FMEA (FAILURE MODE EFFECT ANALYSIS) OF RADIOLOGY DEPARTMENT

Dissertation

Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of

the degree of Master of Business

Administration (MBA)

in

Hospital and Health Management

by

Devanshi Gupta

Under the Supervision and Guidance of

Dr. Alok K Mathur

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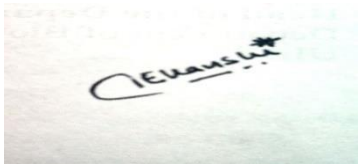
DECLARATION BY STUDENT

I hereby declare that this dissertation titled FMEA (Failure Mode Effect Analysis) of Radiology Department is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



Name of Student: Devanshi Gupta

Date: 21st June,2022

Shri Mata Vaishno Devi Narayana
Superspeciality Hospital
Managed by Narayana Health

NH/SMVDNH/Intern/2022-23/21

Date: June 25th,2022

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Devanshi Gupta** D/O **Lt. Surinder Gupta** student of Indian Institute of Health Management & Research has successfully completed her internship in the Department of Quality from **March 28 to June 25th, 2022.**

During her internship period, she has met the expectation of the organization.

We wish her all the best for her future endeavors.

Shri Mata Vaishno Devi Narayana Superspeciality Hospital HR

Sandeep Mangal
DGM (Human Resource)

*(Shri Mata Vaishno Devi Narayana Superspeciality Hospital, managed by **Narayana Health** is a 242 bedded, NABH accredited hospital. This State-of-the-Art Tertiary care Superspeciality Hospital in collaboration with 'Shri Mata Vaishno Devi Shrine Board', caters to patients across more than 20 different specialities with a special focus on Cardiology & Cardio-Vascular Surgery, Medical & Surgical Gastroenterology, Orthopaedics & Joint Replacement, Renal Sciences, Medical, Radiation & Surgical Oncology (Cancer) and Critical Care Medicine, thus providing the affordable quality care that **Narayana Health** stands for to the people of Jammu & Kashmir).*

CERTIFICATE

This is to certify that dissertation titled FMEA (Failure Mode Effect Analysis) of Radiology Department is a record of the research work undertaken by Devanshi Gupta in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide	School Dean
IIHMR University, Jaipur	IIHMR University, Jaipur
Date	Date

Abstract

Background: As one of the centers for disease detection, the hospital's radiology department was chosen for this study. This one crucial stage will determine how well the patient will recover overall. The purpose of this dissertation was to conduct a Failure Mode and Effect Analysis on the departmental weaknesses of the radiology unit and provide ideas to address such failures for increasing customer satisfaction and unit restructuring. Failures like these represent a gap in the cheese layers that causes system halt, thus they must be carefully rectified and effectively stacked.

Methodology: This qualitative research employing descriptive and non-intervention methods was conducted at the radiology department equipped with X-ray, CT, and MRI technology. Ultrasound and mammography were exclusions of the study. The group consisted of patients who required diagnostic imaging as part of their treatment regimen. 500+ sample patient files were analyzed, and the flaws were marked daily, based on the tests carried out at the hospital's radiological diagnostic unit. Basic random probability sampling was used to collect the data from the various subunits for the day shift diagnostics at the radiology department.

Results: Rankings were assigned based on event severity, incidence, and detection feasibility after the department witnessed the failures. Results were generated using MS excel. The department's top few failures out of a total of 45 defects were then represented by the RPN. The diagnostic technique revealed that the most frequent problem was inappropriate practise or procedure. These flaws were further divided into six main types of mistakes.

Conclusion: When the hospital was made aware of the radiology department's latent difficulties, effective process adjustment was made possible. On the basis of the outcomes produced by the result, suggestions are provided. Through the active participation of seniors and employees, FMEA was effectively used to identify and prioritise potential failure modes of the diagnosis unit.

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Abbreviations

- FMEA- Failure mode and effect analysis
- RFMEA- Radiological Failure mode and effect analysis.
- OPD-Out-Patient Department
- IPD-In-Patient Department.
- ER-Emergency Room
- CT-Computed Tomography
- MRI- Magnetic Resonance Imaging
- RPN- Risk Priority Number
- LMP-Last Menstrual Period
- MO-Medical Officer
- TLD-Thermoluminescent Dosimeter

Chapter 1: Introduction

This research was carried out at the hospital's radiology department since it is one of the epicenters of illness detection. The entire patient recovery plan is dependent on this one critical step. This department is open whole day, every week, with the most patients arriving in the morning and evening. With a high patient load, mistakes are certain to occur at any point throughout the patient diagnostic process. Once identified, these mistakes might offer a boost to the management process as well as consumer satisfaction.

The hospital was observing several inconsistencies in this area, and patient satisfaction was low because of the long wait time for reports. As a result, the study's goal was developed in response to the hospital's requirement to investigate departmental shortcomings to develop better management strategies to minimize client complaints.

This dissertation aimed to undertake a Failure Mode and Effect Analysis on the radiology unit's departmental weaknesses and offer solutions to overcome those failures for the unit’s invigoration and client satisfaction as a result. This research will aid the hospital in detecting any possible threats to the radiology department and may aid in reducing future liabilities. As a consequence, the hospital will be made aware of the hidden difficulties in the radiology department, allowing for effective process reform.

The objectives of the study performed were:

- To check the reasons for defects in the processes, categorizing them based on the Error type.
- To assess the potential of those defects in process, which might result in failure of performance.
- To figure out what else may go wrong in the system.

