The Therac 25

A case study in safety failure

- Radiation therapy machine
- "The most serious computer-related accidents to date"
- People were killed
- Reference:
- Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", _Computer_, 26, 7 (July 1993) pp 18-41.
- Nancy Leveson, "Therac-25 Accidents: An Updated Version of the Original Accident Investigation Paper", from _Software, System Safety, and Computers_, Addison Wesley, 1995.

Therac 25 Background

- Medical linear accelerator developed by Atomic Energy of Canada, Ltd. in mid-1970s
- Delivers 25 MeV photons or electrons of various energies
- Controlled by PDP-11 minicomputer
- Software responsible for safety
- Software adapted from earlier Therac-6 & Therac 20 systems, which had hardware interlocks for safety

The Therac 25

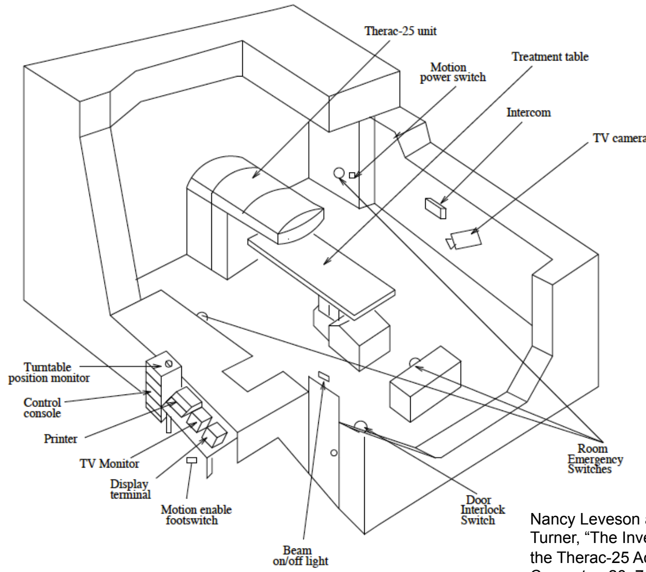


Figure 5: A typical Therac-25 facility after the final CAP.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

Therac 25 Turntable

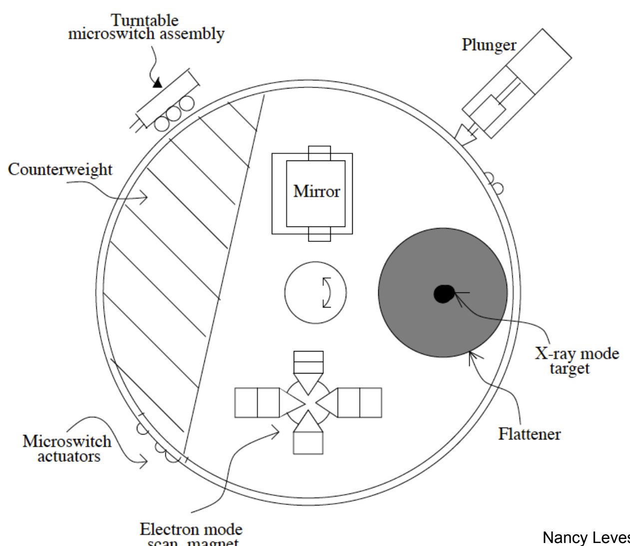
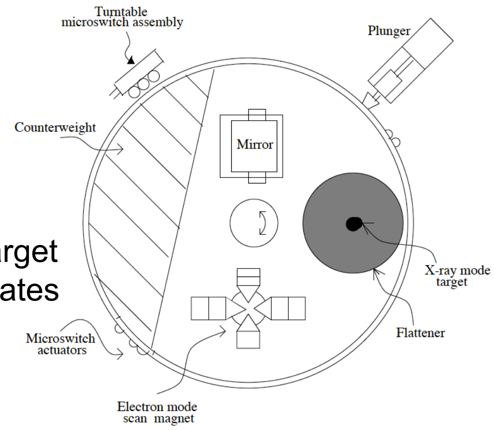


Figure 1: Upper turntable assembly.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

