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Application of Failure Modes and Effects Analysis: An example of 2100 C-series Linear Accelerator

Aime M Gloi PhD, DABR, Javis Jackson CMD, Robert Carroll RTT, Dawn Hemmaz RTT, Mitchell Elis, RTT, Taylor Lisella RTT, Bo Zhan RTT, Alton Hogan RTT

Radiation Oncology-21st Century Oncology of California, USA.
*Corresponding Author
Aime M Gloi PhD, DABR
21st Century Oncology of California
1316 Nelson Avenue, Modesto, CA 95350
USA
Phone:209-575-5870
Fax:209-575-5872
Email: agloi7288@gmail.com

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Abstract

Purpose: We apply Failure Mode and Effects Analysis (FMEA) to investigate and alleviate linear accelerator (linac) downtime issues due to various mechanical and electrical interlocks.

Methods: A working group filled out questionnaires to identify different linac failure modes and assign severity, occurrence, and detectability scores to six frequent interlocks. The three scores were multiplied to obtain an overall risk probability number (RPN) for each interlock. The consistency of scores assigned by the therapists was evaluated using Cronbach's Alpha.

Results: A total of 61 failure modes were identified. Six recurring interlocks were analyzed over a study period of three months, by five therapists. A fault tree was generated for a generic interlock and for the complex hardware (HFWA) interlock. The Cronbach's Alpha statistics show generally poor agreement among the scores assigned by therapists.

Conclusions: On the basis of these findings, the clinic proposed novel solutions for mitigating the risk of linac failures, thus reducing linac downtime and improving patient satisfaction.

Keywords: Failure mode and effects analysis (FMEA), Linear accelerator (linac), Risk probability number (RPN)

1. Introduction

A radiotherapy linear accelerator (linac) is a complex piece of engineering, consisting of multiple components linked together by a web of electrical, mechanical and electronic circuits. Maintaining functionality in these components is crucial, as any failure may delay radiation treatment for patients. The design and safety features of linacs have evolved over time, and now include robust interlocks to prevent unforeseen accidents. Interlocks alert operators to conditions that could cause serious equipment damage or patient injury. At the same time, reducing the frequency of linac interlocks and hence downtime translates into increased patient safety and satisfaction. Downtime, service calls, and associated revenue loss can also be prevented by zeroing in on the exact fault.

Failure Modes and Effects Analysis (FMEA) is a mature and reputable technique that can help achieve all these goals. Its use is advocated by the American Association of Physicists in Medicine (AAPM), Task Group 100, for risk assessment in radiation therapy [1]. FMEA detects potential failure modes, assesses their causes and effects, and provides a solution to reduce the occurrence of each failure. Essentially, FMEA models a fault tree that helps users resolve issues quickly and cut down linac downtime. To date, several studies have been published applying FMEA to various types of radiotherapy[2,3,4,5,6]. The present study will provide basic steps in this direction for linac radiotherapy, and an improvement process for therapists. In general, most linac interlock faults are reported on the treatment console screen, and the tendency of therapists is to override the fault without knowing its extent and nature.

Our specific goal for using FMEA in this pilot study is to reduce the risk probability number (RPN) (a composite risk score defined later in this paper) of common interlocks by three means: enhancing processes through the removal of failure modes, improving the detectability of failure modes, and providing practical recommendations on how to apply this new approach to the linac interlock cases.

2. Materials and Methods

FMEA is a forward management risk analysis method, widely used in industry and lately recommended by Task Group 100 of the AAPM as a powerful tool for modern radiation oncology [7]. It is a bottom- up analytical procedure that pinpoints vulnerabilities in the process. Each potential failure mode of the system is analyzed to determine its effect and classified according to severity. This study applies FMEA as a first step to identify all the sub-processes involved in common linac interlock events. The exercise was carried out by a team of five, comprised primarily of therapists, to tackle the problems faced by a radiotherapy clinic during linac downtime due to mechanical or electrical interlocks. For our system, there are three types of interlocks: Major, Minor, and Dosimetric [8].

a) Major: Most major interlocks arise from conditions that if not corrected could seriously damage the linac.

b) Minor: Minor interlocks involve conditions that can be corrected easily. In this case, treatment can proceed if the interlock is identified and its fix is known by the operator.

c) Dosimetry: Dosimetry interlocks involve conditions caused by transient variation in the beam and are usually fixed by a dosimetry password.

