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# Risk analysis in sterilization services: A first step towards a generic model of risk

NEGRICHI Khalil, DI MASCOLO Maria, FLAUS Jean-Marie

Grenoble-INP / UJF-Grenoble 1 / CNRS, G-SCOP UMR5272 Grenoble, F-38031, France

{Khalil.Negrichi, Maria.Di-Mascolo, Jean-Marie.Flaus}@g-scop.grenoble-inp.fr,

**Abstract:** Sterilization services are vulnerable to risks, due to the contagious nature of their environment and to the degradation that risks can cause to the safety of patients and staff. In relation to this issue, our work aims to reduce the risk level of these services, in order to improve their toughness and their behavior in degraded mode. We develop here a risk model for sterilization services, using a model driven approach. Then we show the relevance of such an approach by comparing it to the conventional approach.

This model represents a first step towards a generic model of risk in different sterilization services.

**Keywords:** Sterilization services, risk analysis, model driven risk analysis, preliminary hazard analysis.

## Introduction

Health services are environments that are very sensible to risks; they have a highly contagious nature as pathogens can easily be transmitted through different channels. Additionally patients are particularly vulnerable because of their low immune system.

These services must be equipped with units that can fight against these weaknesses, among them, sterilization services. Sterilization services are the heart of the fight against the transmission of pathogens via blood and other biological fluids through surgical instruments. By definition, sterilization is the technique designed to remove any microbial germ existing on a medical device. Because of the vast majority of pathogens that can be transmitted (bacteria, fungi, viruses, spores, and other microorganisms), and the variety of microorganisms that exists, this process requires different steps to kill them (pre-disinfection, rinsing, cleaning, drying, packaging and sterilization) [Standard AFNOR, 2005]

Because instruments are designed to be reused, they can transmit pathogens if any of the sterilization steps experiences a failure. In addition to their role in prevention, sterilization units must incorporate hospital policies based on economic criteria to optimize the time and expense. These policies make the sterilization services difficult to manage, generate more risks, could compromise the safety and quality of service, and may lead to serious consequences. All these constraints increase the level of risk, hence we need to perform a risk analysis for this kind of facilities to guarantee a stable and secure functionality.

There are only few studies on risk analysis conducted at sterilization services [Bernard and Lacroix, 2001], [Bertrand and Schlatter, 2009], [Talon, 2011]. These works were based on the use of classical method. The purpose of our work is to perform a risk analysis in sterilization facilities, based on model driven risk analysis method, in order to identify and evaluate the existing risks in sterilization services.

This paper is divided into three parts. We start, in section 1, with a short presentation of risk analysis. The second section focuses on the steps followed to perform risk analysis in sterilization services. Finally, in section 3, we highlight the benefit of the obtained risk model.

## 1. Presentation of risk analysis

By definition, risk analysis is the process of defining and analyzing the risks that may appear in a system. It aims to improve system security by reducing the risks criticality. It can be either qualitative, when different corrective actions are taken, the extent of vulnerabilities are specified, or the security measures are fixed, or quantitative, when probability of an event occurring and its severity are taken into account, which makes it possible to rank events in order to rank risk and to make decisions based upon this ranking [Villemeur, 1992]

Several methods exist to perform risk analysis. They can be divided into two types of methods:

- Classical method such as PHA (Preliminary hazard analysis), FMECA (Failure Mode, Effects and Criticality Analysis) and HAZOP (HAZard and OPerability) [Villemeur, 1992]
- Model driven method such as FIS (Function, Interaction, Structure) and CORAS

As explained in [Tixier et al., 2002] the main limitation of the classical methods can be summarized in the following points:

- The update takes a lot of time.
- The more general the method is, the less it takes into account the specification of the studied case. On the contrary, the more specific the method is, the less it can be transposed to other cases.
- The complexity of the method requires a specified training to implement it.
- There is a great disconnection between the risk analysis methodology and human factors.