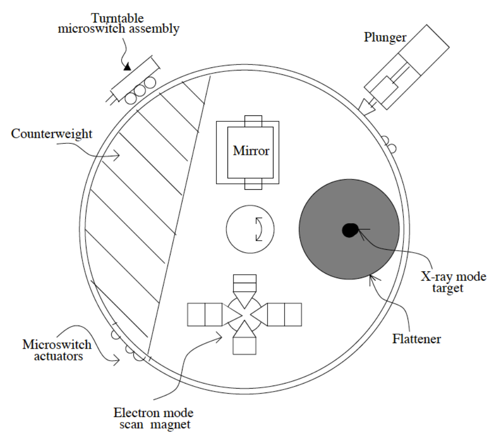
Therac 25 Turntable

- Electron mode
  - 5-25 MEV
  - Magnets scan and spread beam
  - Ion chamber monitor
- X-ray mode
  - 25 MEV electrons hit target
  - “Beam flattener” attenuates
  - 100x beam current
  - Ion chamber monitor
- Field-light mode
  - No current
  - Mirror & light used to check alignment
  - No ion chamber (since not treating)



Therac 25 Turntable

- Computer adjusts turntable position
- Microswitches detect turntable setting
- 3-bit binary code used to encode turntable setting
- Software checks replace hardware interlocks



Nancy Leveson and Clark Turner, “The Investigation of the Therac-25 Accidents”, Computer, 26, 7 (July 1993) pp 18-41.

Operator Procedures

- Position patient on table
- Manually set treatment field size and gantry rotation; attach accessories
- Leave room
- Use VT-100 console to enter patient data, dose data, etc.
- (System compares manual settings with system values)
- If "verified", operator can start machine
- Else must re-enter data

Operator Screen Layout

PATIENT NAME : TEST
TREATMENT MODE : FIX   BEAM TYPE: X   ENERGY (MeV): 25

	ACTUAL	PRESCRIBED	
UNIT RATE/MINUTE	0	200	
MONITOR UNITS	50 50	200	
TIME (MIN)	0.27	1.00	
GANTRY ROTATION (DEG)	0.0	0	VERIFIED
COLLIMATOR ROTATION (DEG)	359.2	359	VERIFIED
COLLIMATOR X (CM)	14.2	14.3	VERIFIED
COLLIMATOR Y (CM)	27.2	27.3	VERIFIED
WEDGE NUMBER	1	1	VERIFIED
ACCESSORY NUMBER	0	0	VERIFIED

DATE	: 84-OCT-26	SYSTEM	: BEAM READY	OP. MODE	: TREAT AUTO
TIME	: 12:55: 8	TREAT	: TREAT PAUSE		X-RAY 173777
OPR ID	: T25V02-R03	REASON	: OPERATOR	COMMAND:	

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

Operator Procedures

- **Complaint**
  - Re-entering all that data manually is very tedious
- **Response**
  - Set things up so that “carriage return” copies previous data for entry
  - Series of carriage returns effectively permits fast re-entry of unchanged parts of data

Operator Procedures

- **Error Conditions**
  - “Treatment suspend” requires complete machine reset
  - “Treatment pause” can be resumed if operator types “P” at console
  - Machine insists on reset after 5 “P”s
  - Malfunction messages fairly common & usually do not affect safety
- **Error Messages**
  - Cryptic
  - Some were of the form “Malfunction NN”

FDA Comment on Manual

The operator's manual supplied with the machine does not explain nor even address the malfunction codes. The [Maintenance] Manual lists the various malfunction numbers but gives no explanation. The materials provided give *no* indication that these malfunctions could place a patient at risk.

The program does not advise the operator if a situation exists wherein the ion chambers used to monitor the patient are saturated, thus are beyond the measurement limits of the instrument. This software package does not appear to contain a safety system to prevent parameters being entered and intermixed that would result in excessive radiation being delivered to the patient under treatment.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

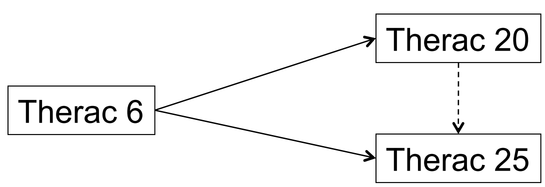
Therac 25 Software Functions

- Monitors machine status
- Sets up machine for treatment
- Turns beam on and off in response to operator
- Monitors interlocks
- If fault, either prevents treatment start or causes a pause/suspend

