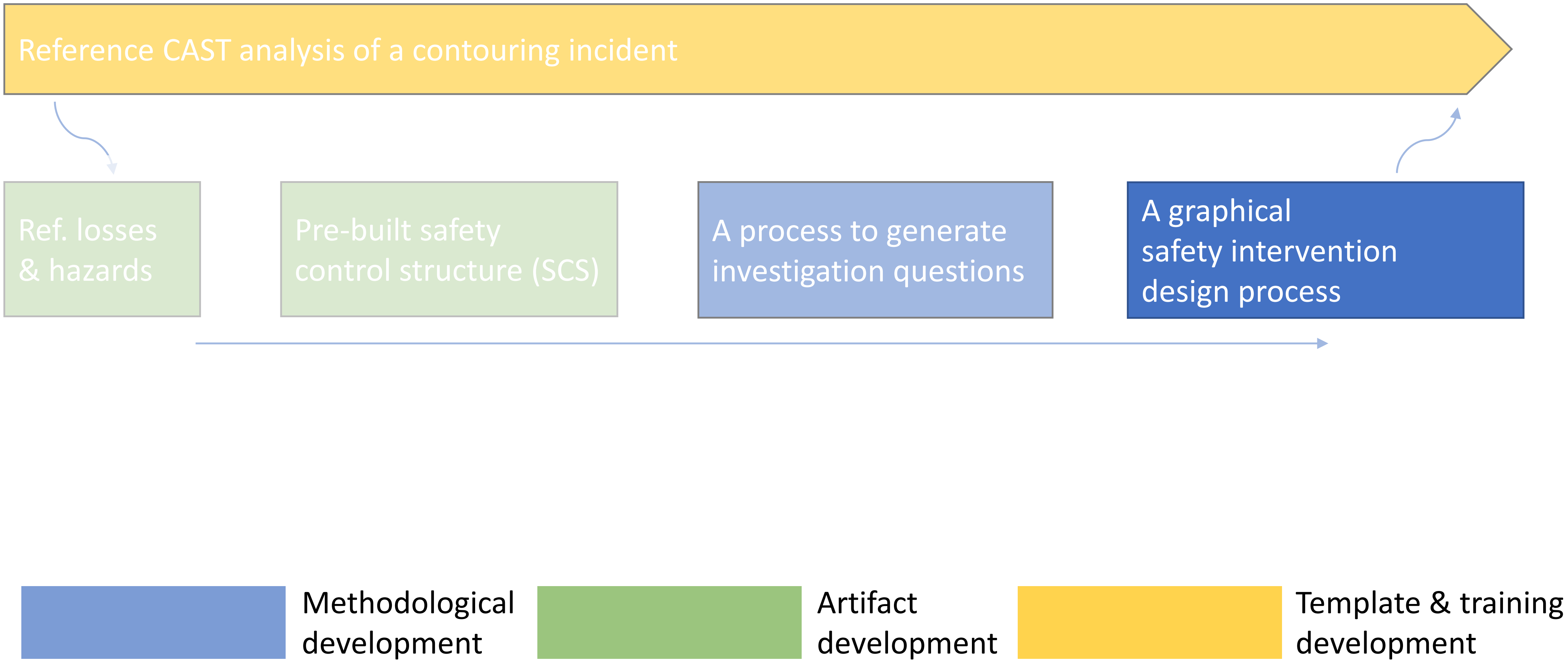
Other controller-specific questions are generated similarly



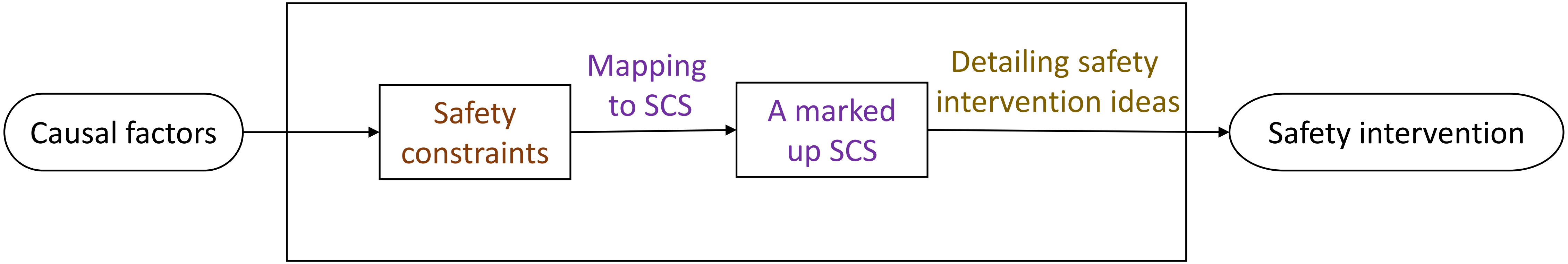
What was the **<controller>**'s understanding of the contemporaneous **<process>** state?

