Using STAMP-CAST to Analyze an Incident in Radiation Therapy

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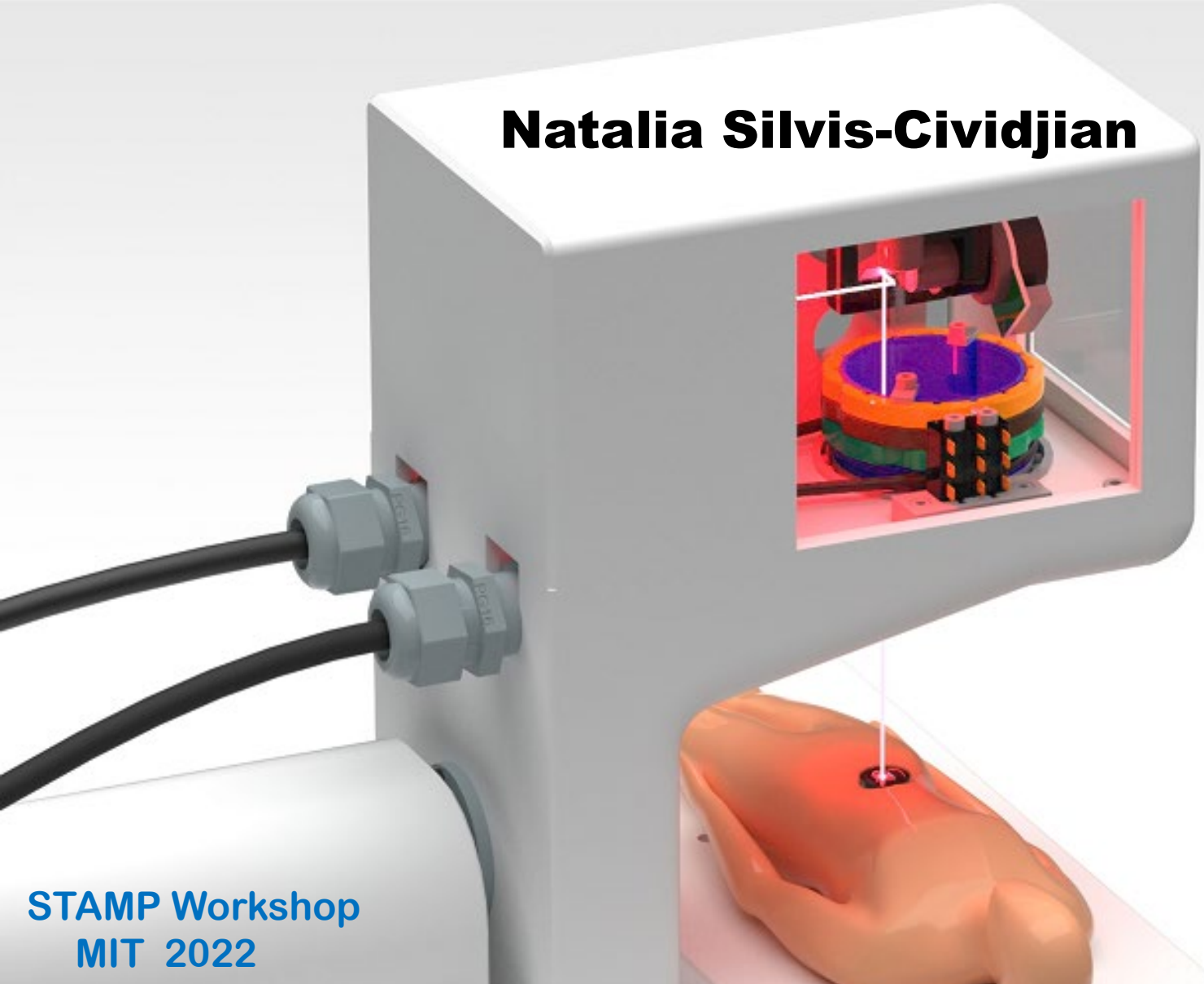