Two typical examples of linac interlocks are:

Pump (Major), characterized by overheating of the linac due to a low water level in the reservoir. For example, it can activate if the temperature exceeds 48 ± 2^{o}, if the city water supply is off, or in case of thermal overload in the water pump.

Flow (Major), characterized by overheating of the linac due to insufficient water flow.

Both events [7] are listed in Varian Clinac instructions, Varian Medical Systems Inc., (Palo Alto, CA, USA). Verifying major interlocks is part of the daily quality assurance (QA) routine, which needs to be performed before the linac is powered on.

If these failures occur during treatment (along with their causes, potential effects, and risk indices), the result will not be fatal for a patient because of the robustness of the interlock. However, they can seriously damage the linac. Specifically, an activated interlock incurs several major consequences for the clinic:

-Machine shutdown, resulting in treatment delay

-Patient frustration

-Overlap in therapist and patient schedules

-Missed treatments, with possible radiobiological effects on patients if the interlock is persistent or recurs

-Staff has to stay late.

-Long diagnosis time for the fault, and there may be no replacement parts on site

-The need to order new parts, and the repair could take a long time

-Potential loss of patient satisfaction and revenue

Based on these concerns, we created a questionnaire (Table 1) to collect inputs and outputs from several observations by five participating therapists during linac interruptions. Each therapist was given an opportunity to inspect the process map, log events, and discuss their own experience. After three months, all responses were collected, and a risk assessment was applied based on the probability of occurrence (O) for each possible failure, the severity (S) of the failure effect if not resolved, and the probability that the failure will not be detected (D). Each failure was scored with a value ranging from 1 (low probability/severity) to 10 (high probability/severity) (Table 2). The product of these three components (O, D, and S) was used to calculate a composite score: RPN.

RPN = S × O × D (1)

The reliability of the data was examined through Cronbach's Alpha, calculated using MedCalc Statistical Software version 16.4.3 (MedCalc Software bvba, Ostend, Belgium). Cronbach's Alpha measures the consistency of inputs provided by different raters. Its formula is:

$$\alpha = \frac{k \times \bar{c}}{\bar{v} + (k-1)\bar{c}} \quad (2)$$

where k refers to the number of scale items (3 in our case), $\bar{c}$ is the average of all covariance between items, and $\bar{v}$ is the average variance of each item. Cronbach's Alpha varies between 0 and 1 and can be broadly interpreted using the Likert scale given in Table 3.

Table 1: Questionnaire for the linear accelerator interlocks

Standard question	Meaning
What could go wrong?	Potential Failure
How could that happen?	Failure Mode
What are the causes of the failure mode?	Cause
How likely is the failure mode to occur?	Occurrence = O
How hard the failure mode to detect before the patient is affected?	Detectability = D
What are the effects if the failure mode goes undetected?	Severity = S
What is the overall risk of the failure mode?	*RPN* = O × D × S

Table 2: Failure Mode and Effects Analysis (FMEA) scoring scale adopted from American Association of Physicists in Medicine (AAPM), Task Group 100 depicting Occurrence, Severity, and Detectability

VALUE	OCCURENCE	SEVERITY	DETECTABILITY
1	Very unlikely	No adverse effect	Always detected
2-3	Low probability	Grade 1 (Mild)	High probability of being detected
4-5	Some probability	Grade 2 (Moderate)	Moderate probability of being detected
6-7	Moderate probability	Grade 3 (Severe)	Some probability of being detected
8-9	High probability	Grade 4 (Life-threatening)	Low probability of being detected
10	Certain Failure	Death	Impossible to detect