Therac 25 Software Structure

- Critical tasks:
  - Treatment monitor
  - Servo
  - Housekeeping
- Non-critical tasks:
  - Checksum
  - Keyboard
  - Calibration
  - etc.
- Concurrent access to shared memory, “test” and “set” of variables not indivisible, race conditions

Software Family Tree



Some software for the machines was interrelated or reused. In a letter to a Therac-25 user, the AECL quality assurance manager said, “The same Therac-6 package was used by the AECL software people when they started the Therac-25 software. The Therac-20 and Therac-25 software programs were done independently starting from a common base” [4]. The reuse of Therac-6 design features or modules may explain some of the problematic aspects of the Therac-25 software design. The quality assurance manager was apparently unaware that some Therac-20 routines were also used in the Therac-25; this was discovered after a bug related to one of the Therac-25 accidents was found in the Therac-20 software.

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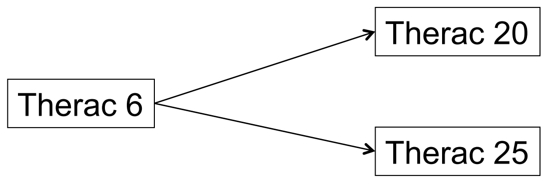
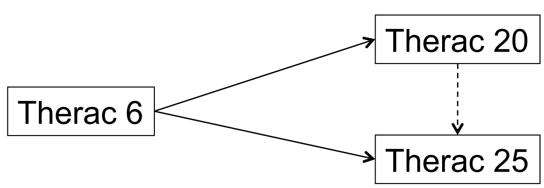
Therac 25 Software Development



- Evolved from Therac 6 system (1972-1976)
- Written in PDP-11 assembler
- Custom operating system

Therac 25 Software Development



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- Minimal unit and software testing
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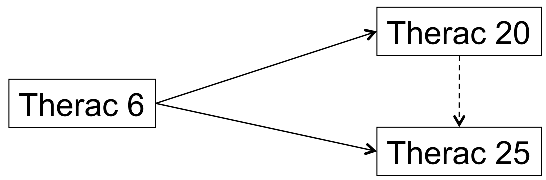

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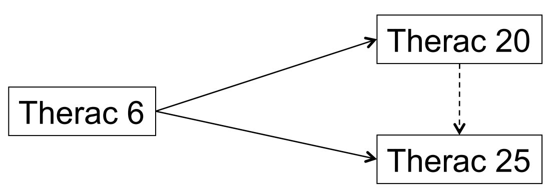

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- Incorporated some Therac 20 code, as well
- Q/A testing was 2700 hours of use as integrated system
- **Programmer left AECL in 1986, little information available about his background**

Hazard Analysis

Hazard Analysis. In March 1983, AECL performed a safety analysis on the Therac-25. This analysis was in the form of a fault tree and apparently excluded the software. According to the final report, the analysis made several assumptions about the computer and its software:

1. Programming errors have been reduced by extensive testing on a hardware simulator and under field conditions on teletherapy units. Any residual software errors are not included in the analysis.
2. Program software does not degrade due to wear, fatigue, or reproduction process.
3. Computer execution errors are caused by faulty hardware components and by "soft" (random) errors induced by alpha particles and electromagnetic noise.

The fault tree resulting from this analysis does appear to include computer failure, although apparently, judging from the basic assumptions above, it considers hardware failures only. For example, in one OR gate leading to the event of getting the wrong energy, a box contains "Computer selects wrong energy," and a probability of 10^{-11} is assigned to this event. For "Computer selects wrong mode," a probability of 4×10^{-9} is given. The report provides no justification of either number.

Nancy Leveson, "Therac-25 Accidents: An Updated Version of the Original Accident Investigation Paper", from *Software, System Safety, and Computers,* Addison Wesley, 1995.