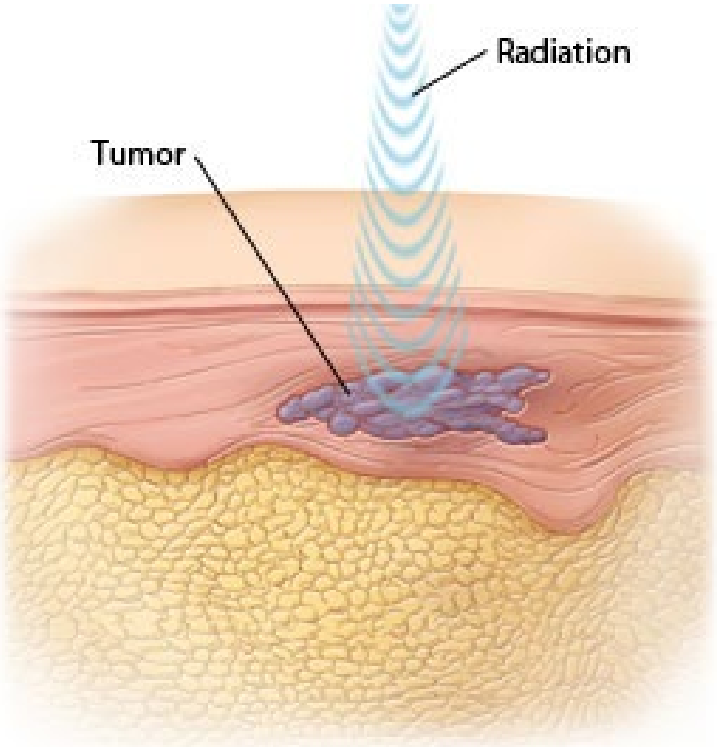
vrije Universiteit amsterdam

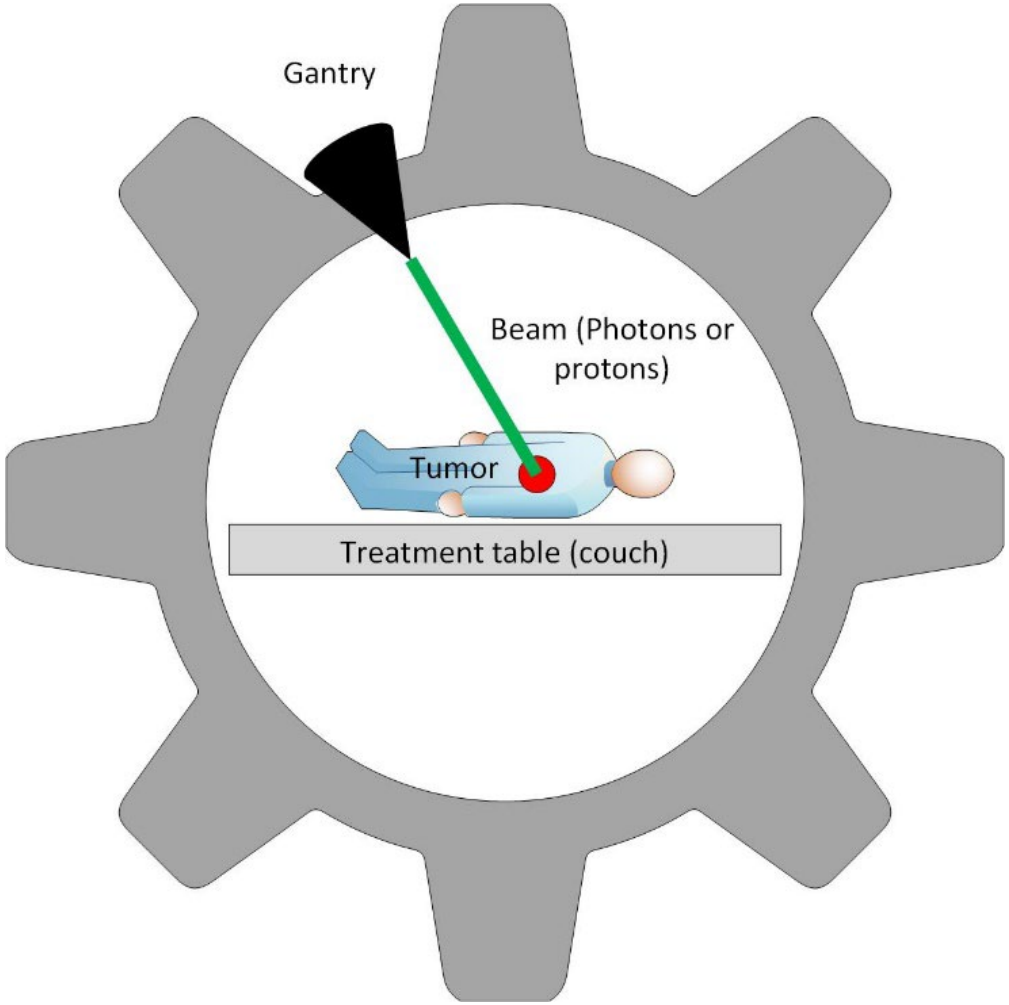
STAMP Workshop
MIT 2022

Outline

- Radiation therapy (RT)
- Applying CAST to analyze an incident
- Lessons learned
- Conclusions & future work

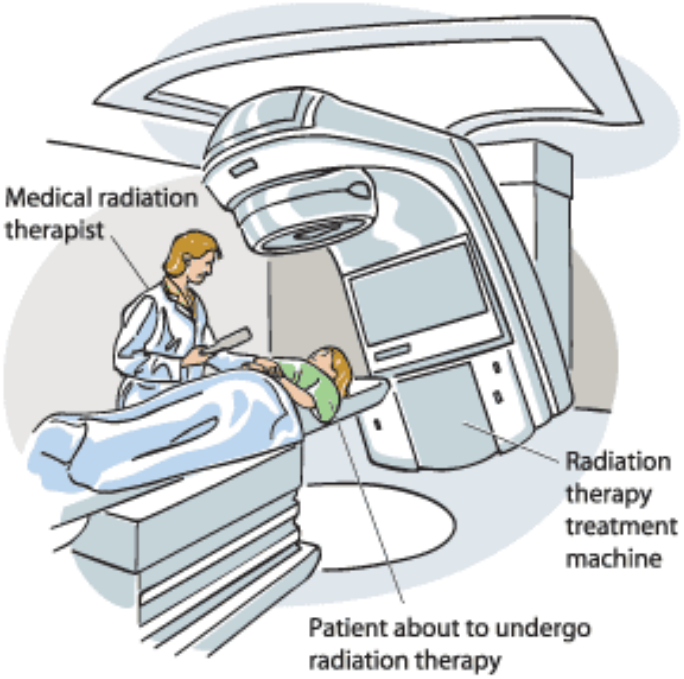
Radiation Therapy (RT)





- Patient diagnosed with cancer is sent to radiotherapy department for treatment
- CT simulation
- Oncologist delineates tumor and OAR on CT image and writes prescription
- Radiographers and medical physicists design a treatment plan
- QA team tests the treatment plan on the linac
- Treatment plan is approved by oncologist
- Linac radiographers prepare patient and linac for radiation delivery
- Radiation is delivered safely and according to treatment plan
- Oncologist sees the patient for follow-up

https://www.medbroadcast.com/



Trade-offs

- High-precision tumor exposure
- Fast treatment
- High patient throughput
- Cutting edge technology

VS.

- Spare healthy organs
- Thouroughly analyze incidents
- Improve the process and safety culture

Win the battle against cancer

Design a harmless, safe process

Objective

- RT is a complex safety critical socio-technical system
- RT safety standards recommend FMEA and FTA
- STAMP is a rising star in industry, but not in RT

How does it

work

and

feel

to use STAMP for an RT incident analysis?

computer systems engineer with some experience in STPA in RT [1]

safety-aware radiographers specialized in risk management

The team

[1] Silvis-Cividjian, N., Verbakel, W., & Admiraal, M. (2020). *Safety Science*, *122*.

Research questions

- *RQ1.How does CAST work for incidents analysis in RT?*
  - Can an outsider conduct it?
  - Is it easy to learn for the RT staff?
  - Can we speed up by reusing artifacts from an STPA?
  - What is difficult/interesting?