…

Presentation Road Map



A graphical safety intervention design process



Identify objective/intent without the means

Locate a broad set of candidate interactions

Instantiate a safety intervention idea

A graphical safety intervention design process (2)

1. Defining safety constraints at multiple hierarchical levels

Treatment Planner

Process model flaw
- Did not know the need to fuse the MR image

Contextual/process model factors
- A physician order was required for MR image fusion… The original planning request did not include the fusion order.
- The TPS did not require MR image fusion before plan completion.
- …

⬇

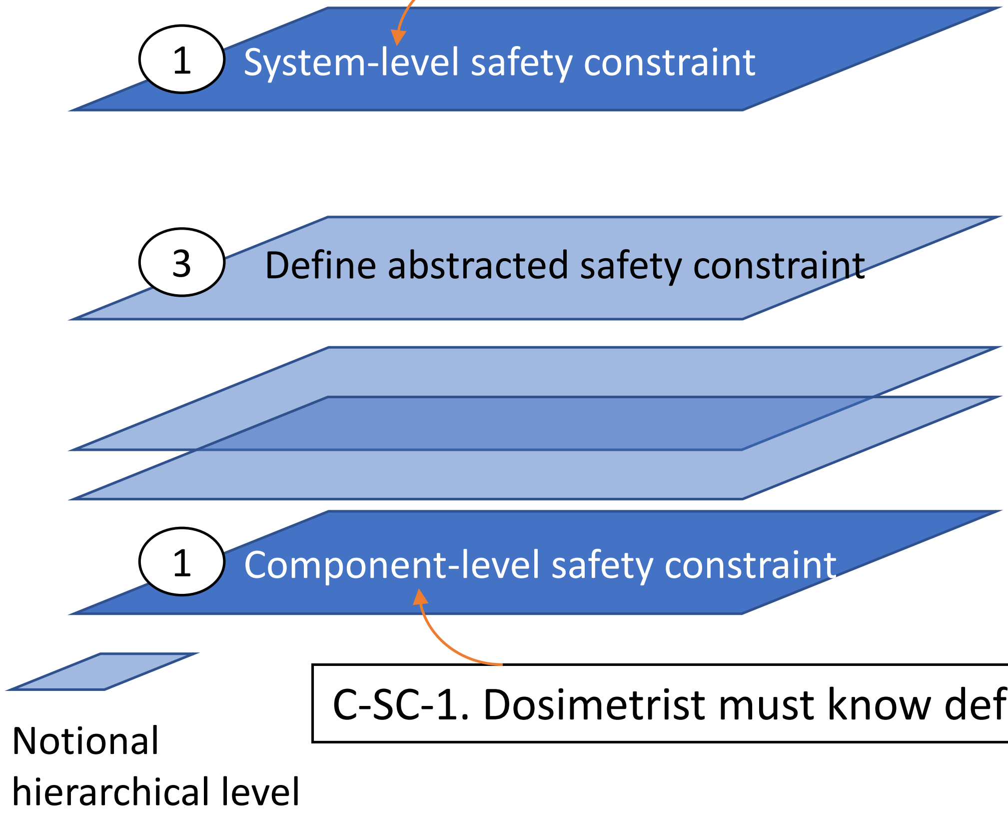
C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.
…
C-SC-3. Treatment planning team members must be informed of any deviation from normative practices.

(C-SC = for Component-Safety Constraint)

A graphical safety intervention design process (3)

1. Defining safety constraints at **multiple** hierarchical levels

“Dose must be delivered to the right patient at the right amount and location.”