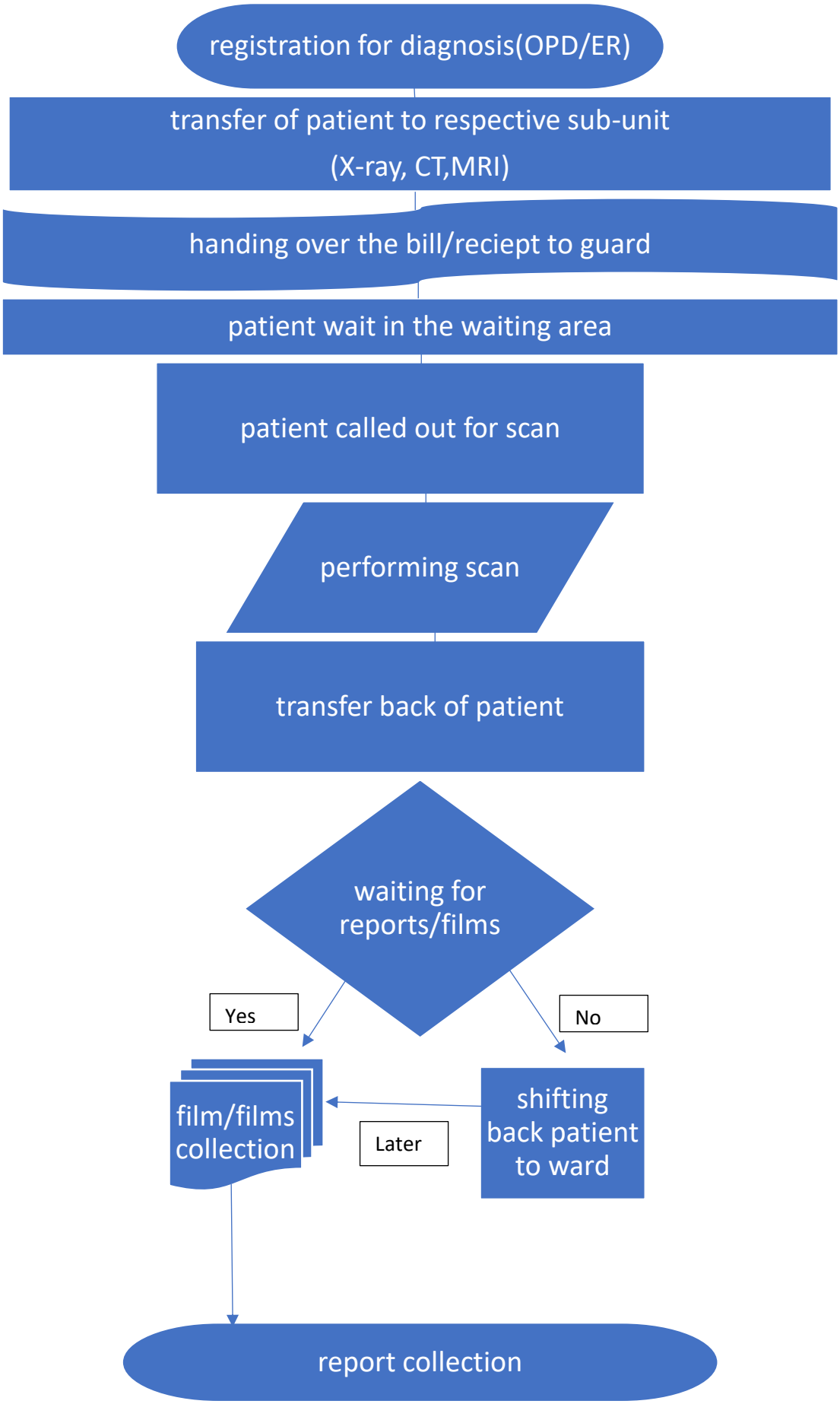

Figure 1. Showing the process flow for OPD/ER patients in Radiology department.

