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THE FMECA ANALYSIS AND THE MECHANICAL FAILURES IN RADIOLOGY

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1. Introduction

This study consisted in a risk analysis of the possible failures involving all the technical elements of the medical devices used in the Radiology unit in hospital. It has been used the FMEA technique [1,2,3] in order to analyze failures.

2. Materials

An interdisciplinary working group, coordinated by the Technology Assessment of Trieste, was formed to analyze failures of two ultrasound and two X-ray devices that occurred in 7 years. A software with a medical device inventory and their relevant failures was installed at the hospital in Livorno [4].

3. Methods

The data collected were elaborated using the FMEA methodology [2]. The FMEA uses RPN index (Risk Priority Number) which is calculated with three rating stairs and assigns a risk score to each type of failure. The highest value is a relevant risk to the patient and/or operator in the use of Medical Devices.

$$RPN = S * O * D$$

S *Severity*: is an assessment of the significance of the failure mode's effect on item operation, causing possible damage to patients. It is assigned by the working group.
O *Occurrence*: denotes the frequency or probability of occurrence of each failure mode is determined in data base of medical devices
D *Detectability:* means detection, i.e. an estimate of the chance to identify and eliminate the failure before the system or customer is affected.

RPN may then be used for prioritization in addressing the mitigation of failure modes.

4.Results

The group chose 4 devices (2 ultrasound and 2 fixed X-ray devices) and collected the following data which refer to a period of time of 7 years: 155,391 X-ray (Fig.1) and 62,405 ultrasound devices (Fig.2).

Fig. 1. Fixed X-ray device.

Fig. 2. Ultrasound device.

182 electrical, electronic, mechanical, software and staff training failures were detected. The mechanical failures are described in Table 1.

Types	Mechanical failures
I.	fragility of materials
II.	worn-out belt
III.	a low engine power
IV.	blocked keyboard and trackball
V.	deposit box/cassette poorly flowing
VI.	poor/non-existent lubrication
VII.	insufficient cleaning of sensors and filters
VIII.	radiation button short circuit

Tab. 1. Description of mechanical failures.

Then an improvement plan has been drawn up for all failures and then a 2nd RPN Index has been calculated [5]. Comparing 1st and 2nd RPN, the working group estimated a reduction of the risk of failures in a range between 20% and 85.7% (1).

$$\Delta RPN\ \% = \frac{1° RPN - 2° RPN}{1° RPN} * 100 \qquad (1)$$

5.Remarks and Conclusion

- In order to perform these studies is important to have a well-populated computerized Data Base and well-designed for the collection of all the important data of medical devices.
- With regard to mechanical failures, the group formulated performance improving solutions which are described in table n.2.
- The corrective actions identified are being implemented with a resulting improvement in devices performances for the patients and the health professionals safety.
- This FMEA risk analysis has been shared with the A.S.U.I.'s radiology department in Trieste for training purpose.

Types	Possible failure improvements
I.	substitution wit high-fatigue strength materials
II.	movement chain (crown-pinion system)
III.	design change, use of optical sensors in place of the mechanical limit switch
IV.	Touchscreen
V.	barcode identifier format cassette/optical limit switches/digital radiography (DR) systems
VI.	self-lubricating on principal movements
VII.	localized aeration system
VIII.	remote manual action: assess transmission problems, battery life and interference

Tab. 2. Description of solution for mechanical failures.

It is known that developments in technology are key to the improvement of medical diagnosis and safety at work.

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