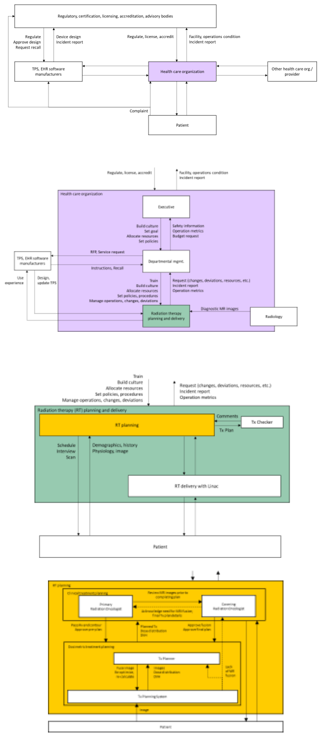


A-SC-1. RT planning must incorporate clearly defined soft tissue boundaries when indicated.

(A-SC = Abstracted-Safety Constraint)

2

Identify the intervening hierarchical levels

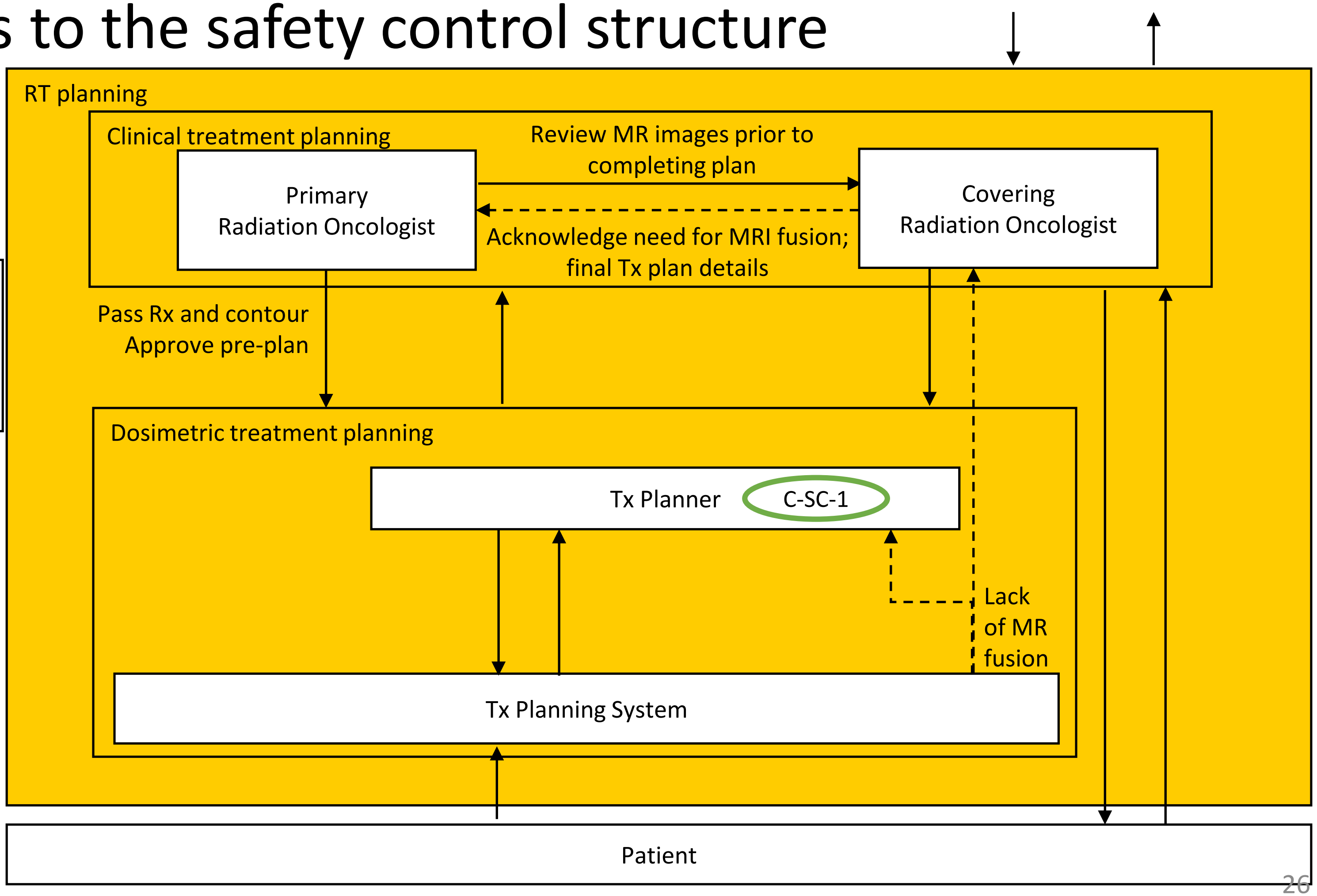


C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.