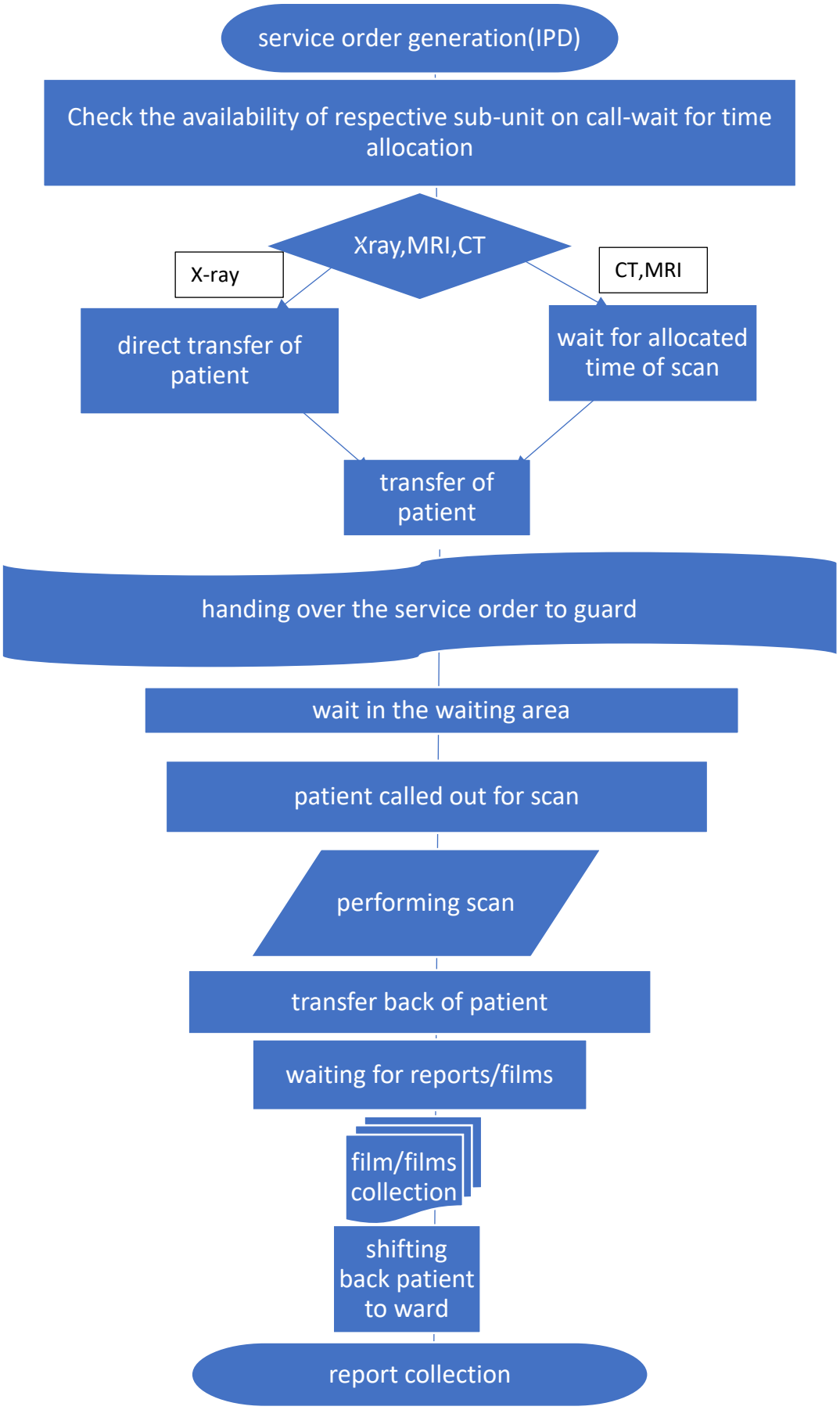

Figure 2. Showing the process flow for IPD patients in Radiology department.

For a better understanding of the department's shortcomings, the two images up top depict the patient flow for OPD/ER and IPD patients.

Scope of services	Radiology
	128 slice CT
	1.5 Tesla MRI
	Color Doppler
	X-Ray fluoroscopy
	Mammography
	Fibroscan
	Ultrasound

Table 1. Showing the scope of services offered by the radiology unit of NH, Jammu.

Chapter 2: Review of literature

FMEA (Failure Mode and Effects Analysis) is an effective delivery of services and preventive strategy based on cooperation that is used to define, identify, analyse, prevent, eliminate, or regulate conditions, reasons, and outcomes of probable failures in a system, process, project, or service. FMEA necessitates the prediction of mistakes as well as the discovery of measures to avoid occurrences. The FMEA technique may be used to increase efficiency and effectiveness, save money, and improve quality in addition to improving safety. The use of preventive rather than defensive tactics in dealing with failures, or action performed before an emergency arises, is one of the fundamental parts of FMEA.FMEA is a way to uncover both buried and evident errors and failures in a system, as well as taking the required actions to eliminate them. As a result, FMEA may be used by businesses to improve the quality of their products and services on a regular base. (10)

According to Pareek A, an imaging centre, often known as a radiology centre, is a facility equipped to produce a variety of radiologic images. The most important diagnostic tool for many ailments is radiology, which is also crucial for corrective therapy and situational analysis for the same therapies. It could be visualised in a plethora of forms, each with a prototypical set of concrete characteristics that add to the intricateness. (9)

As there are many negative effects in a radio department, to thwart these adequate ascertainment, declaration of patients, limiting pharmaceutical incapacitation, reduction or avoidance leading to radiation facade, safe patient monitoring, and stewardship of reliable departmental components, understanding the entire patient journey is crucial to determining whether a department is operating properly. Leading to relevance of Radiological FMEA approach. FMEA can be implemented as part of a larger plan, as a personal initiative, or both. Strong analytical and stenographic facilitation is responsible for the department's smooth completion of FMEA. (1)

According to a project by Abujudeh and Kaewlai on the soundness assessment of diabetic patients before interventional treatments to de-escalate the rate of patient catastrophes (2009). The following are the prerequisites for successful RFMEA process: (1)

Prerequisites of FMEA	Professionals pins down well-functioning staffs at all levels.
	All stakeholders have assigned works
	Paradigm interims established
	Brainstorming conceptualisations
	Elucidating contributory factors
	Testing the blueprint after foundation and rectification.

Larson et al. published "Key Concepts of Patient Safety in Radiology" in 2015, which emphasized on medical mistakes in hospitals that cause harm to both patients and hospitals. These mistakes are destined to happen at any time, and the system (modern method) rather than the person (old method) is to be blamed, paving the way to delve deeper into the source of the system's occurrence. These mistakes can happen at any point throughout the patient's journey: during screening, evaluation, transmission, and even beyond. (6) Error was characterised as an execution error, which elaborates as the inability of a planned operation to be executed as anticipated or the planning mistake where incorrect plan is adopted to accomplish a goal. (3) including exhaustive error classifications (6,3)

1) Chang et al's JCAHO patient safety categorization for near misses and adverse occurrences, which states five attributes: impact-medical or non-medical; type-patient management, communication; domain-staff, patient, or associated environments; cause-system or human; protection and mitigation. (3)
2) Technology, human, and organisational faults are the three main types of blunders according to Van der Schaaf's Eindhoven Classification Model. (11)
3) A taxonomy of human errors that includes skill-based, knowledge-based, and rule-based activities.