- *RQ2. What is the added value of CAST?*
  Compared our CAST with an existing PRISMA analysis

PRISMA = Prevention and Recovery Information System for Monitoring and Analysis, a method prescribed by the Dutch Healthcare Inspection
[Schaaf TW van der. PRISMA incidenten analyse. Een instrument voor risicobeheersing in de zorgsector. Kwaliteit in beeld, 1997; 5: 2-4. 10]

Assembly basic information → Model safety control structure → Analyze each component in loss → Identify control structure flaws → Create improvement program

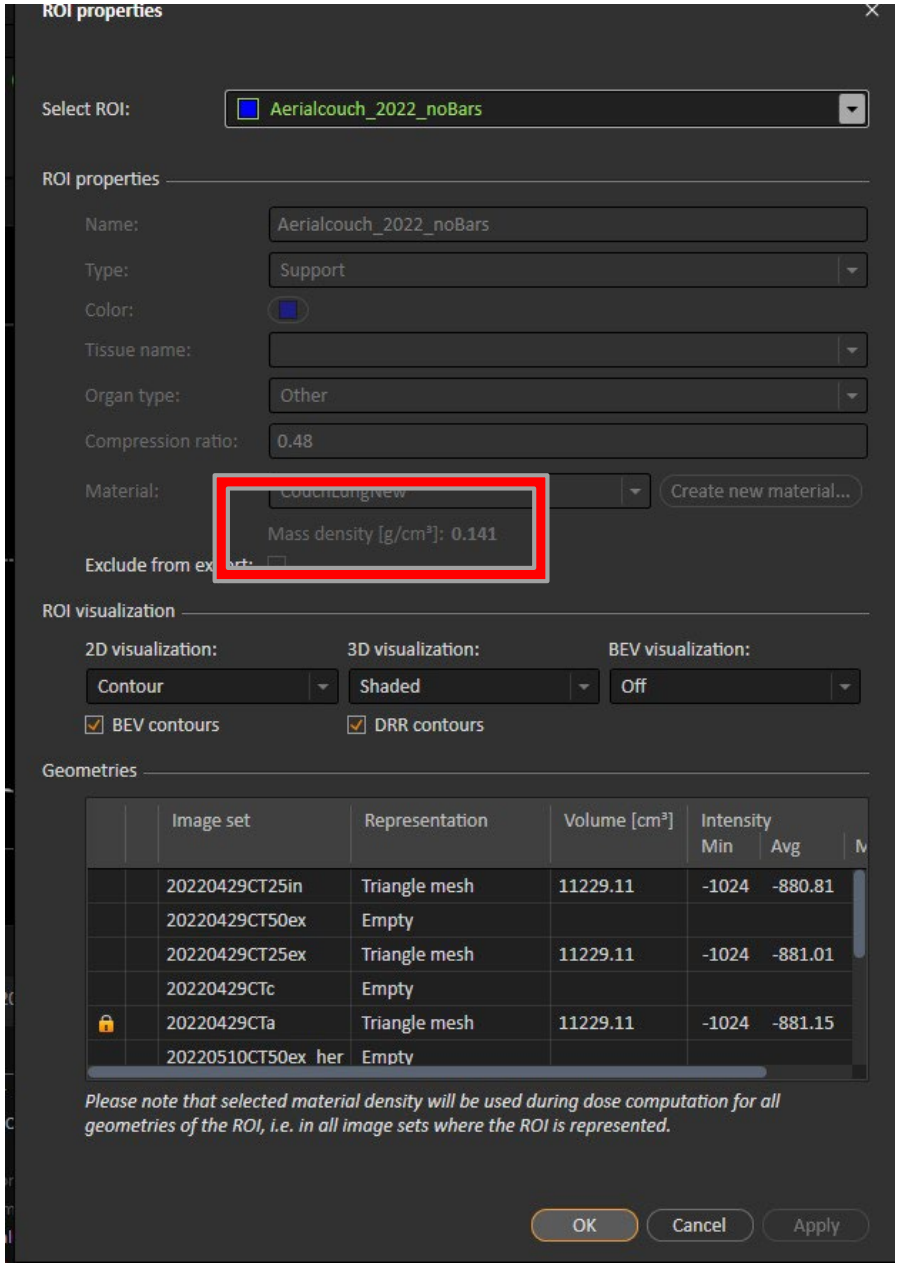
First facts

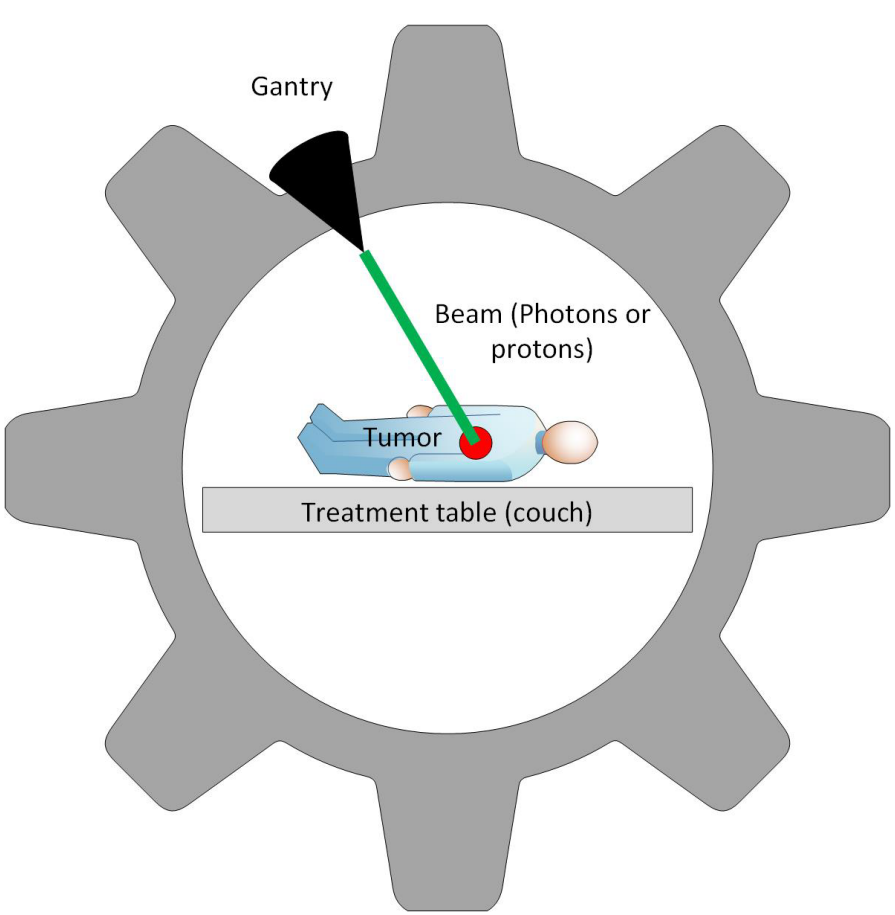
- A new RT process
- MP input a wrong table density in planning software