A graphical safety intervention design process (4)

2. Map the safety constraints to the safety control structure

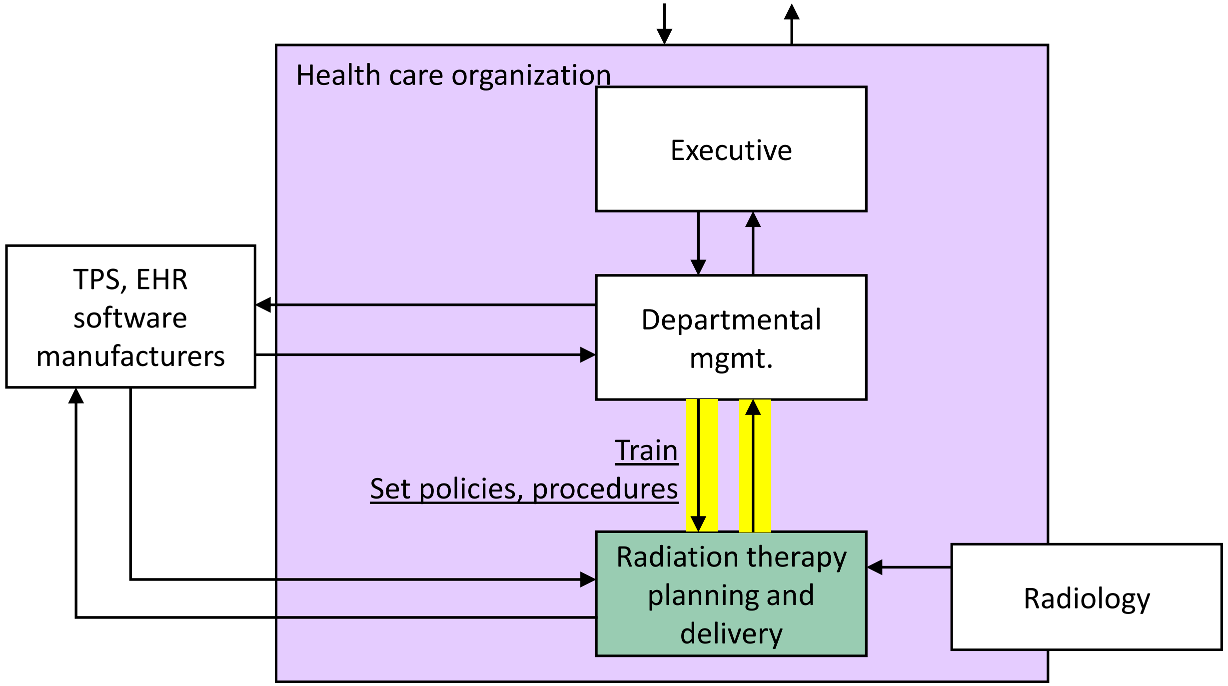
C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.