Eventually, all error-prevention measures are included. (6)

The three types of radiological delusions that can occur during the reporting process are

1. Pre-analytical delusions
2. Analytical delusions
3. Post analytical delusions

Post-analytical delusions are generally brought on by technical difficulties and procedure-related issues, whereas pre-analytical delusions are primarily brought forward by lack of vocal construction ability between imaging physicians and disease experts. (8) Wrong, missing, or delayed diagnosis, heterogeneity may have primary/ secondary, inborn and acquired detrimental capacity, or might not lead to any attrition if pragmatically trivial. (5,12)

Itri et al. discussed the predictability and causative variables of diagnostic errors through root cause analysis in their article of 2018 on "fundamentals of diagnostic errors in imaging." Errors might also result in a loss of revenue for the hospital. A safety model titled the Swiss cheese model was also used to illustrate defences (cheese layers) and active failures (holes in layers). (5)

Systemic causes of errors, such as workplace obstacles, staff overload, technical inaccuracies, contrast timing, lack of patient information, system failure, lack of team spirit, and communication, were also described, with a systemic way of solving these by ground level engagement of every staff member in policy revisions, sympathetic culture building, and process evaluations to check for loopholes, taking into consideration each individual's point. Finally, encouraging employees to confess errors and inspiring them to know and understand mistakes can help an organisation progress. (5)

Omer Onder et al. discussed in 2021 on how errors are a part of radiological diagnosis and efficient communication leads to proper patient management in their article "Errors, inconsistencies, and underlying bias in radiology with case examples: a pictorial review." Poor communication-related errors, under-reading errors, technique-related errors, history-related errors, and biases that may develop before/during the diagnosis are examples of these errors. Finally, understanding of these flaws and biases leads to better patient handling through the development of disciplinary measures. (8,2,4)

Chapter 3: Methodology

1. RESEARCH QUESTION

What actions taken by the radiological diagnosis department at Nararyana Hospital in Katra, Jammu, between the months of April and June which resulted in flaws in the overall diagnostic process and further failure of the complete patient care management?

2. RESEARCH DESIGN

In order to determine the type and scope of failures happening in the hospital's radiology department, qualitative research employing exploratory/descriptive and non-intervention methods was conducted. Primary and secondary data were used to analyze the findings.

3. STUDY SETTING

The radiology department with its X-ray, CT, and MRI equipment serves as the study's location. Mammography and ultrasound are not included. All OPD/ER and IPD patients who needed diagnostic imaging as part of their treatment plan were included in the group.

4. SAMPLE SIZE AND TECHNIQUES EMPLOYED

Based on the tests conducted at the hospital's radiological diagnostic section, 500+ sample patient files were examined, and the secondary data from the night shift was also collected the following day. For the day shift diagnostics at the radiology department, basic random probability sampling was utilized to gather the data. The department's primary tool for gathering samples was the consent and requisition forms.

To note the defects only primary data was accessed based on daily observations in the unit.

5. ETHICAL CONSIDERATIONS

1) All the prominent actions were performed after the organization's approval on the same.
2) Appropriate measures were used to ensure data security, privacy, and confidentiality of the study population.

Chapter 4: Result

For each process step listed below, the failure scenarios, their consequences, causes, and current controls are displayed together with the process step and key input. The RPN is generated after taking into account the severity, incidence, and detection.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
Registration for diagnosis	Bill generation OPD	wrong scan/sevice written	wrong service performed	8	lack of attention	6	dual identification of person through MRN and ID band	Human error	3	144
Registration for diagnosis	service order generation for IPD	right patient name for right scan but wrong service MRN	bill transcription on another person	7	lack of attention to MRN	5	dual identification of person through MRN and verbal	Transcription error	3	105
Registration for diagnosis	bill generation for OPD	registration person not available in radiology reception	patient has to relocate to other reception for bill generation	4	understaffing	7	alloted time for each shift	Incorrect practise/procedure	4	112

Figure 3. Showing the registration for diagnosis as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
transfer of pateint	transfer of (IPD/ER) patient to wheelchair	seat belts not used for transfer, lift not operational/in use for other stretcher bed patient transfer, GDA unavailable	patient could fall	5	non-operational seat belts, irresponsive staff	7	maintainence check for seat belts	Management error	3	105
transfer of pateint	transfer of (IPD/ER) patient to the desired departmen	delays due to nurse paperwork, patient sent before the	delay in the entire process-patient not transfer on time, other patients at	3	understaffing, reckless behaviour	7	pre-scheduling of IPD patients	Human error	6	126
transfer of pateint	OPD patient	patient goes for other tests	delay in the entire process	2	lack of knowledge	6	nil	Incorrect practise/proc	7	84

Figure 4. Showing the transfer of patient as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
waiting in the waiting area	wait while the name is called out	prioritisation of known patients	waiting patients outrage	2	prioritization of few patients before others	4	calling patients based on bill generation time	Incorrect practise/procedure	7	56
waiting in the waiting area	wait while the name is called out	patient/attendants standing while waiting	makes wait time seems more	3	lesser number of wait chairs at	6	only patients are allowed to sit in waiting	Management error	5	90
waiting in the waiting area	wait while the name is called out	improper communication of wait time before scan	patient outrage, patient crowd at waiting area	4	understaffing ,IPD and OPD patient load at the same time	6	OPD patients are given priority for scans in the morning, only	Communication error	8	192

Figure 5. Showing the waiting before scan as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
calling patients for scan	patient called for scan	confusion between similar name patient	wrong scan performance	4	not using MRN as identification for patients	5	MRN and UHID used for patient identification, then verbal confirmation is used	Human error	3	60