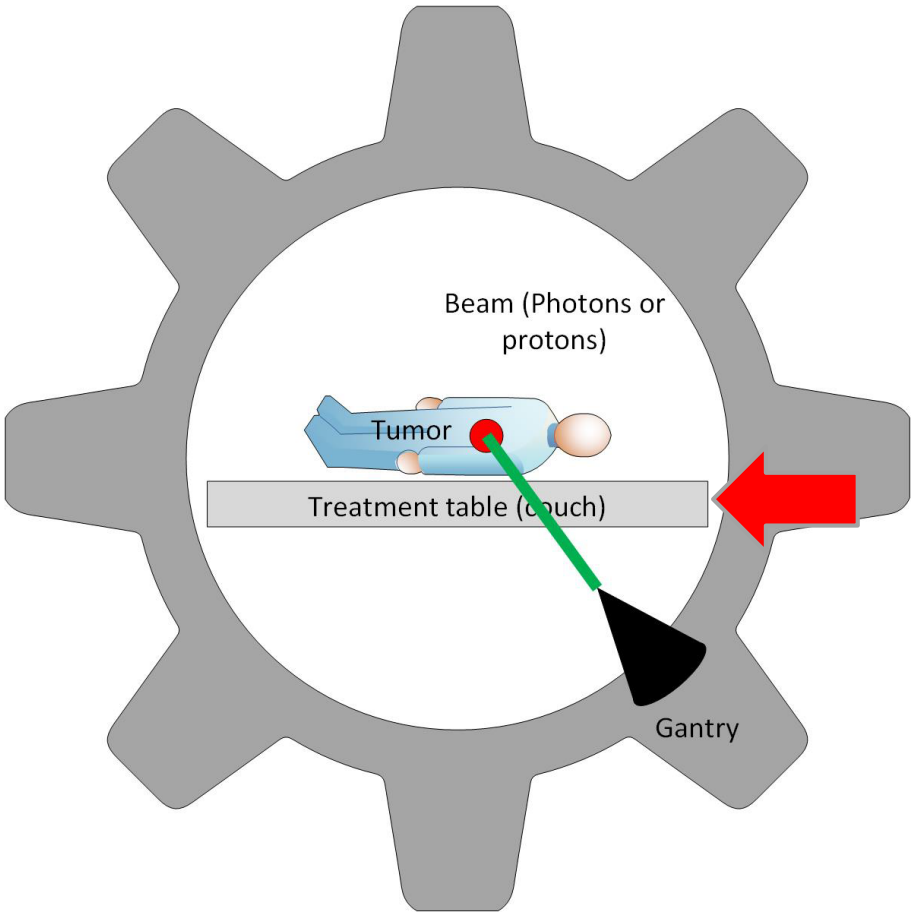
1.8 instead of 0.18

- Fault was discovered too late by another MP
- 2 lung cancer patients received wrong treatment

Question: Why is the table a risk?







Wrong table specs is a NOT a hazard

Wrong table specs IS a hazard

- **LOSS:**

  A1. Patient is injured by ionizing radiation

- **HIGH-LEVEL HAZARDS :**

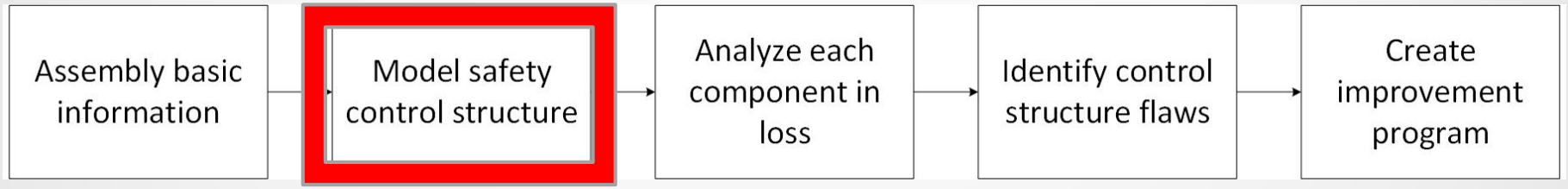
H1.1 Patient received a wrong dose of radiation in the tumor.

H1.2 Patient received a wrong dose of radiation in the healthy tissues.

SAFETY CONSTRAINT VIOLATED:

A patient should always receive radiation treatment as prescribed by the oncologist (dose, place and time).