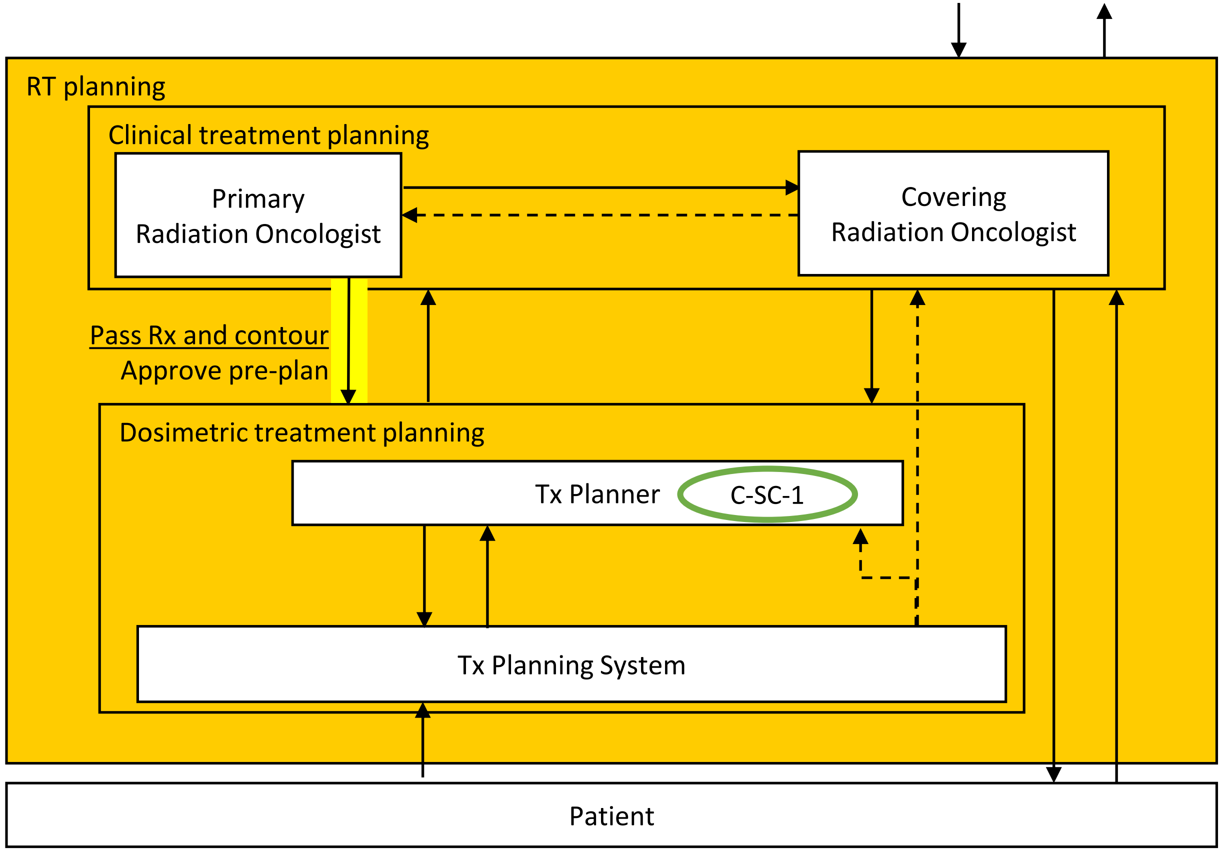


A graphical safety intervention design process (5)

3. Detail safety intervention ideas by

a) Identifying the interaction(s) of opportunity, and





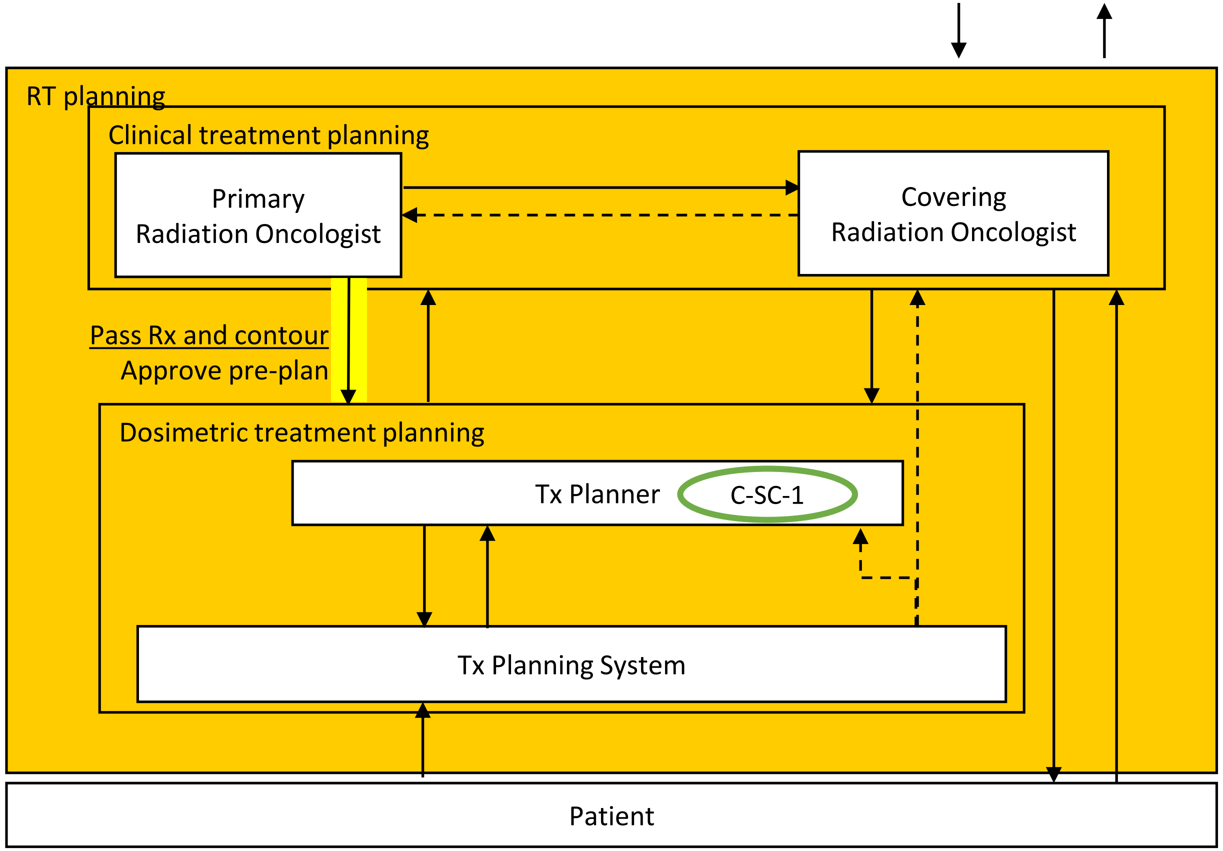
C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.