Accident History

- 11 Therac 25’s installed (5 US, 6 Canada)
- Six accidents involving massive overdoses between 1985 and 1987
- Machines recalled in 1987
- Related problems in Therac 20 discovered later but hardware interlocks prevented injuries

Accident History

- June 3, 1985
  - Kennestone Regional Oncology Center, Marietta, Ga.
  - Never really investigated
- July 26, 1985
  - Hamilton, Ontario
  - AECL decides failing microswitch was cause
  - Independent consultant recommended adding a potentiometer
- September 1985
  - AECL makes first round of changes and notifies customers

Yakima Valley, December 1985

- Therac 25 modified in September 1985 in response to earlier overdose problems in Hamilton, Ontario.
- Woman treated in December 1985
- Developed parallel-striped red pattern on right hip
- Treatments continued until January 6, 1986 because reaction was not determined to be abnormal
- Hospital staff investigated various causes such as heating pad patient slept on. But were puzzled because nothing seemed to fit.
- Eventually described problem as “cause unknown”

Yakima Valley, 1985

- In report written after another overdose a year later, medical physicist said:

> At that time, we did not believe that [the patient] was overdosed because the manufacturer had installed additional hardware and software safety devices to the accelerator.
>
> In a letter from the manufacturer dated 16-Sep-85, it is stated that "Analysis of the hazard rate resulting from these modifications indicates an improvement of at least five orders of magnitude"! With such an improvement in safety (10,000,000 percent) we did not believe that there could have been any accelerator malfunction. These modifications to the accelerator were completed on 5,6-Sep-85.

Nancy Leveson and Clark Turner, “The Investigation of the Therac-25 Accidents”, Computer, 26, 7 (July 1993) pp 18-41.

E.g., East Texas, March 1986

- History of 500 patients treated successfully
- Prescribed: 22MeV electrons, 180 rads
- Operator selected x-rays by mistake, used cursor keys to change to electrons
- Machine tripped with “Malfunction 54”
  - Documentation explains this is “dose input 2” error
- Operator proceeded; machine tripped again

E.g., East Texas, March 1986

- Patient felt something wrong on first jolt, tried to get up
- Video/audio links to room not functioning
- Patient felt jolt on arm while getting up, pounded on door
- Treatment cancelled for day
- Calibration checks seemed normal
- Later found patient had gotten 16,500-25,000 rads over 1 cm square
- Patient eventually died after 5 months

E.g., East Texas, March 1986

- AECL engineers could not replicate a Malfunction 54
- AECL home office engineer said machine could not overdose patient
- AECL suggested patient got an electric shock
- No grounding problems found
- Machine returned to service April 7, 1986

East Texas/ April 11,1986

- Prescription 10 MeV, area 7 x 10 cm
- Operator used cursor keys to change x-rays to electrons, saw "beam ready", and turned machine on
- Loud noise, shutdown, malfunction 54
- Patient in great pain
- Patient died three weeks later

East Texas/ April 11,1986

- Machine taken out of service
- ETCC eventually reproduced malfunction 54
  - Data entry speed critical factor
  - Observed 4000 rad dose
- AECL later measured 25,000 rads
- In lawsuit, earlier “cursor up” problems reported, which AECL believed to have been fixed

Tvler Accident Race Condition

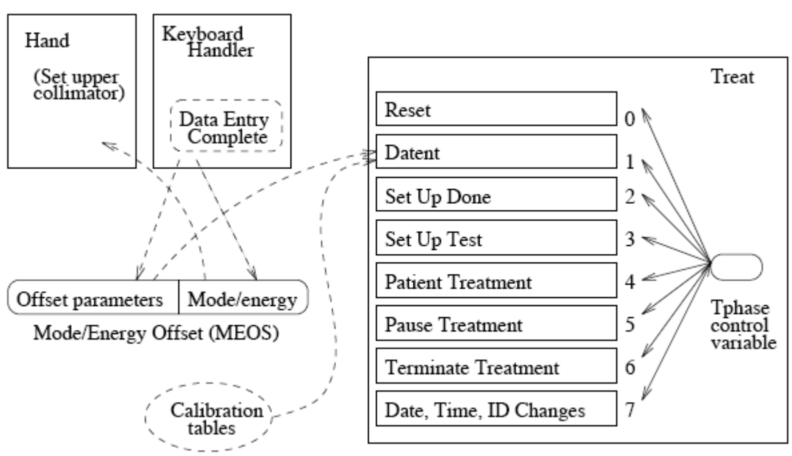

Figure 3: Tasks and subroutines in the code blamed for the Tyler accidents.