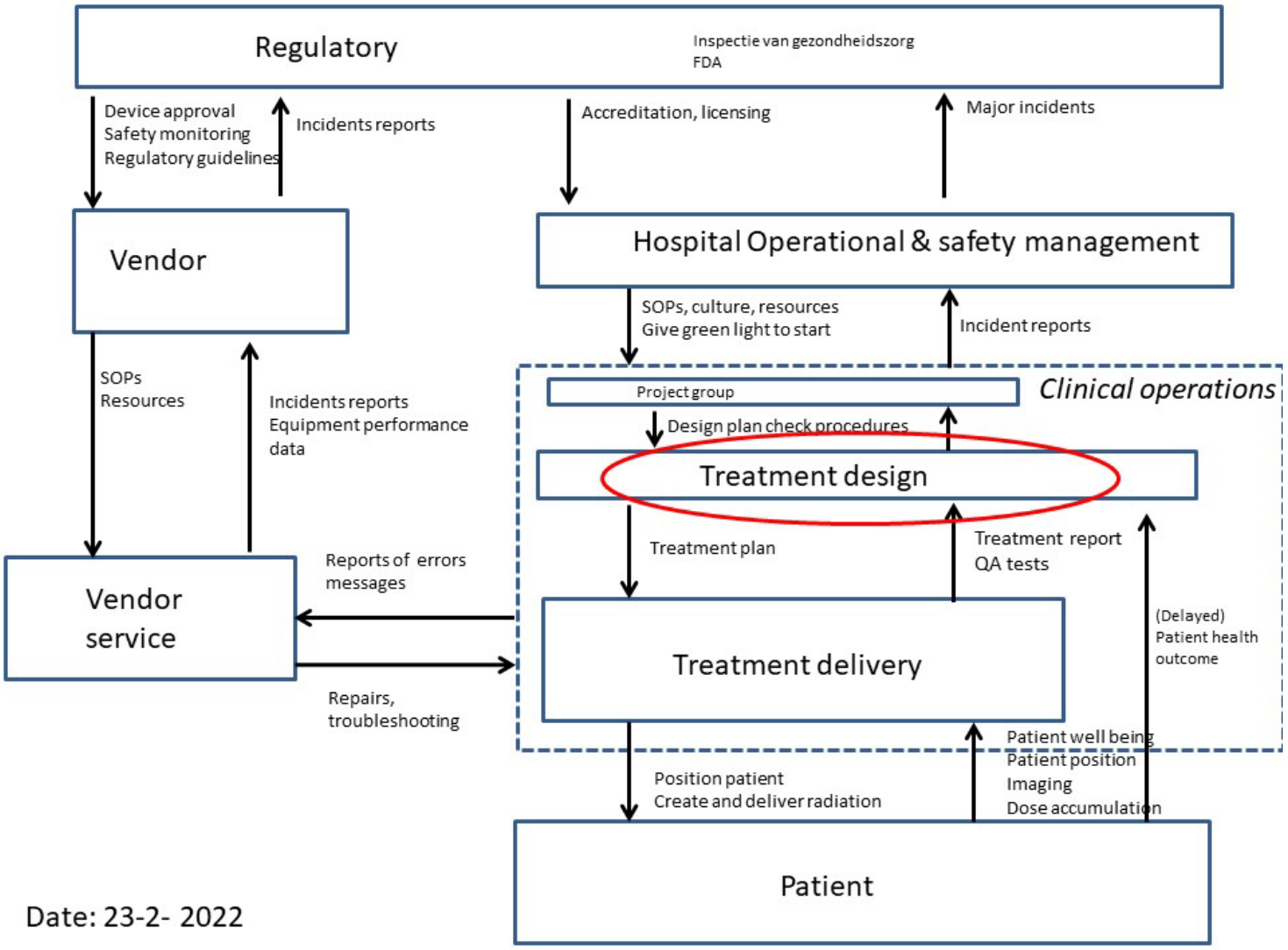
Sources:
Pawlicki, Todd, Aubrey Samost, Derek W. Brown, Ryan P. Manger, Gwe-Ya Kim, and Nancy G. Leveson. 2016. 'Application of systems and control theory-based hazard analysis to radiation oncology', *Medical Physics*, 43: 1514-30



CAST leading philosophy

- *"Accidents happen because of control flaws"*
- Even if somebody made a mistake, other controllers in the safety net, together with safety constraints in place could have prevented the error to propagate and lead to a loss
- Identify controllers which could have prevented and did not.