Figure 6. Showing the calling patients for scans as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
performance of scans	scan performance at respective subunit	patient not ready clinically for scan, patient overload	delay in the entire process	3	lack of knowledge of procedure,understaffing,	5	creatinine value reporting before scan, prescheduling of IPD patients	Incorrect practise/procedure	5	75
performance of scans	scan performance at respective subunit	nurse unavailable for cannula insertion	delay in the entire process	3	understaffing	6	calling different nurse for insertion	Management error	7	126
performance of scans	scan performance at respective subunit	patient sent without file, consent and requisition form	staff not known about patient history(could get communicable disease), legal action could be taken against hospital, patient could die/get critical,allergic reaction against contrast	8	understaffing, lack of knowledge of importance of consents and other paperwork	9	files, forms and requisition forms mandatory before scans	Incorrect practise/procedure	4	288
performance of scans	scan performance at respective subunit	patient sent with improper consent and requisition form	contrast details not mentioned on requisition form, LMP not mentioned	7	patient harm, delay in diagnosis	9	files should be sent along with the patient for proper history check and scan, with filled consent and requisition form	Incorrect practise/procedure	4	252
performance of scans	scan performance at respective subunit	patient not informed about dress change	delay in the entire process	3	understaffing, lack of knowledge of procedure	6	screening by the staff	Incorrect practise/procedure	4	72
performance of scans	scan performance at respective subunit	improper screening of patient for metallic obejects/electrodes	ReDos of scans,patient harm	9	No screening before scan performance	7	screening by the staff	Incorrect practise/procedure	5	315
performance of scans	scan performance at respective subunit	critical/panic values not documented by staff	No documentaion maintainence by staff, difficult to reach the informed person and have a control over the entire process	4	technical staff not allowed to create a panic value	8	critical value register maintainance(not in use), percentage of critical values	Incorrect practise/procedure	4	128
performance of scans	scan performance	technical staff not wearing	staff safety is at stake, No	9	no proper storage	9	common storage space	Incorrect practise/proc	4	324

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
performance of scans	scan performance at respective subunit	patient not mentally ready for scan	delay in scan , next patient's wait time increases	3	no psychological counselling before scan	6	regular monitoring of wait time in policy (not in use)	Incorrect practise/procedure	5	90
performance of scans	scan performance at respective subunit	unstable patient IPD with sedation requirements	waste of time getting patient ready	8	sedative required for patient but MO not present along with patient.	9	MO must be present with unstable patient sent for scan, sedation monitoring sheet	Incorrect practise/procedure	7	504
performance of scans	scan performance at respective subunit	scan missing from the software	ReDos of scans,dissatisfaction of customers	8	lack of attention, understaffing	3	percentage of redos(not in use)	Incorrect practise/procedure	8	192
performance of scans	scan performance at respective subunit	technical staff forgot to lock door while scan performance	staff received radiations	9	staff ignorant to flourescent light while scan performance, door not locked	4	flourescent light while scan performance/locked doors	Incorrect practise/procedure	9	324
performance of scans	scan performance at respective subunit	patient unstable while scan performance, empty oxygen cylinder, unavailable nurse staff	interruption in scan, patient sufferings	9	natural cause	3	crash cart available for use, oxygen cylinder for use	Incorrect practise/procedure	5	135
performance of scans	scan performance at respective subunit	nurse/respective nurse unavailable while the scans are being performed	patient could suffer	7	understaffing	6	nil	Management error	6	252
performance of scans	portable Xray	no cassette identification	misplace of scans	6	no knowledge	10	nil	Incorrect practise/proc	5	300
performance of scans	Patient details on syngovia software	wrong MRN or patient name on the software	wrong report generation	8	lack of attention or overload of patients	3	identifying patient through MRN or UHID instead of names	transcription error	5	120
performance of scans	administration of contrast	contrast medium out of stock	delay in taking patient on table	4	understaffing of nurse, improper managemnt of inventory	3	nil	Management error	5	60
performance of scans	administration of contrast	cannula out while administration	delay in scan of patient	7	improper cannula insertion	3	nil	Incorrect practise/procedure	7	147

Figure 7. Showing the performance of scan/procedure as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
transfer Back of patient	taking patient from table to stretcher bed	patient fall, discomfort while transfer/tear of patient clothes while lifting	patient injury due to fall	6	no use of lift sheets while patient transfer from table to bed	8	nil	Incorrect practise/procedure	4	192
transfer Back of patient	patient getting up from table after scan	patient fall as the position of table not fit to move	patient fall/injury, disatisfaction	5	miscommunication to get up before setting the table location	1	nil	Incorrect practise/procedure	5	25
transfer Back of patient	taking patient from table to stretcher bed	unavailable GDA/nurse staff	delay in patient transfer after scan	2	GDA busy in staff's personal work, staff unavailable	6	2 GDA staffs allloted to the department	Incorrect practise/procedure	6	72

Figure 8. Showing the transfer back of patient as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
waiting for reports/film	film generation	film generated but no record	more number of films used for	2	understaffing to keep track	8	record keeping	Management error	3	48
waiting for reports/film	film generation	films out of stock	delay in film generation	2	no extra inventory of	4	inventory maintenance	Management error	5	40
waiting for reports/film	film generation	printing machine not	delay in film generation,	2	technical issue	5	inform engineering	Electronic error	4	40
waiting for reports/film	transfer to MOKSHA software for report generation	film generation system not connected with the reporting software(MOKSHA)/technical error	delays in report generation,disatisfaction of customer	3	technical lag,	4	engineering staff informed	Electronic error	3	36