A graphical safety intervention design process (6)

- 3. Detail safety intervention ideas by
  a) Identifying the interaction(s) of opportunity, and
  b) Specifying the means of fulfillment

C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.

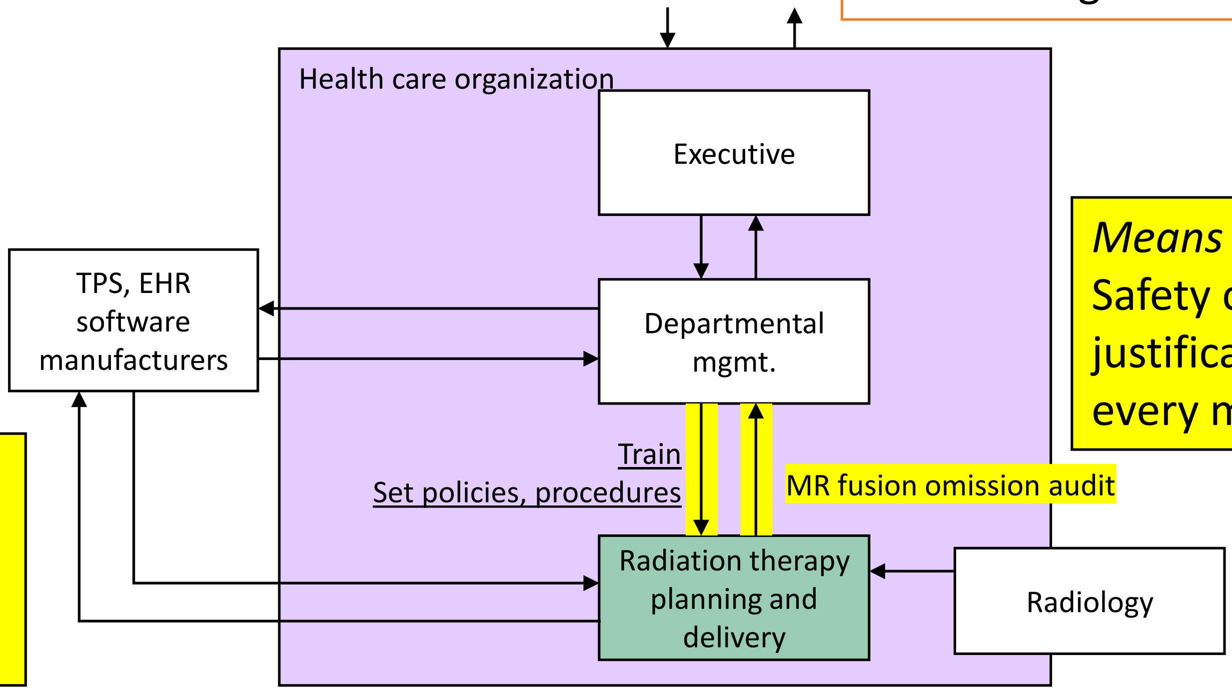
Means of fulfillment:
Modify Rx template to require justification if MR image fusion is to be omitted



A graphical safety intervention design process (7)

- 3. Detail safety intervention ideas by
  a) Identifying the interaction(s) of opportunity, and
  b) Specifying the means of fulfillment

C-SC-1. Dosimetrist must know definitively the need for MR image fusion at the start of treatment planning.