High-level control structure



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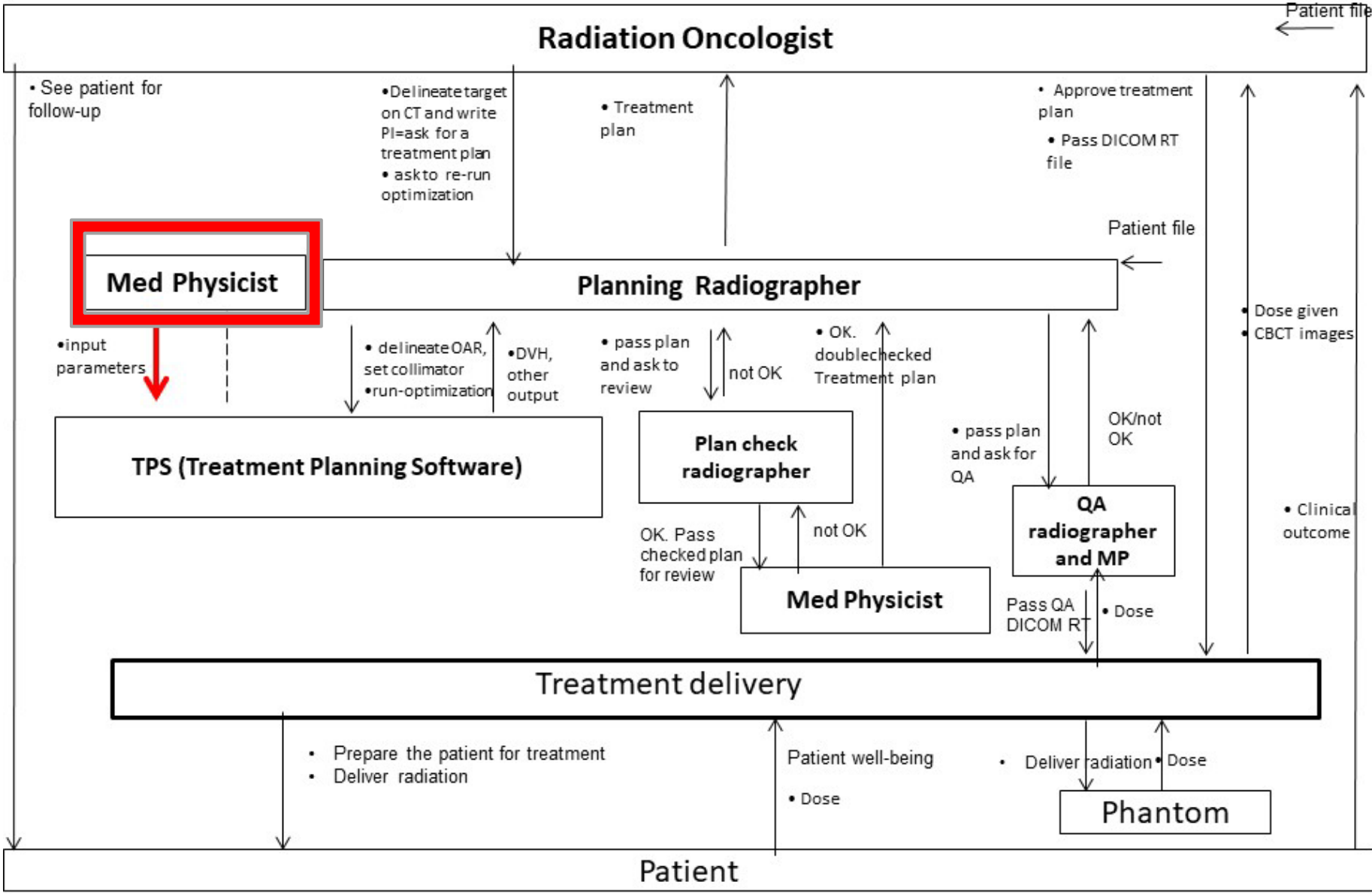
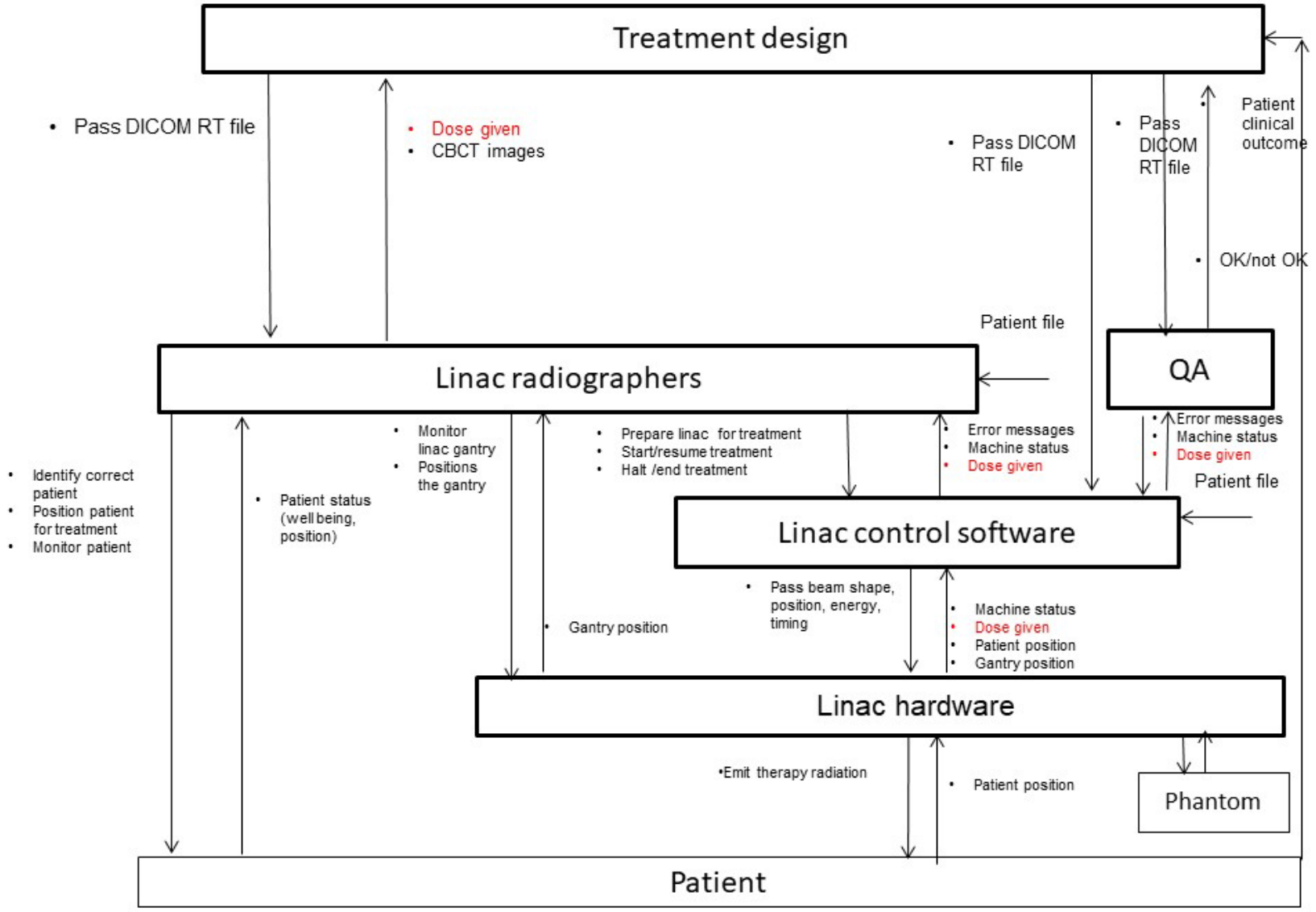
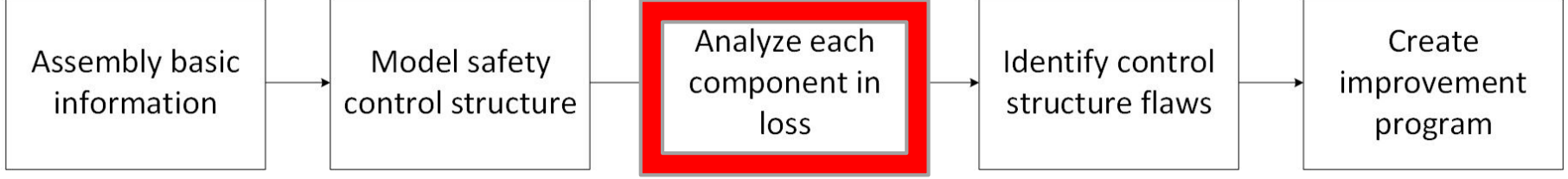


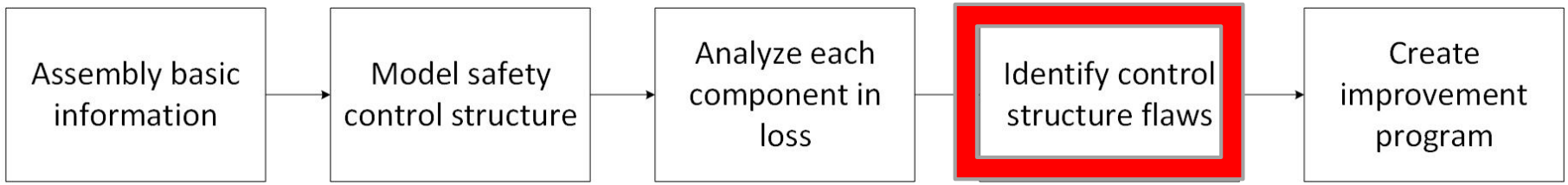
Treatement design safety control structure (incomplete, only with controllers relevant