Figure 9. Showing the waiting for reports/films as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
film collection	collection of films after scan	film collection at the same area of scan	patient overcrowding at waiting area	3	culture of film dispatch at the same location of scans	10	report and film collection at dispatch counter	Management error	4	120
film collection	collection of films after scan	wrong film given to wrong patient	delay in treatment, regeneration of film, film overuse	5	guards/GDA staff handing over the film to patient	6	film dispatch at dispatch counter	Human error	4	120
film collection	collection of films after scan	file not sent along with patient film(both IP and OP)	delay in treatment	5	understaffing, guards/GDA dispatching the films	6	nil	Human error	5	150
film collection	collection of films after scan	misplaced films	reprint of films	5	delay in treatment, dissatisfaction	7	nil	Human error	7	245

Figure 10. Showing film collection as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
report collection	report generation	error in report generation	wrong diagnosis	8	patient overload, lack of attention, distractions	1	percentage of errors reporting	Human error	6	48
report collection	report generation	delivery of report to wrong person	wrong treatment plan generation	5	lack of attention,understaffing	2	nil	Human error	4	40

Figure 11. Showing report collection as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
shifting IP patient to ward	shifting patient with films and brought files	misplaced file	delay in patient shift	5	technical staff showing file to radiologist in reporting room	4	nil	Human error	4	80

Figure 12. Showing shifting IP patients to ward as a process step.

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	Error type	DET	RPN
environment management	check for temperture and moisture	diagnostic machines improper functioning	delay in scans, inoperable machines	8	maintainence staff irregularity in checking	1	regular mintainence check	Electronic error	1	8
environment management	maintainence check of devices	due preventive maintainence and calibration checks	imaging quality degradation	7	maintainence staff irregularity in checking	1	regular mintainence check	Management error	1	7
environment management	display of quaterly TLD doses in department	updated TLD dose reports not displayed in the department	staff demotivation to wear TLD	3	staff safety at stake, quality of the department left uncommunicated	8	updated reports should be displayed in the department along with the licenses	Management error	4	96

Figure 13. Showing environment management as a process step.

Top 20 RPNs are collectively represented in the below figure to depict the failures that are more critical and should be given priority based on their values and importance according to the hospital setting.

Process steps with their failure mode	Sum of SEV	Sum of OCC	Sum of DET	Sum of RPN
Registration for diagnosis	**8**	**6**	**3**	**144**
wrong scan/sevice written	8	6	3	144
transfer of pateint	**3**	**7**	**6**	**126**
delays due to nurse paperwork, patient sent before the scheduled time of scan, GDA unavailable	3	7	6	126
waiting in the waiting area	**4**	**6**	**8**	**192**
improper communication of wait time before scan	4	6	8	192
performance of scans	**102**	**89**	**80**	**3407**
nurse unavailable for cannula insertion	3	6	7	126
cannula out while administration	7	3	7	147
critical/panic values not documented by staff	4	8	4	128
improper screening of patient for metallic obejects/electrodes	9	7	5	315
no cassette identification mark used for multiple xrays	6	10	5	300
nurse/respective nurse unavailable while the scans are being performed	7	6	6	252
patient sent with improper consent and requisition form	7	9	4	252
patient sent without file, consent and requisition form	8	9	4	288
patient unstable while scan performance, empty oxygen cylinder, unavailable nurse staff	9	3	5	135
scan missing from the software	8	3	8	192
technical staff forgot to lock door while scan performance	9	4	9	324
technical staff not wearing TLD badges, misplaced TLD, TLD left at home	9	9	4	324
unstable patient IPD with sedation requirements	8	9	7	504
wrong MRN or patient name on the software	8	3	5	120
transfer Back of patient	**6**	**8**	**4**	**192**
patient fall, discomfort while transfer/tear of patient clothes while lifting	6	8	4	192
film collection	**18**	**29**	**20**	**635**
file not sent along with patient film(both IP and OP)	5	6	5	150
film collection at the same area of scan	3	10	4	120
misplaced films	5	7	7	245
wrong film given to wrong patient	5	6	4	120
Grand Total	**141**	**145**	**121**	**4696**

Figure 14. Showing Top 20 RPN with the failure mode.

The below table (table 2) shows the error type categorization of failure mode along with their RPN. The errors are classified in 6 fields including: Communication Error, Electronic Error, Human Error, Incorrect Practice/procedure, Management Error and Transcription error.

Error type	Sum of RPN
Communication error	192
Electronic error	84
Human error	1013
Incorrect practise/procedure	3687
Management error	944
Transcription error	225

Table 2. Showing the error types along with the RPN.