Means of fulfillment:
Safety committee to audit justification for MR fusion omission every month.

Means of fulfillment:
Allow MR image fusion omission only for patient-based reasons

A graphical safety intervention design process (8)

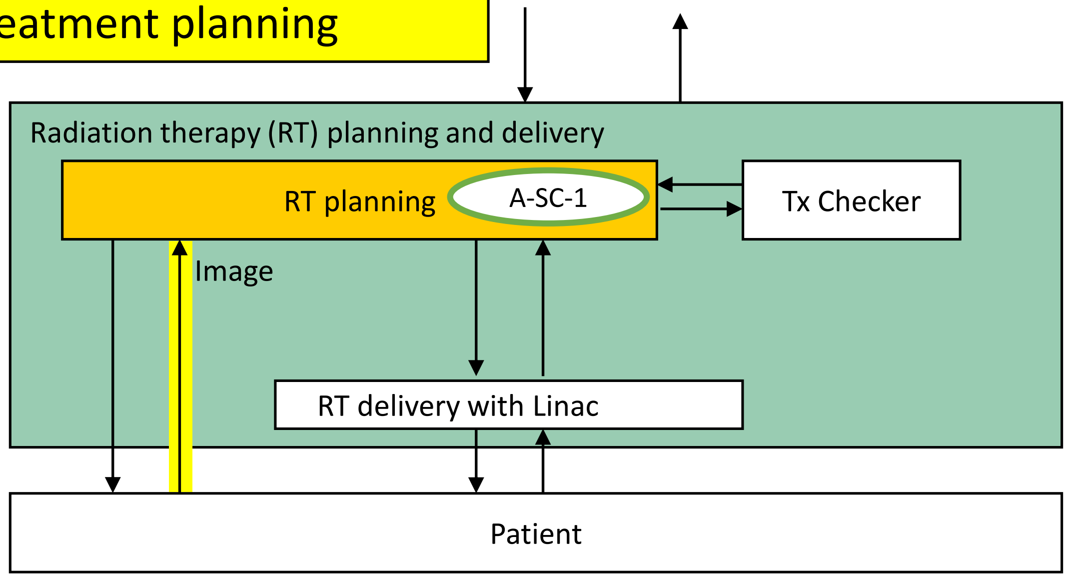
Facilitating design for **hazard elimination**

Abstracted safety constraint

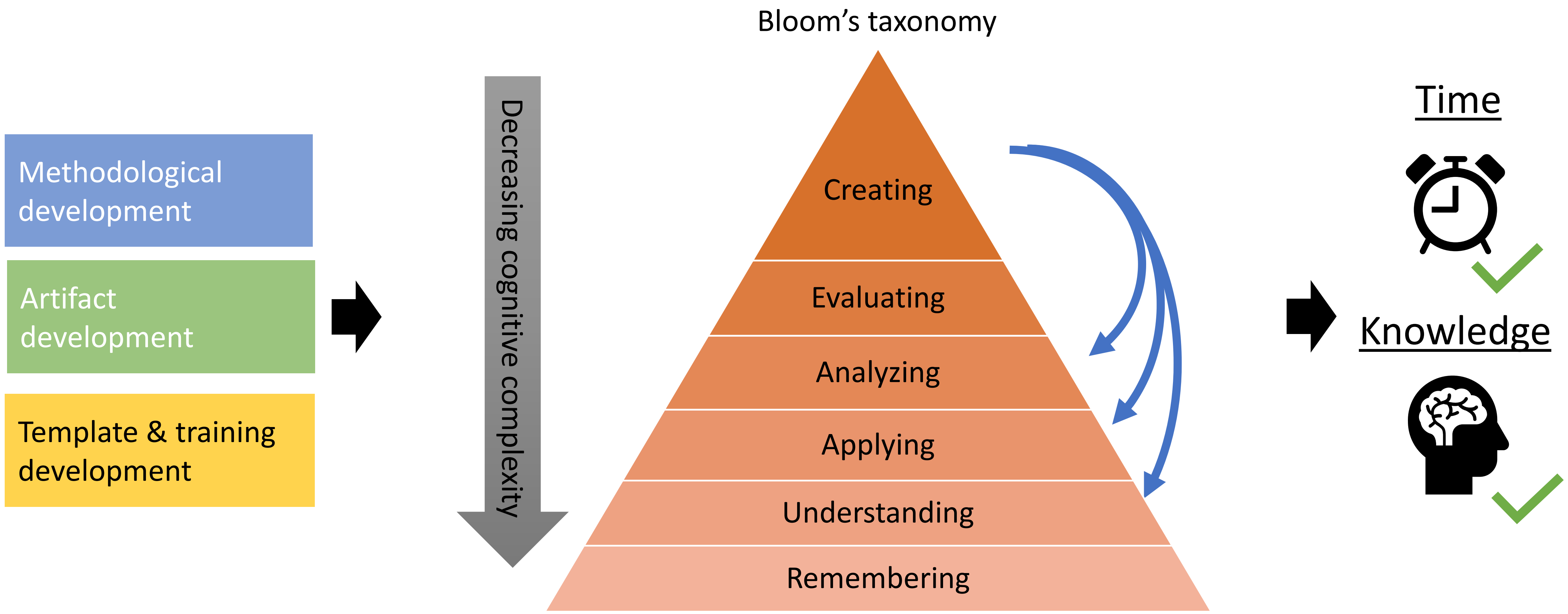
A-SC-1. RT planning must incorporate clearly defined soft tissue boundaries when indicated.