Treatment delivery safety control structure

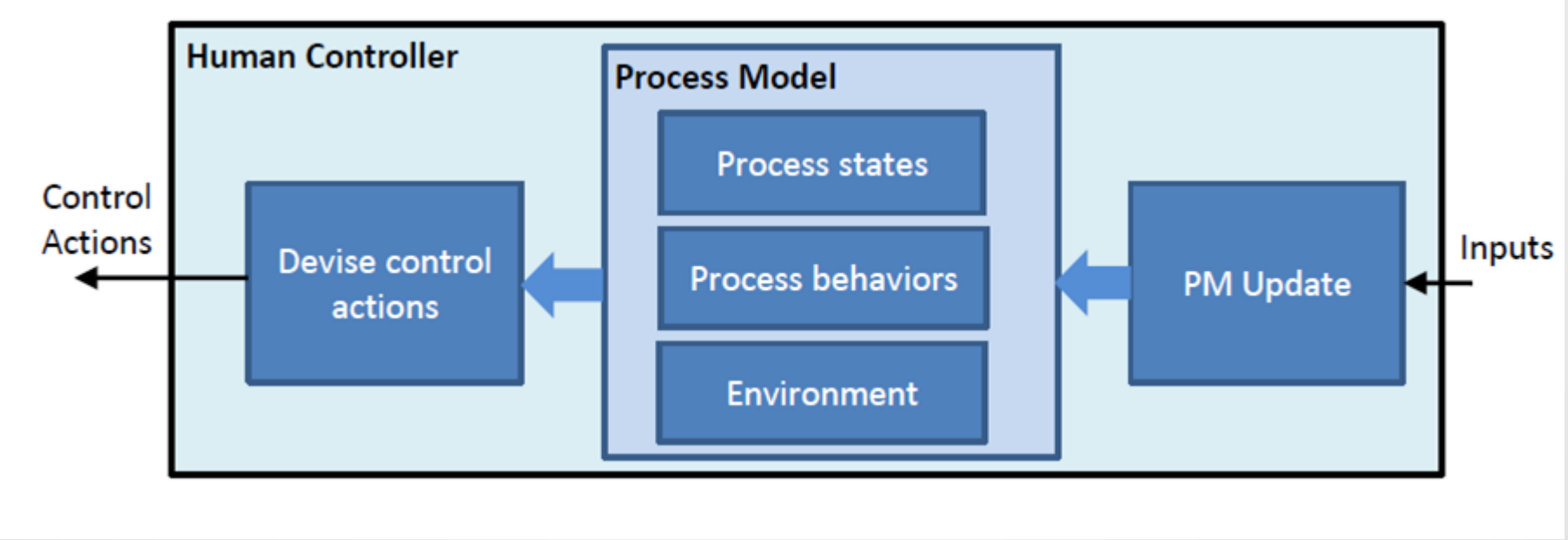


Controller	Responsability	Contribution
Medical Physicist	Input table data in TPS	Input wrong data
TPS (software)	Assist operators in the design of the plan	Did not detect wrong input
QA team	Test the treatement plan on linac	Did not test in all gantry positions Did not measure dose given to patient
Physics team	Designs & test treatment plan Communicates check procedures to the team	Did not include a check of the table specs Did not communicate all the procedures to new hires
Safety management	Conducts hazard analysis Writes safety policy	Did not include “Wrong table specification” as a possible failure mode in the analysis
Operational Management	Gives green light to new processes	Gave green light to a new RT process too soon, before it was safe



Controller	Contribution	Why?
MP	**Input wrong data**	TPS suggested 1.8 as default!
TPS	**Did not detect wrong input**	Was not implemented.
QA	**Stopped testing the plan too soon** **Did not measure dose given to patient**	This is how the old process works. European standards. Dose measurements at patient are not technically possible in the new process
Physics team	**Did not include a check of the table specs input** **Did not communicate all the procedures to new hires**	Confidence in high-educated MP? Did not see table as a risk
Safety management	**Did not include "Wrong table specification" as a possible failure mode in the hazard analysis**	Nobody thought about the table as a risk factor There was no time to go into so much detail
Operational Management	**Gave green light to the new process too soon, before it was**	It was pressure to start fast the new process

Extended STPA model for human controllers



[Thomas & France, 2016]

- **Human controller:** ***QA team***
- **Control action:** ***Test plan on the linac***
- **Control algorithm:** ***Deliver the plan to a water phantom in the same position like the patient. If dose is according to the oncologist prescription, then approve. If not, then send plan back to the treatment plan design team.***

UCA: QA team stopped to test too soon. WHY?

Causal scenarios *(these are speculations)*

Mental model flaws

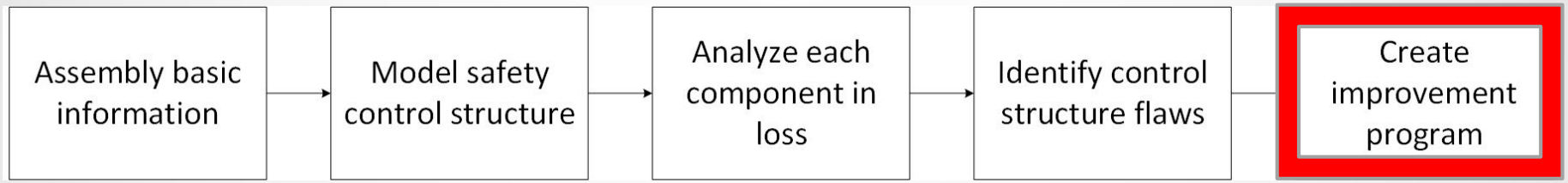
- *They thought "wrongly" that for other gantry angles the dose will be the same? Dose at gantry yes, but the dose at the patient not.*
- *Or maybe they assumed that treatment does not use the gantry under the table?*
- *Followed the procedures because they thought wrongly that in the old process these worked fine. But new process is different, where a wrong table specification was much more critical.*

Context factors

- *It was a new process. Technically it was not possible to measure the dose given to the patient. Is this an excuse? QA team did not dare to convey their doubts to management about the safety of the process?*

Unanswered questions

- ***Why did people close to the fire hesitate to participate in our CAST analysis?*** **No time, less interest because it is an old incident?**
- ***Why did the MP accept the default value 1.8 instead of 0.8?*** **Seemed familiar, same digits?**
- ***Why did the physics team not warn the management that the process is not safe yet?***
- **…many more**



Recommendations-1 (CAST vs PRISMA)

- **For the RT department**

- In a new process, carefully reuse existing hazard analyses and procedures by taking new risks into consideration. Was not there.
- The hazard analysis should be communicated to the manufacturers. Was not there.
- Plan checklist should include checks of the input. It was there.
- Plan checklists and protocols should be well communicated inside the organisation, also to new hires. Was not explicitly for new hires, but in general it was there.
- QA tests should cover all possible situations during treatment. It was there but they accepted that technically it cannot be realized yet.
- QA test procedure should be communicated towards oncologists. It was there.
- The physics team director should dare to say to the clinic manager that the testing is not ready and that a process cannot be launched yet. It was there, maybe not with these words. They even recommended a checklist to help decide that CAST did not.
- Staff should be open to discuss past incidents. Partially yes. They recommended more safety awareness in the physics team.
- There should be a shorter line with the software manufacturers. Users like RT operators should dare to speak up about the quality of the software. Was not there.

