Therapy Equipment Delivers Radiation Overdoses
2004-2009

In September of last year, a physicist at a healthcare facility was trained on use of the BrainLAB stereotactic radiation therapy system. During this training, the physicist realized that the system had been incorrectly calibrated, as the wrong chamber had been inserted into the machine. The facility realized that the chamber had been incorrectly inserted at installation in 2004, and that patients who used the portion of the machine calibrated by that chamber had received radiation overdoses over those five years.

The facility is working through the impacts of these errors, the causes of the error, and what needs to be done to keep an issue like this from ever happening again.

First let's examine the impacts to the goals resulting from this error. There's an impact to the patient safety goal due to potential for deaths and injuries. (Because these patients were already sick - sometimes very sick - the facility is still determining what impact the overdoses may have had.) There has not yet been mention of an employee impact - the physicist who set up the machine is no longer at the facility - so we'll just put a "?" after Employee Impact. The event was reported to The Joint Commission (no reports were required by law), which can be considered an impact to the compliance goal. The organizational goal was impacted due to potential lawsuits against the hospital. The patient services goal was impacted because 76 patients received an average overdose of 50% (other patients received overdoses that were considered within the acceptable range for treatment). Because radiation was involved, there is the potential for an environmental impact. However, there is no evidence that any radiation leaked to the environment, we'll put a "?" by the environmental goal as well. Lastly, the property and labor/time goals were impacted because of the additional follow-up exams, testing, support, and treatment, which the facility will provide for all those affected by the issue.

Once we've determined the impact of the event, we can begin an analysis of how it happened. Or, what were the causes? The goals were impacted due to the overdose to several patients. The overdose occurred because the radiation therapy machine was miscalibrated and the miscalibration was not discovered for five years. The machine was miscalibrated because the incorrect chamber was installed and the chamber installation was not verified. The physicist chose the wrong chamber and the equipment representative (who was on hand for the installation) did not notice the error. At this point, it's unclear why the physicist chose the wrong chamber and why the equipment representative did not notice the error.

The miscalibration was not noticed for five years because any re-calibration of the machine depended on the chamber which was incorrectly installed. So although the machine was not delivering the correct amount of radiation, the problem was with the calibration itself, resulting in a propagating error. According to the facility, none of the patients showed any unusual side effects that would indicate they were getting too much radiation. However, some of the symptoms may take years to develop. Additionally, no other staff members were trained on the equipment for five years. It was a second staff member who was trained on the equipment who finally noticed the error.

Even though there are some questions still remaining in our Cause Map, we can develop some solutions, as the facility in question (as well as other stakeholders) is doing. One suggestion is to do an external calibration of the machine - i.e., use a calibration method that is completely separate from the machine to determine if the correct amount of radiation is being delivered. Also, have an independent verification that each piece of the equipment was installed correctly. Require the equipment representative to sign off on the installation. Last but not least, train other staff members to operate the equipment as backup. The facility is working with the FDA to assist in its efforts to increase the safety of radiation use in healthcare settings. (See our previous blog about this topic.)

Step 4 to avoid radiation therapy errors: verify HOW MUCH - how much radiation therapy is required, and how much is the patient actually getting.