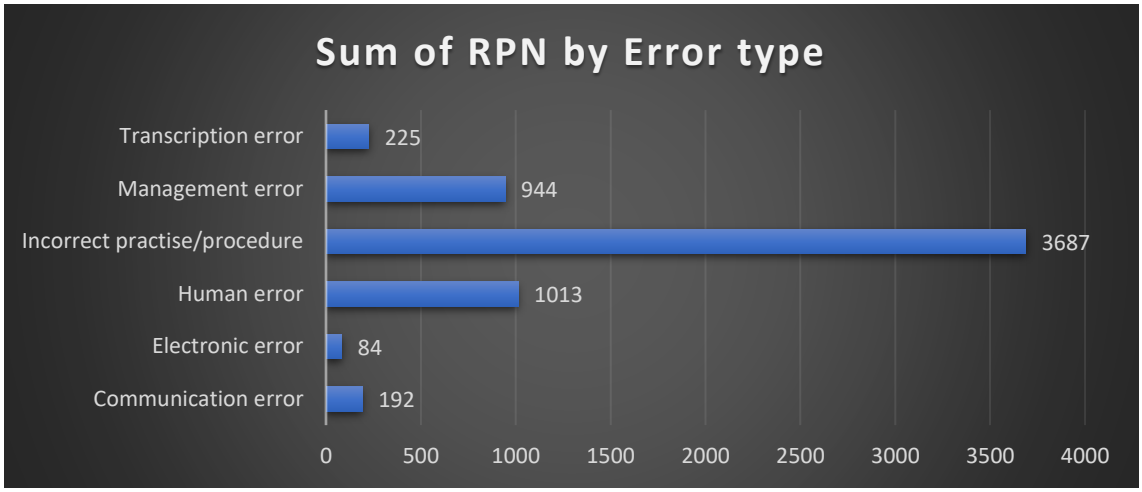

Figure 15. Showing the error type and sum of RPNs in the form of bar graph

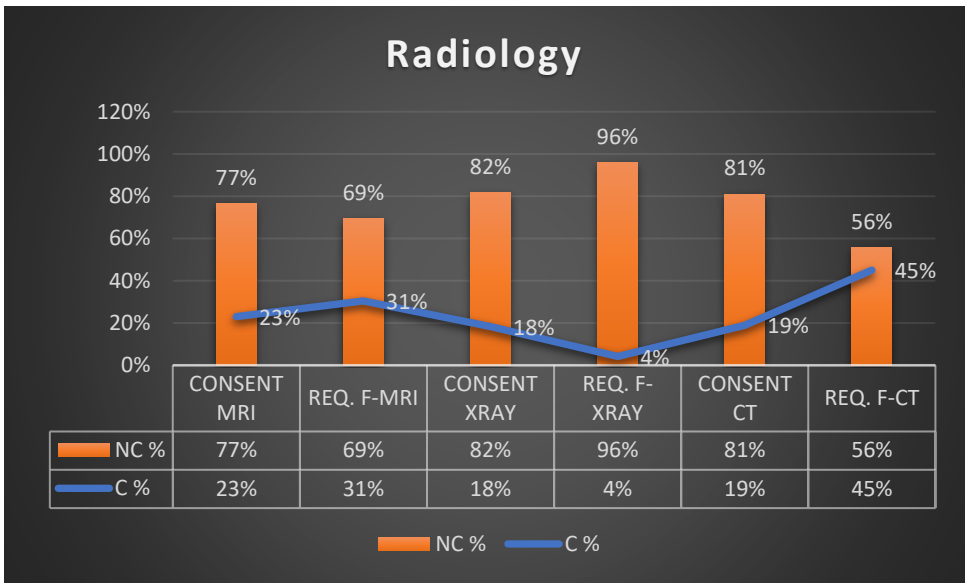

Figure 16: Showing the consent and requisition forms' compliance percentage.

The above table shows the compliance and non-compliance percentage of the unit's consent and requisition forms, segregating each in 3 different subheadings of MRI, X-Ray, CT. Clearly showing the low compliance rate of X-Ray unit of the department.

Error type	Potential Failure Mode	Sum of RPN
Communication error	improper communication of wait time before scan	192
Electronic error	printing machine not working due to technical issue	40
Electronic error	diagnostic machines improper functioning	8
Electronic error	film generation system not connected with the reporting software (MOKSHA)/technical error	36
Human error	delivery of report to wrong person	40
Human error	wrong scan/service written	144
Human error	confusion between similar name patient	60
Human error	delays due to nurse paperwork, patient sent before the scheduled time of scan, GDA unavailable	126
Human error	error in report generation	48
Human error	file not sent along with patient film (both IP and OP)	150
Human error	misplaced file	80
Human error	misplaced films	245
Human error	wrong film given to wrong patient	120
Incorrect practise/ procedure	cannula out while administration	147
Incorrect practise/ procedure	critical/panic values not documented by staff	128
Incorrect practise/ procedure	improper screening of patient for metallic obejects/electrodes	315
Incorrect practise/ procedure	no cassette identification mark used for multiple xrays	300
Incorrect practise/ procedure	patient fall as the position of table not fit to move	25
Incorrect practise/ procedure	patient fall, discomfort while transfer/tear of patient clothes while lifting	192
Incorrect practise/ procedure	patient goes for other tests	84
Incorrect practise/ procedure	patient not informed about dress change	72
Incorrect practise/ procedure	patient not mentally ready for scan	90
Incorrect practise/ procedure	patient not ready clinically for scan, patient overload	75
Incorrect practise/ procedure	patient sent with improper consent and requisition form	252
Incorrect practise/ procedure	patient sent without file, consent and requisition form	288
Incorrect practise/ procedure	patient unstable while scan performance, empty oxygen cylinder, unavailable nurse staff	135
Incorrect practise/ procedure	prioritisation of known patients	56
Incorrect practise/	registration person not available in radiology reception	112

procedure		
Incorrect practise/ procedure	scan missing from the software	192
Incorrect practise/ procedure	technical staff forgot to lock door while scan performance	324
Incorrect practise/ procedure	technical staff not wearing TLD badges, misplaced TLD, TLD left at home	324
Incorrect practise/ procedure	unavailable GDA/nurse staff	72
Incorrect practise/ procedure	unstable patient IPD with sedation requirements	504
Management error	nurse unavailable for cannula insertion	126
Management error	contrast medium out of stock	60
Management error	due preventive maintainence and calibration checks	7
Management error	film collection at the same area of scan	120
Management error	film generated but no record maintained	48
Management error	films out of stock	40
Management error	nurse/respective nurse unavailable while the scans are being performed	252
Management error	patient/attendants standing while waiting	90
Management error	seat belts not used for transfer, lift not operational/in use for other stretcher bed patient transfer, GDA unavailable	105
Management error	updated TLD dose reports not displayed in the department	96
Transcription error	right patient name for right scan but wrong service MRN	105
Transcription E.	wrong MRN or patient name on the software	120

Table 3. Showing the errors along with their failure modes.