Table 3: Likert scale for interpretation of Cronbach's Alpha

Cronbach's Alpha	Internal consistency
α≥0.9	Excellent
0.9>α ≥0.8	Good
0.8>α ≥0.7	Acceptable
0.7>α≥0.6	Questionable
0.6>α≥0.5	Poor
0.5>α	Unacceptable

3. Results and Discussion

We identified 61 possible failure modes in the Varian linac. For this study, a total of 36 failure modes were observed by therapists, which we group into the six most frequent interlock faults. The interlock faults and their different failure modes are summarized in Table 4. The values of O, S, and D assigned to each interlock fault by the five therapists who participated in the study are shown in Table 5 (a, b, c). Their product is the RPN. The RPNs range from 1 to 512. Note that the highest RPN obtained from the study, 512, is still much lower than the maximum possible value of 1000 (S × O × D = 10 × 10 × 10). The riskiest sub-process with an RPN of 512 appears to be related to the Multileaf collimator (MLC).

This evaluation reveals that infrequent, severe events do happen. The therapists generally assigned low D scores to the events (i.e., high detectability), indicating that regular performance maintenance checks are a good way of preventing these failure modes from occurring. Increasing the detection rate is a realistic way to reduce the risk. The occurrence, detectability, and severity scores are illustrated in Figure 1 (a, b, and c, respectively). The average RPN ranking of each interlock fault is shown in Figure 2. The RPN scores are highly variable, mainly because the different therapists strongly disagree on relative frequency (each failure mode is ranked as both most frequent and least frequent, by different therapists). However, on average, the MLC interlocks had the highest RPN scores and time interlocks had the lowest. The clinic took an immediate and simple action to increase the time factor during treatment planning, especially for field in field plans. Furthermore, a reliability analysis test was carried out on the input data from various therapists. There was significant variation in scoring and reporting amongst therapists, as displayed in Table 6. Cronbach's Alpha shows inconsistency in all three measures, although the occurrence rating is noticeably less consistent (Cronbach's Alpha = 0.2979) than the severity and detectability measures. This was to be expected, since the majority of the failure modes are unpredictable.

Figure 3 shows the fault tree for a generic linac interlock along with basic mitigation steps. The process map separates obviously into four sub-processes: interlock, Varian book, identification, and service call. Figure 4 illustrates the fault tree of a specific hardware failure (HWFA) interlock response. This case is the most difficult to understand, as the user interface does not provide any hints. Most often, operators override the interlock in service mode without having any idea of which underlying components are involved. In this case, 10 sub-processes were identified.

We have showed in this study that FMEA methods can be used to actively evaluate the source of some linac interlocks. We identified 6 interlock faults with a high frequency of occurrence. The interlock with the lowest RPN is related to dose times and can be easily avoided by increasing the time factor in the treatment planning system (TPS). To address the other interlocks, we developed and implemented some stringent and mandatory periodic QA test procedures based on the fault tree analysis. Since adopting these new standards, we observed a 60% reduction in service calls via our log-book.

Furthermore, we adopted a rigorous schedule of preventive maintenance inspection (PMI) on the linac used for most Intensity-modulated radiation therapy (IMRT) and Volumetric modulated arc therapy (VMAT) treatments. Additional steps such as disassembling, cleaning motors, and cleaning T-nuts were incorporated into the MLC maintenance routine. Similarly, the collimator's chains and carousel were lubricated, as well as the gantry's chain and motor. The MLC rail carriages, voltage power supply, and velocity tests were checked periodically. Such intensive preventive maintenance is essential to reduce the MLC, RPN.

