Outline

What	Problem(s)	Tungsten particles left in body
When	Date	2010-2011
	Different, unusual, unique	Clinical research trial
Where	Facility, site	Two different hospitals
	Unit, area, equipment	XOFT/iCAD Axxent Flexishield Mini
	Task being performed	Protects the body from unwanted radiation

Impact to the Goals

Patient Safety	Potential for long-term risk	
	Potential for surgical removal of affected areas	
Employee Impact	?	
Compliance	?	
Organization	Suit against hospital and manufacturer	?
Patient Services	Difficulty in reading mammograms	?
Environmental	N/A	?
Property, Equip, Mtls	Microshield device recalled	?
Labor, Time	?	?
		?
Frequency	30 women affected	
	Annualized Cost	?

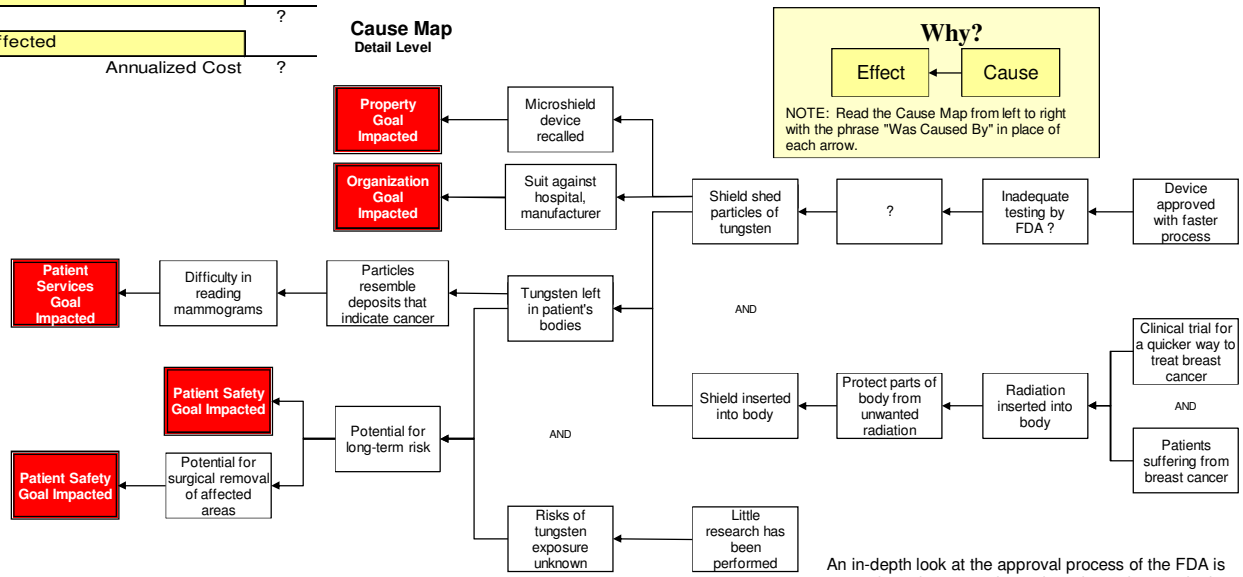
Tungsten Particles Remain in Patient's Bodies After Clinical Trial 2010-2011

Thirty women who participated in a research clinical trial that hoped to revolutionize the treatment of breast cancer are now facing the possibility of long-term effects from tungsten particles left in their body or disfiguring surgery. The trial involved radiation treatment that could be performed in one short session instead of over many weeks, offering obvious benefits to the patients. However, during follow-up checks after the trial, many women found particles of tungsten, a heavy metal, in their breasts and chest muscles.

Some physicians have recommended removal of the affected areas. The choice between that, or living with the risk of tungsten particles - whose long-term effect has not been thoroughly studied - is an impact to the patient safety goal. In addition the particles will look like calcium deposits, which can be an indication of cancer, in future mammograms, resulting in an impact to the patient services goal. The device has since been recalled, which is an impact to the property goal, and at least one suit has been filed against the manufacturer of the device and the hospital performing the trial. It is believed that 30 women are affected.

The health issue of leaving the tungsten within the patient's body is caused by a particle of unknown long-term safety being deposited in the body. The tungsten appears to have been shed by a device used during radiation treatment to prevent radiation from reaching other parts of the body. It's still unknown how a device that would shed particles into a patient's body made it into a human clinical trial. What is known is that the device went through the accelerated FDA approval process known as 510(k) for devices that are similar to devices that have already been approved. It's unclear which device was considered similar enough to allow for the approval of this one, but there have been many concerns that the FDA's approval process is insufficient

Cause Map
Detail Level



An in-depth look at the approval process of the FDA is currently underway to determine where changes in the process may result in a more thorough review and, most importantly, prevent an issue like this one from reoccurring.

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