Nancy Leveson and Clark Turner, “The Investigation of the Therac-25 Accidents”, Computer, 26, 7 (July 1993) pp 18-41.

Race Condition

The keyboard handler parses the mode and energy level specified by the operator and places an encoded result in another shared variable, the 2-byte Mode/Energy Offset variable (MEOS). The low-order byte of this variable is used by another task (Hand) to set the collimator/turntable to the proper position for the selected mode and energy. The high-order byte of the MEOS variable is used by Datent to set several operating parameters.

Initially, the data-entry process forces the operator to enter the mode and energy except when the photon mode is selected, in which case the energy defaults to 25 MeV. The operator can later edit the mode and energy separately. If the keyboard handler sets the Data Entry Complete flag before the operator changes the data in MEOS, Datent will not detect the changes because it has already exited and will not be reentered again. The upper collimator (turntable), on the other hand, is set to the position dictated by the low-order byte of MEOS by another concurrently running task (Hand) and can therefore be inconsistent with the parameters set in accordance with the information in the high-order byte. The software appears to contain no checks to detect such an incompatibility.

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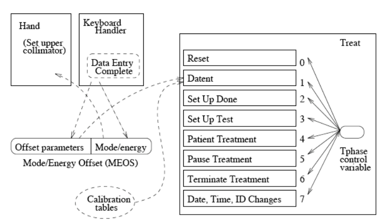
Datent Subroutine

```
if mode/energy specified then
    begin
        calculate table index
        repeat
            fetch parameter
            output parameter
            point to next parameter
        until all parameters set
        call Magnet
        if mode/energy changed then return
    end
if data entry is complete then set Tphase to 3
if data entry is not complete then
    if reset command entered then set Tphase to 0
return
```



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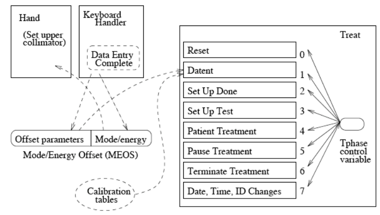
Magnet Subroutine

```
Magnet:
    Set bending magnet flag
    repeat
        Set next magnet
        call Ptime
        if mode/energy has changed, then exit
    until all magnets are set
    return

Ptime:
    repeat
        if bending magnet flag is set then
            if editing taking place then
                if mode/energy has changed then exit
    until hysteresis delay has expired
    Clear bending magnet flag
    return
```



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East Texas Govt & User Response

- Report to FDA on April 15, 1986
- Sent letter recommending temporary fix to all users

Effective immediately, and until further notice, the key used for moving the cursor back through the prescription sequence (i.e., cursor "UP" inscribed with an upward pointing arrow) must not be used for editing or any other purpose.

To avoid accidental use of this key, the key cap must be removed and the switch contacts fixed in the open position with electrical tape or other insulating material. For assistance with the latter you should contact your local AECL service representative.

Disabling this key means that if any prescription data entered is incorrect then [an] "R" reset command must be used and the whole prescription reentered.

For those users of the Multiport option, it also means that editing of dose rate, dose, and time will not be possible between ports.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

Response, continued

- FDA comment

> We have reviewed Mr. Downs' April 15 letter to purchasers and have concluded that it does not satisfy the requirements for notification to purchasers of a defect in an electronic product. Specifically, it does not describe the defect nor the hazards associated with it. The letter does not provide any reason for disabling the cursor key and the tone is not commensurate with the urgency for doing so. In fact, the letter implies the inconvenience to operators outweighs the need to disable the key. We request that you immediately renotify purchasers.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

Response, continued

- First fix plan – June 13, 1986
  - Fixed software to eliminate specific bug
  - Modified software sample-and hold circuits to detect pulse above a threshold. Shut down if have one pulse exceeding threshold, rather than 3.
  - Malfunctions 1-64 now suspend treatment, not pause it
  - Added circuit to turn off beam independent of software
  - Modify editing software to limit cursor up, etc.
  - Modify manuals
- FDA had numerous internal concerns
- FDA Letter of 7/23 agreed conceptually, but complained about lack of specific information to evaluate plan. Requested detailed description of software development procedures.

Response, continued

- FDA Internal Memo of October 20

Unfortunately, the AECL response also seems to point out an apparent lack of documentation on software specifications and a software test plan.