Reducing the severity and occurrence scores of a failure mode are mainly dependent on improving human response to the fault and linac maintenance, respectively. Therefore, the easiest way to reduce the RPN of severe failures is by increasing their detection probability. Some authors in the literature have proposed schemes to monitor MLCs and detect problems early. First, Abe et al. [9] suggested a predictive maintenance model with daily QA generating log files. The files are automatically transferred to a database and interrogated to establish baseline values. The logs are analyzed daily to estimate performance stress using statistical process control (SPC) methods. Any major deviation triggers an alert to the operators. Similarly, Shoales et al.[10] used pulse width modulation (PWM) analysis to diagnose MLC mechanical malfunctions as part of a routine monthly QA procedure. Litzenberg et al. [11] recommended restricting the maximum leaf speed to improve MLC performance for VMAT deliveries, addressing a possible cause of lag between the MLC controller and the linac. Zhang et al.[12] highlighted the impact of Dose rate in MLC speed and thus root mean square (RMS) error. Finally, attention should be given to the MLC initialization process, which provides valuable information from touch test results (TTR). This information can provide advance warning about potential leaf drive system compression failures.

In conclusion, FMEA is a powerful tool that could be employed to improve quality and efficiency in radiotherapy by actively and systematically identifying potential failure risks. However, the present study suffers from some limitations.

First, our results are derived from a small clinic where human resources are too limited to conduct a thorough FMEA investigation. Further, the focus of our analysis is narrow, as the clinic was seeking immediate relief in the form of reducing treatment delays and service calls. Second, the scores provided by the therapists are subjective and inconsistent, because of their low expertise and high rotation frequency on the linac. However, the exercise allowed us to better exploit existing materials such as the Varian booklet as a reference for the meaning of different interlocks and troubleshooting. We decided to implement and post a fault tree for important interlocks that could be used as a guide to streamline troubleshooting and avoid unnecessary calls to Varian service. Furthermore, a fault log was implemented to identify trends and patterns in the interlocks, and to secure continuing education for the therapists. Most of the bad consequences of failure modes can be alleviated by embracing a simple fault tree analysis.

Table 4: Failure Mode and Effects Analysis of most common linear accelerator component failure modes in our study

Common Linac Faults	**Potential Failure**	**Failure Mode**	**Failure Causes**
MLC	Delays in treatment.	More VMAT treatment infrequent or lack of PMI	Motors, dirts, network connection.
HWFA	Frozen linac. No gantry nor collimator movement.	Random.	Incorrect PRO voltage PRO power voltage outside tolerance Mismatch of primary and secondary potentiometers on the gantry and upper collimators. MLC interlock.
Flow	Potential linac damage.	Water level and temperature not checked before powering the linac.	Water flow for cooling is below limits. Water leakage from loose hose connection. Bend magnet temperature is too high.
Ion1, Ion2	Machine down.	Transverse or radial ion chamber power supply is less than -400 V.	Crack in ion chamber. Broken coaxial cable.
Time	Delay in treatment.	The displayed beam-on time is greater than the value set for time.	Too little time was entered for the treatment. For VMAT, a mechanical problem or low dose resulted in longer treatment time. MU1 and MU2 readouts failed.
UDRS	Interruption in treatment.	Underdose rate is determined by too few MU.	Too few MU per servo period. AFC out of tune.