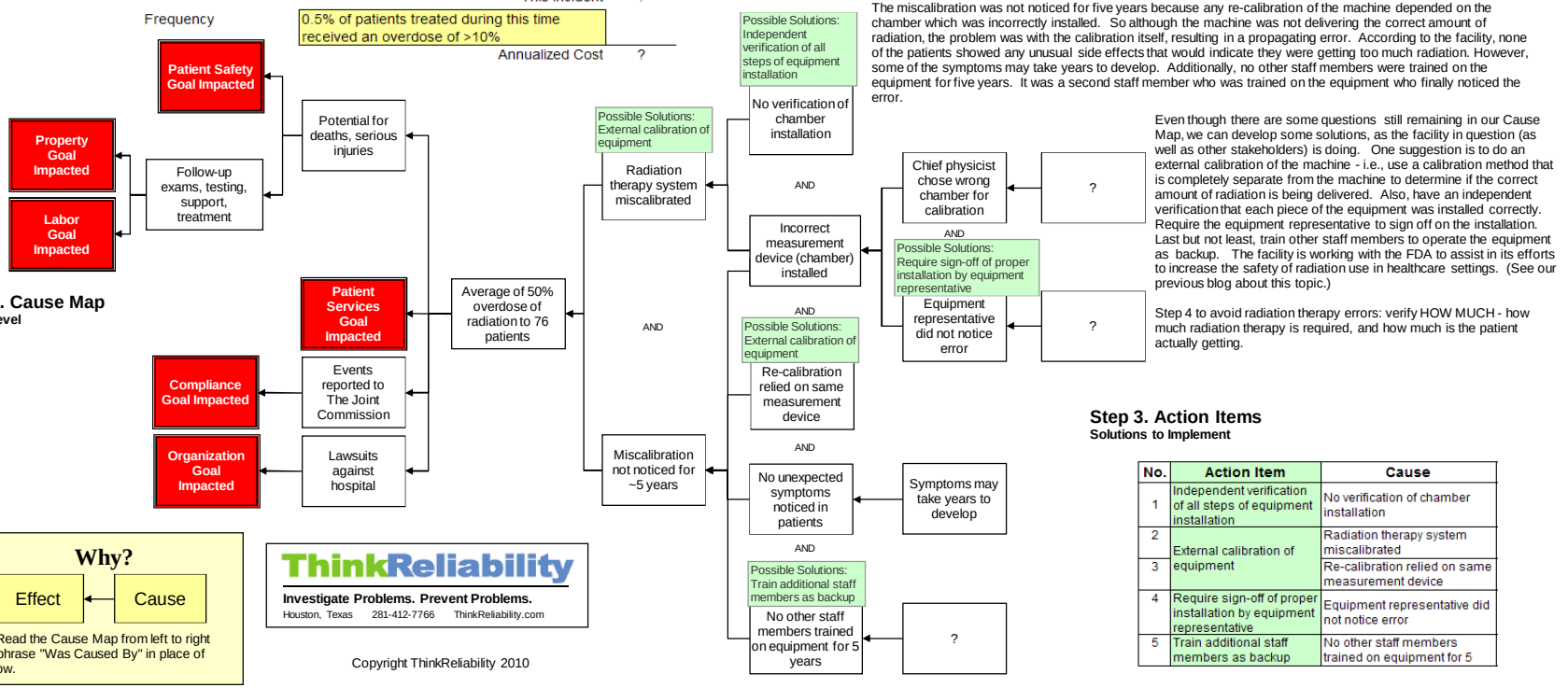
Step 1. Problem Outline
Define the problem

What	Problem(s)	76 patients received too much radiation, machine miscalibrated
When	Date	2004 to September 2009
	Different, unusual, unique	Machine calibrated incorrectly
Where	State, city	Springfield, MO
	Facility, site	CoxHealth
	Unit, area, equipment	BrainLAB stereotactic radiation therapy
	Task being performed	Radiation treatment

Impact to the Goals

Patient Safety	Potential for deaths, serious injuries	
Employee Impact	?	
Compliance	Events reported to The Joint Commission	
Organization	Lawsuits against hospital	
Patient Services	Average of 50% overdose of radiation to 76 patients	
Environmental	?	
Property, Equip, Mtls	Follow-up exams, testing, support and treatment	?
Labor, Time		
	This incident	?
Frequency	0.5% of patients treated during this time received an overdose of >10%	
	Annualized Cost	?

Step 2. Cause Map
Detail Level



Step 3. Action Items
Solutions to Implement

No.	Action Item	Cause
1	Independent verification of all steps of equipment installation	No verification of chamber installation
2	External calibration of equipment	Radiation therapy system miscalibrated
3		Re-calibration relied on same measurement device
4	Require sign-off of proper installation by equipment representative	Equipment representative did not notice error
5	Train additional staff members as backup	No other staff members trained on equipment for 5

Why?

Effect ← Cause

NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.

ThinkReliability
Investigate Problems. Prevent Problems.
Houston, Texas 281-412-7766 ThinkReliability.com

Copyright ThinkReliability 2010