RISK ANALYSIS IN STERILIZATION CENTRES

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Risk analysis is based on two main concepts: hazard and risk.
Hazard is a potential situation that can produce negative effects on people and environment
Risk is the probability that a specific hazard causes negative effects on people and environment .
So we can say that risk is possibility of damage.
Risk analysis must be developed with a methodology following these characteristics:

- it must identify all the possible hazard and estimate the risks
- risks must be managed depending on their priority
- supplied documentation must be available and simply updatable

Risk estimation depends on the probability that damage happens and its impact.

Our methodology is driven by the following assumption: the hazard related to everyone depends on which kind of task he is accomplishing and where he is working . So we can build an analysis based on the hazards related our work environment and our activities (the products we use , machines , mode of operating….)
To meet our goals we must reduce the risk probability for both employees and patients.
In order to comply with UNI CEI EN ISO 14971:2007 "application of risk management to medical device" we decided to adopt FMEA (failure modes *and effects analysis)* methodology used for analyzing the different types of failure modes related to a process, a product or system.
For FMEA the steps to follow are:

- divide process, product or system into elementary subsystems.
- for each subsystem
  - catalogue all the possible failure modes and describe the risks related to each activity
  - for each failure:
    - catalogue all the possibile causes
    - catalogue all the possible effects
    - catalogue all the existing procedures preventing each specific risk

With this methodology we detected the different harms that can occur both to patients and operators.
The risk estimation was developed considering the combination of the following components:

- PROBABILITY that damage happens (P)
- LEVEL of effect (G)
- DETECTION of damage (R)

IG * IP * IR = IPR
IPR * IE * IUE = IRR

IG = Index of level
IE = Index of remedy effectiveness
IP = Index of probability
IUE = Index of additional effectiveness
IR = Index of detection
IRR = Index of remaining risk
IPR = Index of risk priority

We must determine if the risk can be considered acceptable or not. To do this we identified three areas:

1. not acceptable area
2. acceptable area
3. ALARP (As Low As Reasonably Practicable) area

In the first area then risk is not tolerated; in the second area the risk is considered acceptable and we don't need to reduce it; in the ALARP area risk reduction is a must and we can tolerate the risk only if all the detected solutions cannot be implemented or the implementation costs are higher than the benefits produced.