Table 5a: Occurrence ranking per therapists

MLC	HWFA	Ion1, Ion2	UDRS	FLOW	TIME
8	2.0	1	1	2	2
4	2.0	4	1	1	4
4	6.0	1	1	2	1
7	6.0	1	2	1	2
6	5.0	2	1	1	3

Table 5b: Detectability ranking per therapist

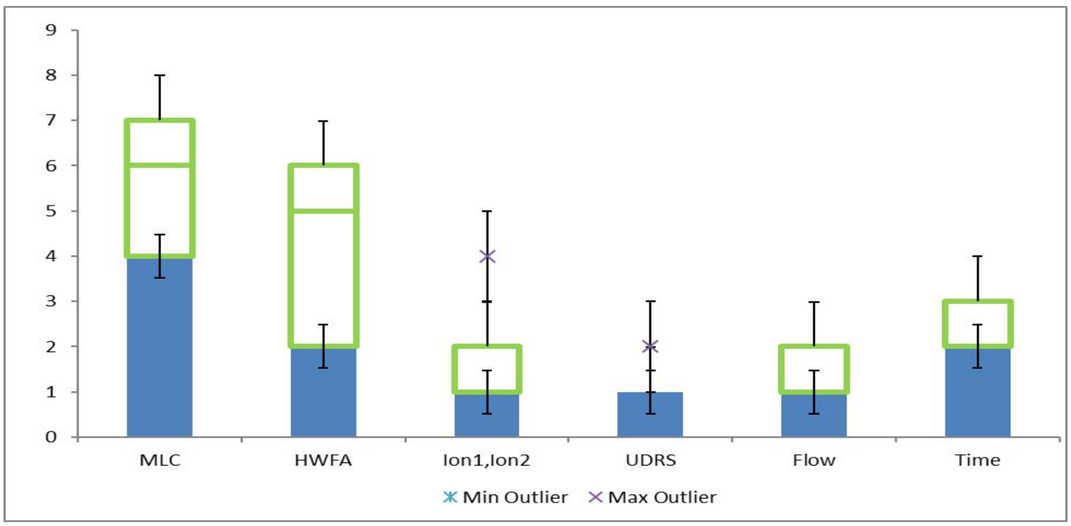
MLC	HWFA	Ion1, Ion2	UDRS	FLOW	TIME
8	2.0	2	1	3	1
8	7.0	3	1	2	2
3	6.0	2	1	2	1
3	6.0	2	2	2	1
7	5.0	2	1	1	1

Table 5c: Severity ranking per therapists

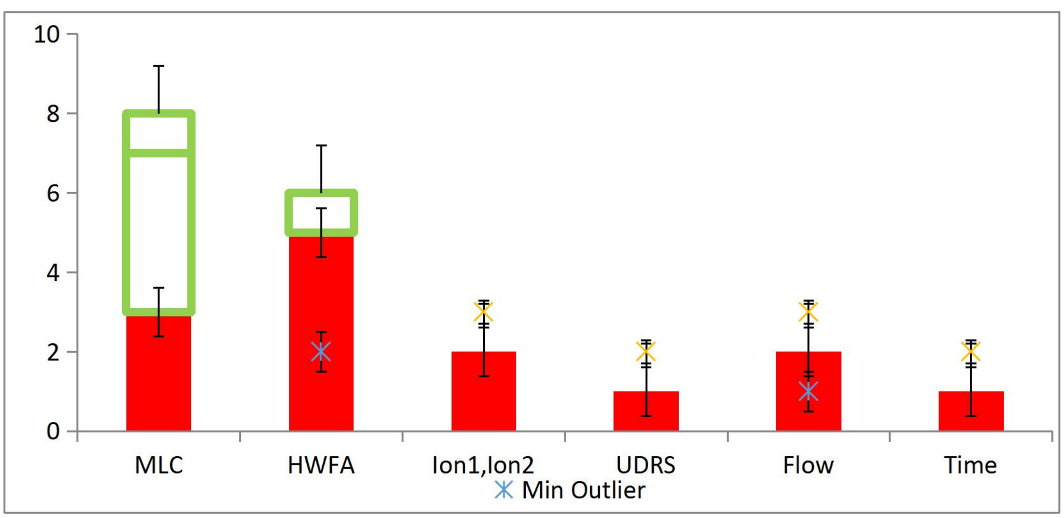
MLC	HWFA	Ion1, Ion2	UDRS	FLOW	TIME
8	4	4	1	5	1
8	5	4	1	3	1
3	3	4	1	4	1
3	3	4	2	3	1
7	7	6	1	4	1

Table 6: Cronbach's Alpha (consistency test)