Component-level safety constraint

Means of fulfillment:
MRI-only treatment planning



Reduced task cognitive complexity for novices



Summary

Methodological development

- A process to generate investigation questions
- A graphical safety intervention design process

Artifact development

- Ref. losses & hazards
- Pre-built safety control structure
- Reference controller responsibilities

Template & training development

- Reference CAST analysis of a contouring incident
- Cases illustrating systemic factors

Time

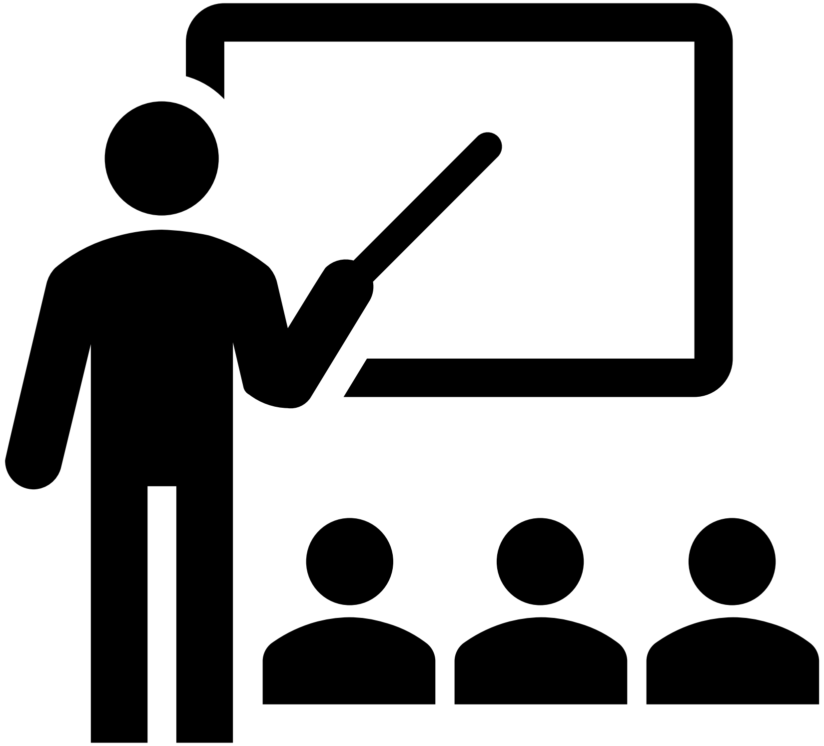
Knowledge

Efficient, consistent CAST application in health care

Next steps

A field test

- Implementation at
  UCSD Moores Cancer Center
- Comparison studies
  - Causal factors
  - Safety intervention recommendations
- Usability study



Acknowledgement

Prof. Nancy Leveson (MIT)

Prof. Beth Rosenberg (Tufts)

Prof. John Carroll (MIT)

Lisa Singer, MD, PhD (DFCI/BWH)

Elizabeth Huynh, PhD (DFCI/BWH)

System Safety and Cybersecurity Group (MIT)

Thank you

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