. . . concerns include the question of previous knowledge of problems by AECL, the apparent paucity of software QA [quality assurance] at the manufacturing facility, and possible warnings and information dissemination to others of the generic type problems.

. . . As mentioned in my first review, there is some confusion on whether the manufacturer should have been aware of the software problems prior to the [accidental radiation overdoses] in Texas. AECL had received official notification of a lawsuit in November 1985 from a patient claiming accidental over-exposure from a Therac-25 in Marietta, Georgia. . . If knowledge of these software deficiencies were known beforehand, what would be the FDA's posture in this case?

. . . The materials submitted by the manufacturer have not been in sufficient detail and clarity to ensure an adequate software QA program currently exists. For example, a response has not been provided with respect to the software part of the CAP to the CDRH [FDA Center for Devices and Radiological Health] request for documentation on the revised requirements and specifications for the new software. In addition, an analysis has not been provided, as requested, on the interaction with other portions of the software to demonstrate the corrected software does not adversely affect other software functions.

The July 23 letter from the CDRH requested a documented test plan including several specific pieces of information identified in the letter. This request has been ignored up to this point by the manufacturer. Considering the ramifications of the current software problem, changes in software QA attitudes are needed at AECL.

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Response, continued

- Second revised plan December 22, 1986
  - Included meaningful messages, software modifications, expanded test plan, etc.
- Sent "Component and Installation Test Plan" on Jan 26, 1987.
  - Company explained that delays were due to investigation of a new accident on Jan 17, in Yakima, California.

Yakima Valley, January 1987

- Plan: 2 film verification exposures (3 & 4 rads) + 79 rad photon treatment
- Performed two film exposures
- Operator used hand controls to rotate table to field-light position & check alignment
- Operator set machine but forgot to remove film
- Operator turned beam on, machine showed no dose & displayed fleeting message
- Operator proceeded from pause

Yakima Valley, January 1987

- After another machine pause, operator reentered room.
- Patient complained of burning sensation
- Patient developed severe striped burns
- Patient died in April
- Hospital obtained similar pattern on film by running machine with turntable in field light position

Responses

- Voluntary Class II recall 8/1/85
- AECL accident report April 15, 1986
- First version of corrective action plan 6/13/86
- Second Yakima overdose 1/17/87
- Fifth (final) corrective action plan 7/21/87
- Interim safety analysis report 1/29/88
- Final safety analysis report 11/3/88

Therac 25 Turntable

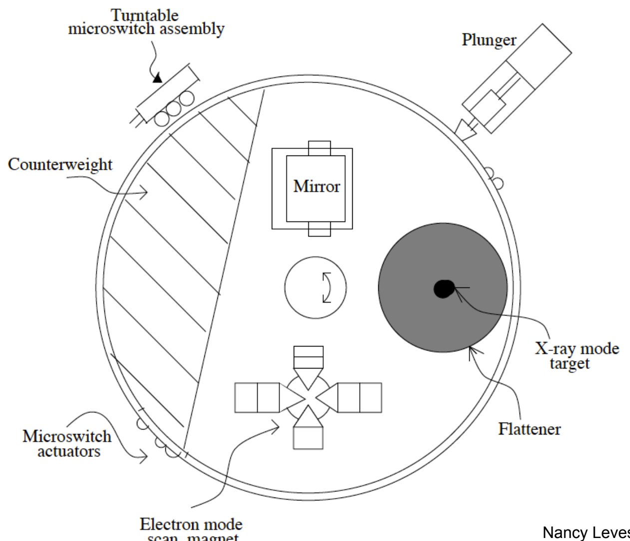

Figure 1: Upper turntable assembly.