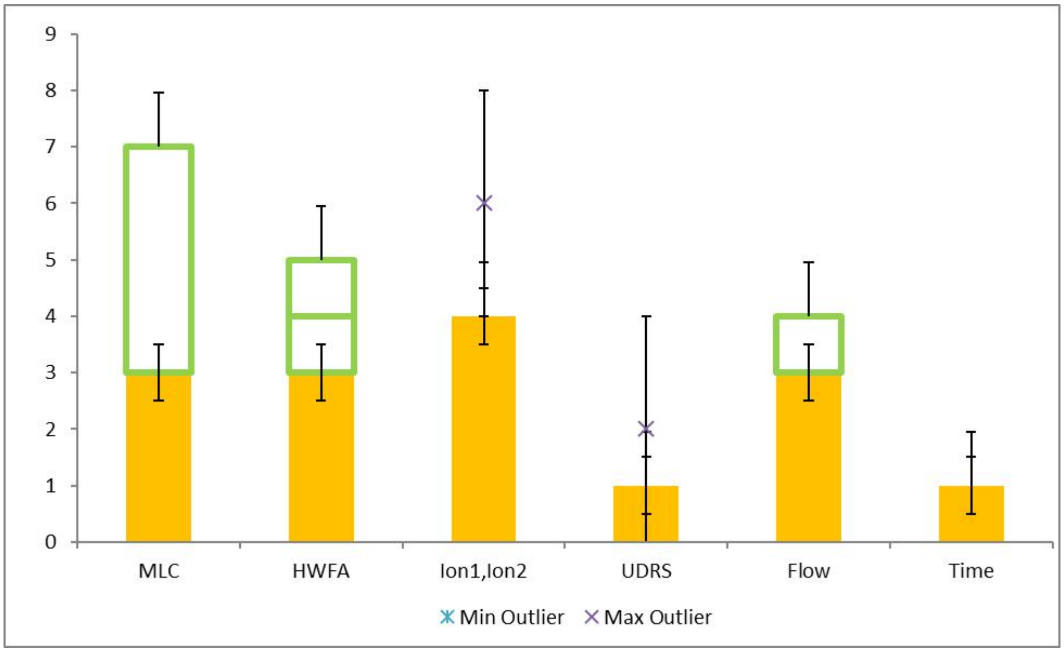
Scale Statistics	Occurrence	Detectability	Severity
Cronbach's Alpha	0.2979	0.5168	0.6955
95% lower confidence interval	-1.0122	-0.3848	0.1273



a)



b)



c)

Figure 1: Whisker-Box plots for occurrence (a), lack of detectability (b), and severity (c) scores for linear accelerator interlocks. Box plots are shown with maximum, minimum, mean, median, 25th and 75th percentile values