Chapter 5: Discussions

The purpose of this investigation was to pinpoint the radiology department's shortcomings and how they affected the security of procedures. There were 45 failure modes in total, which were categorized based on the diagnostic procedure phases. The findings indicated that the majority of failure scenarios are related to the effectiveness of the scan process phase. The RPN by error analysis revealed that incorrect practice or method was the most frequent error, followed by human error, management error, etc. When we looked more closely at the most common error, we discovered that it was caused by a number of factors, including unstable patients who needed sedation, technical staff who were not wearing TLD badges, an absence of cassette identification stickers that prevented multiple cassettes from being used simultaneously, patients who were sent without treatment files, consent forms, or requisition forms, and inadequately filled out forms.
Cost-based FMEA could not be used in the research for this process FMEA. Some of the failures shown in this qualitative study may have happened more frequently throughout the study's time frame, leading to a greater occurrence rate and, ultimately, a higher RPN. Furthermore, since the values representing severity, detection, and occurrence are based on an likert scale, rank reversal may occur when S, O, and D are multiplied together, resulting in less serious issues receiving higher RPN, as noted by Lipol and Haq in 2011 (7).

Higher patient satisfaction, effectiveness of corrective measures in the department, ease of process flow, better revenue management, enhanced quality and safety of employees as well as patients would result from the research's use in a population environment.

Chapter 6: Conclusion

The sedation of unstable patients was one of the top 5 failures in the radiology unit since they were brought in without the MOs and anesthesiologists, wasting time on that patient as the technical team waited for the patient to remain stable without anesthesia. The technical staff's failure to lock the door while the scan is being executed, may expose someone other than the patient; the improper screening of patients prior to scans for metallic or other objects that could necessitate repeat scans; the complete absence of stickers to identify the cassettes when performing multiple portable X-rays; and the transfer of patients to the radiology department for scans or biopsies without a proper file, consent, or request form.

The hospital's deficiencies for adopting safe radiography operations must be addressed in accordance with the top 20 failure incidents depicted in the research. The hospital can address the top 5 RPNs initially in order to work effectively on these inconveniencies, and the next 5 RPNs will be addressed after that for the department's sustained progress. Technical, nursing, and GDA employees must complete safety education and training to be able to manage the entire process. A few problems, such as lack of workers in the department, might be resolved by assigning other unit's staff to the radiology unit during staff absence to increase customer satisfaction and efficiency. Once the patient arrives for the scan, a few procedures need to be double-checked, including the cannula's appropriate insertion and the presence of any metallic items or other things that can interfere with the scan.

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Annexure

Effect	Criteria: Severity of Effect Defined	Ranking
Hazardous: Without Warning	May endanger operator. Failure mode affects safe system operation and / or involves noncompliance with government regulation. Failure will occur **WITHOUT** warning.	10
Hazardous: With Warning	May endanger operator. Failure mode affects safe System operation and / or involves noncompliance with government regulation. Failure will occur **WITH** warning.	9
Very High	Major disruption to process. 100% of product may have to be scrapped. System / item inoperable, loss of primary function. Customer very dissatisfied.	8
High	Minor disruption to process. Product may have to be sorted and a portion (less than 100%) scrapped. System operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to process. A portion (less than 100%) may have to be scrapped (no sorting). System / item operable, but some comfort / convenience item(s) inoperable. Customers experience discomfort.	6
Low	Minor disruption to process. 100% of product may have to be reworked. System / item operable, but some comfort / convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Minor disruption to process. The product may have to be sorted and a portion (less than 100%) reworked.	4
Minor	Minor disruption to process. A portion (less than 100%) of the product may have to be reworked on-line externally.	3
Very Minor	Minor disruption to process. A portion (less than 100%) of the product may have to be reworked on-line but internally.	2
None	No effect.	1

Table 4. Showing the severity scale used for analysis.

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High:	≥ 1 in 2	< 0.33	10
Failure is almost inevitable	1 in 3	≥ 0.33	9
High: Generally associated with processes similar to previous	1 in 8	≥ 0.51	8
processes that have often failed	1 in 20	≥ 0.67	7
Moderate: Generally associated with processes similar to	1 in 80	≥ 0.83	6
previous processes which have	1 in 400	≥ 1.00	5
experienced occasional failures, but not in major proportions	1 in 2,000	≥ 1.17	4
Low: Isolated failures associated with similar processes	1 in 15,000	≥ 1.33	3
Very Low: Only isolated failures associated with almost identical processes	1 in 150,000	≥ 1.5	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes	≤ 1 in 1,500,000	≥ 1.67	1

Table 5. Showing the occurrence scale used for analysis.

Detection	Criteria: Liklihood the existence of a defect will be detected by test content before product advances to next or subsequent process	Ranking
Almost Impossible	Test content detects < 80 % of failures	10
Very Remote	Test content must detect 80 % of failures	9
Remote	Test content must detect 82.5 % of failures	8
Very Low	Test content must detect 85 % of failures	7
Low	Test content must detect 87.5 % of failures	6
Moderate	Test content must detect 90 % of failures	5
Moderately High	Test content must detect 92.5 % of failures	4
High	Test content must detect 95 % of failures	3
Very High	Test content must detect 97.5 % of failures	2
Almost Certain	Test content must detect 99.5 % of failures	1

Table 6. Showing the detection scale used for analysis.