Recommendation -2 (CAST vs PRISMA)

- **For AAPM (American Association of Medical Physicist) task group.** The guidelines for QA should take the table into consideration in the QA end-to-end testing of this new process. Also, they should speed up the research on how to measure the dose at the patient. Was not there.

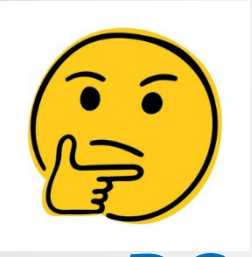
- **For Dutch safety regulatory authorities**: Audit of QA SOPs should not only check that the procedures are in place, but they should dive into detail, checking for example that the end-to-end QA tests cover all possible situation during treatment. Domain knowledge about the audited physical process is needed in the team. This needs time and expertise. Was not there.

- **For RT manufacturer.**
- [Communication] The manufacturer should be involved in the hazard analysis process in the facility. They should listen to the complaints from the users. Was not there.

- [SW] Implement more input sanity checks. Software makers should know more about the physical process they are controlling and its risks. These risks should drive their design, development and testing. Using defaults in GUI is dangerous, maybe it should be prohibited? Was not there.

- [HW] A technical method must be found on short term to measure the dose at the patient during QA and treatment in the new process. Was not there.

- *RQ1. How did CAST work for RT?*
  - **Graphical modeling using control structures helped to extend the responsability beyond the usual suspects.**
  - **Good guidance to continue generating questions when traditional analysis stops, especially for human operators.**
  - **We could speed up the modeling process by partly reusing artifacts from previous STPA/CAST analyses.**



RQ1. How did CAST work for RT?

- **Interviewing people close to the fire is challenging and needs diplomacy. People feel very fast offended.**
- **The succes of the analysis depends on how much the CAST analyst knows about the process and the organisation.**
- **The RT department found the graphical modelling of the process cumbersome and time-consuming. They are satisfied with the PRISMA method and do not plan to use CAST in the future. Maybe they will use it only for new processes. However, they liked the feedback loops that generated new interesting questions. They will think about software in the future.**

RQ2. What is the added value of CAST?

- **CAST found the same major problems as the PRISMA method**
- **CAST found new causality. This was possible to be discovered by a systems engineer, an outsider with little domain knowledge.**
- **Software emerged as an actor that can prevent but also harm and contribute to an accident! We could say that "software in fact helped the operator to make the mistake". Traditional methods such as FMEA, FTA or PRISMA treat software as perfect.**
- **CAST could generate new recommendations especially related to technology (software and hardware) and high-level players, outside the organization, such as the manufacturer or the regulatory agents.**

Conclusions

It is not easy to persuade RT teams to adopt STAMP-CAST

However,

We demonstrated that STAMP-CAST reveals new causality and generates additional safety-related recommendations.
This was achieved with less resources and domain knowledge.

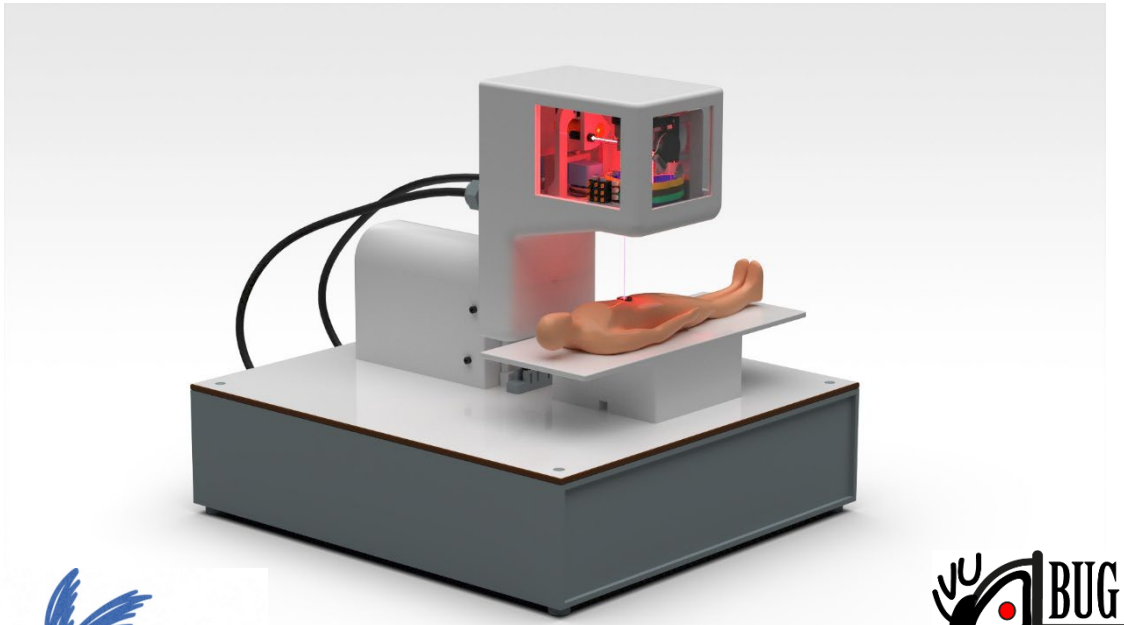
Future work

- Investigate more past incidents using STAMP-CAST in an international RT team that guarantees anonymity
- Analyze new RT incidents in parallel with other methods and compare.
- Promote STAMP-CAST in academia and RT community

Acknowledgements

- Nancy Leveson and John Thomas (MIT)
- Todd Pawlicki (UCSD)
- All practitioners who fight for a safer RT process

Thank you!



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A replica of the Therac-25 linac built at the Vrije Universiteit Amsterdam, as part of the VU-BugZoo project, a cooperation between Computer Science dept and the VU Beta Technology Center.