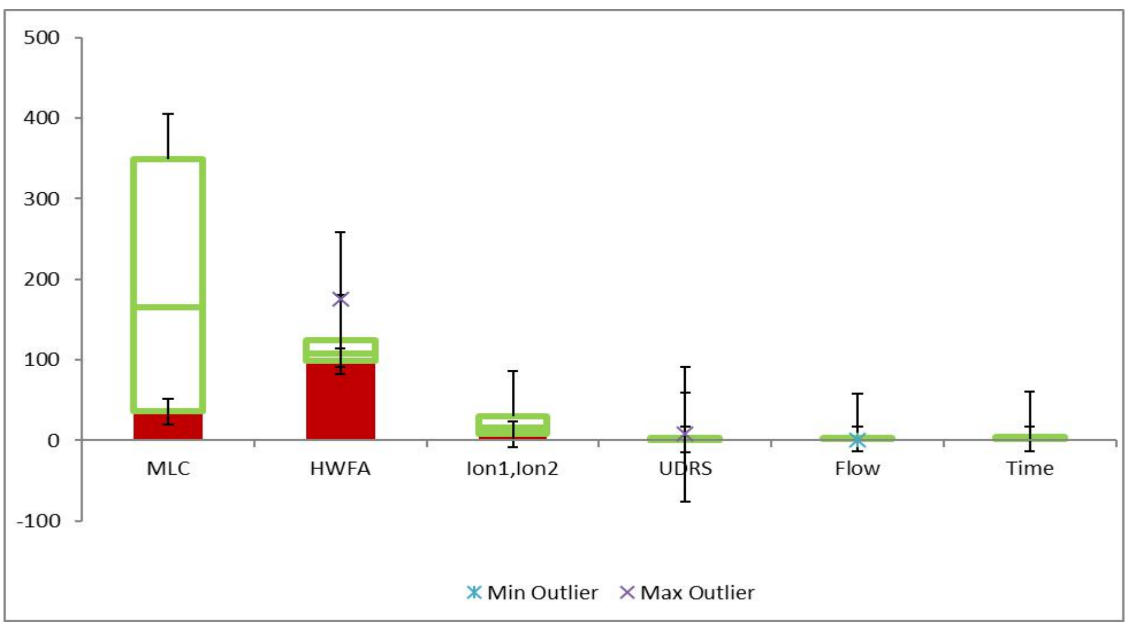


Figure 2: Risk Probability Numbers (RPN) calculated for the six interlock types

General case:

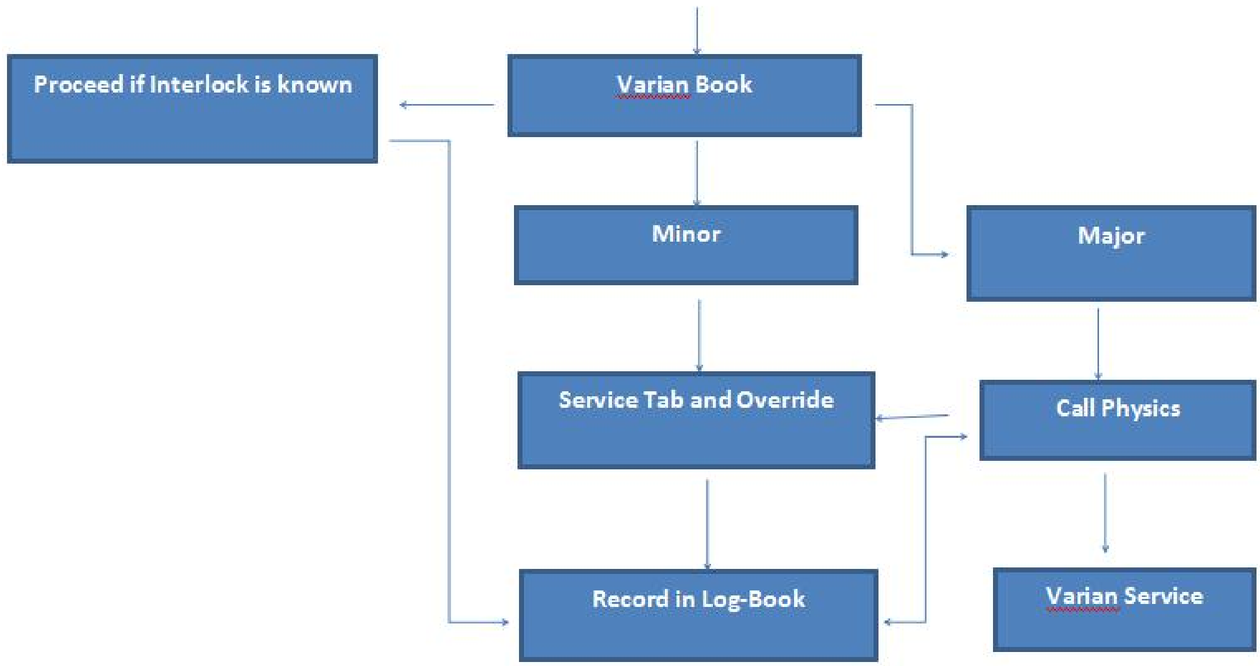


Figure 3: Fault tree for linear accelerator generic interlock

Specific case:

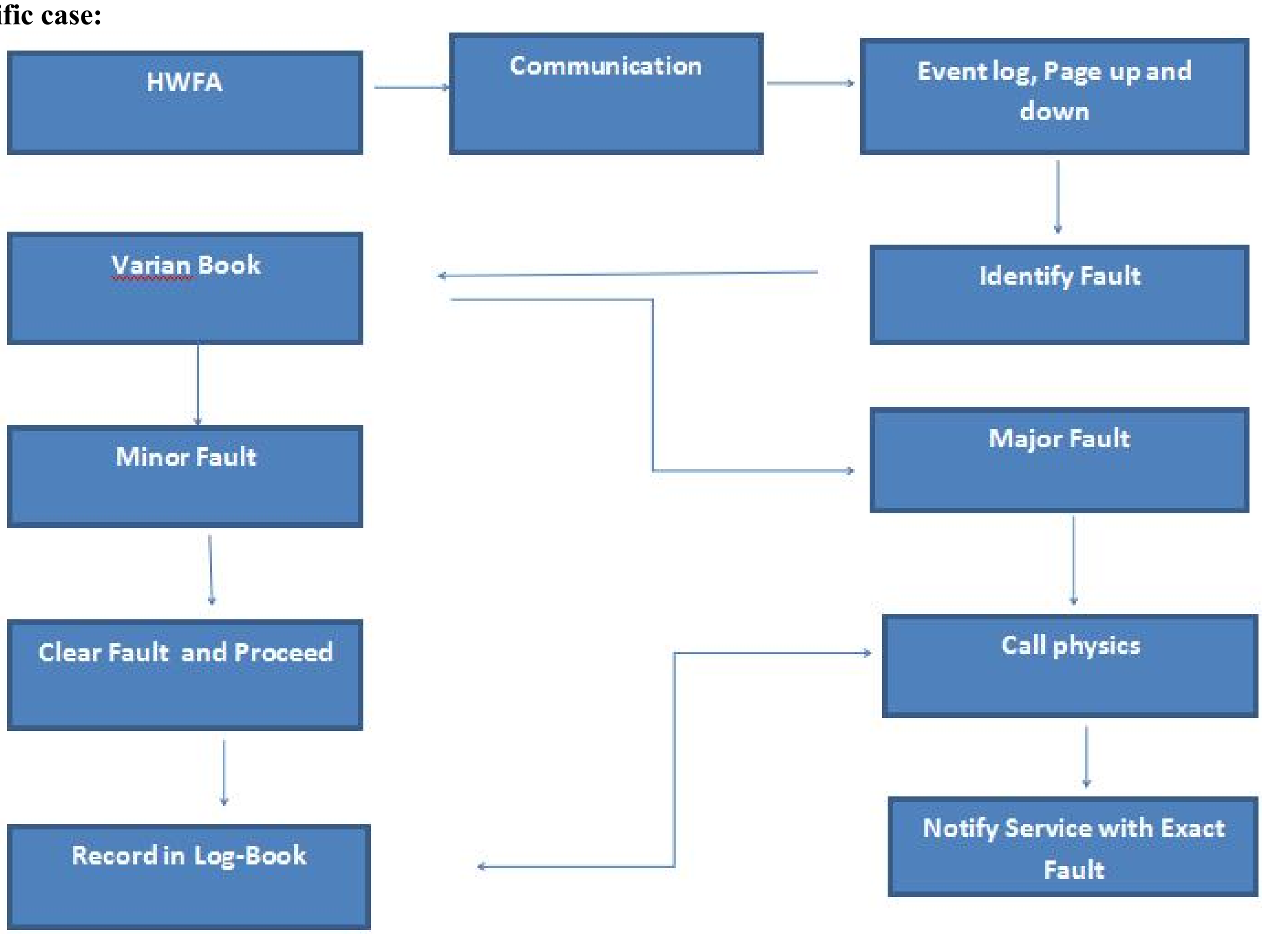


Figure 4: Fault tree for linear accelerator specific interlock hardware failure (HWFA)

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