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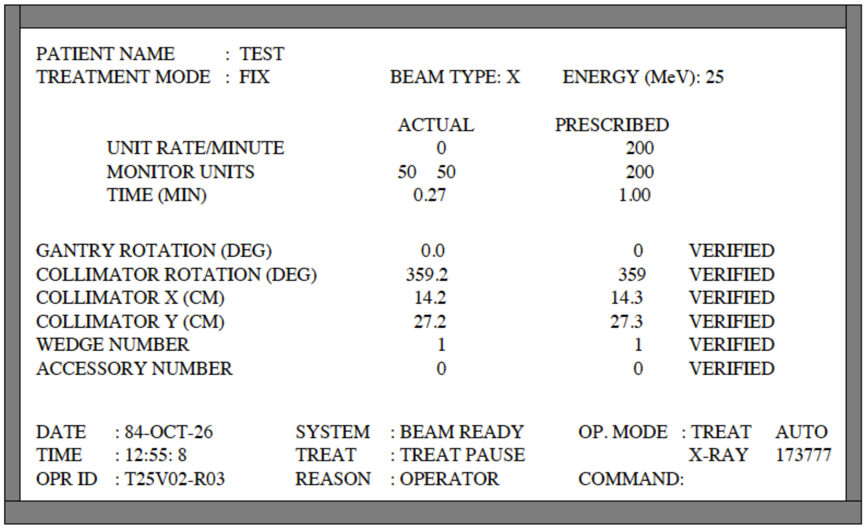
Operator Screen Layout



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Yakima Accident Race Condition

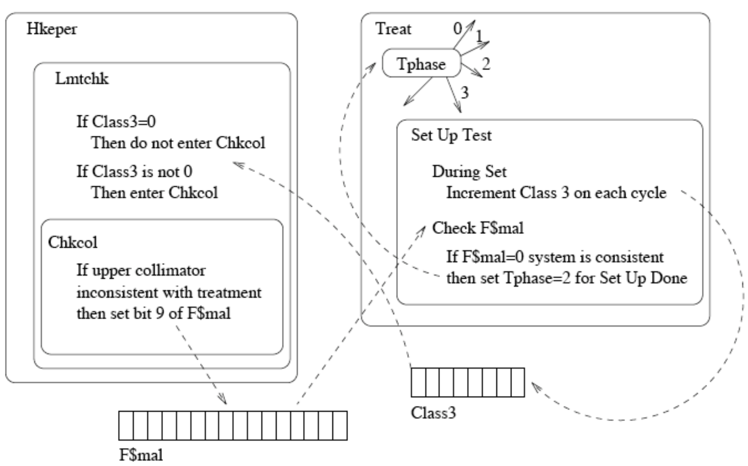

Figure 4: The Yakima software flaw.

Nancy Leveson and Clark Turner, "The Investigation of the Therac-25 Accidents", Computer, 26, 7 (July 1993) pp 18-41.

The Race Condition

During machine setup, Set-Up Test will be executed several hundred times since it reschedules itself waiting for other events to occur. In the code, the Class3 variable is incremented by one in each pass through Set-Up Test. Since the Class3 variable is 1 byte, it can only contain a maximum value of 255 decimal. Thus, on every 256th pass through the Set-Up Test code, the variable overflows and has a zero value. That means that on every 256th pass through Set-Up Test, the upper collimator will not be checked and an upper collimator fault will not be detected.

The overexposure occurred when the operator hit the "set" button at the precise moment that Class3 rolled over to zero. Thus Chkcol was not executed, and F$mal was not set to indicate the upper collimator was still in field-light position. The software turned on the full 25 MeV without the target in place and without scanning. A highly concentrated electron beam resulted, which was scattered and deflected by the stainless steel mirror that was in the path.

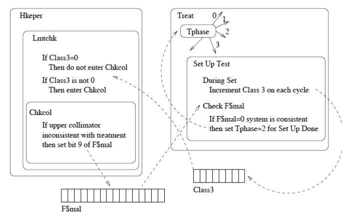

Figure 4: The Yakima software flaw.

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Corrective Action Plan

- Numerous hardware and software changes
- All interruptions related to dosimetry not continuable
- independent hardware & software shutdowns
- potentiometer on turntable
- hardware interlocks
- "dead man switch" motion enable
- Fix documentation, messages, & user manuals
- etc

Lessons (Leveson & Turner)

- Complacency
- Assumption that problem was understood without adequate evidence (“the last bug” fallacy).
- Sole reliance on software for safety
- Systems engineering practices

Lessons (Leveson & Turner)

- Documentation key from beginning
- Use established software engineering practices
- Keep designs simple
- Build in software error logging & audit trails
- Extensive software testing and formal analysis at all levels
- Revalidate reused software
- Don’t rely only on software for safety
- Do incorporate redundancy
- Pay careful attention to human factors
- Involve users at all phases