An interesting approach to improve risk analysis efficiency is to use a model based method such as CORAS [Ketil et al, 2002] and FIS [Flaus, 2008]. We propose here to perform a risk analysis in sterilization services using a model-driven method, and to highlight the advantages of model-driven methods, compared to classical methods. In our work, we lay on the FIS method, because it is simpler to use than CORAS. Furthermore, the FIS method is more suited to production systems, and thus to the case of sterilization services that we aim to analyze here.

The FIS method (Function, Interaction, Structure) was published for the first time in 2008. Then it was applied on various kinds of systems [Flaus et al., 2010]. This method allows organizing and structuring the risk information in a model which makes them easier to use later.

The FIS model is based on the decomposition of the installation to analyze as a set of systems. For each system, we identify its functions and resources. According to the FIS model, a system is represented as a box (see Figure 1) that contains resources, functions and interactions between them.

A function is defined as the role of a group of resources, expressed in terms of purpose. Resources can be items, used to conduct the activities of the process; they can be hardware (machines and materials), human (staff) and organizational (operating modes, procedure...). Interactions are presented as the relationships between functions and resources. From a dysfunctional point of view, we can add later the dangerous phenomena and failures to the model. Each dangerous phenomenon and failure is associated with a resource or a function, which are already defined. The model also gives the possibility to indicate that a failure can trigger another one, allowing us to represent the propagation of failures in the system (see Figure 2).

At this point, it is essential to highlight the fact that the organization of information regarding the risks in a model facilitates their use later. For example, from a FIS model, we can automatically generate the results of classical methods such as PHA table (see table 2), FMECA table (see table 3), HAZOP table, fault trees...

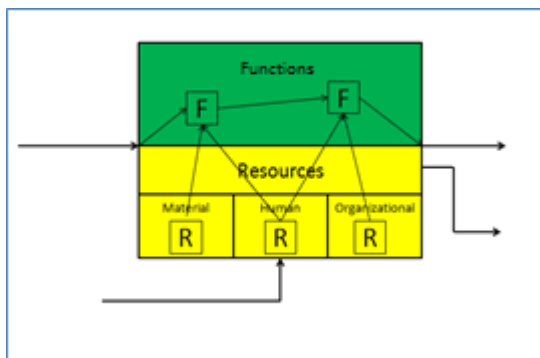


Figure 1: Basic model of a system according to FIS

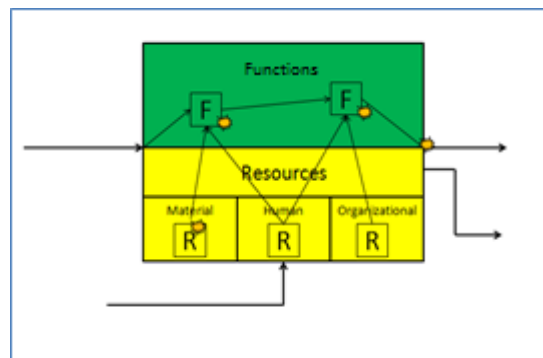


Figure 2: Propagation of failures in an elementary FIS model

## 2. Risk analysis of the sterilization facilities with a model driven approach

### 2.1. Structuro-functional modeling of a sterilization service

As mentioned above, the first step in the FIS approach is to build a structuro-functional model to describe the system. To perform the structuro-functional modeling of the sterilization services, we conducted visits to the sterilization service of the university hospital of Grenoble. We also analyzed documents of the French and international standard about the sterilization process, but also medical documents about sterilization good practices, and the conclusions of survey conducted in the Rhône-Alpes region on the practices used in the sterilization services within the region [Reymondon et al., 2008]. At the end of these visits and literature review, we were able to define the following functions:

- Pre disinfect and transfer medical devices
- Rinse medical devices
- Wash medical devices
- Dry medical devices
- Pack the medical devices

- Sterilize medical devices groups
- Transfer medical devices groups to the surgical block
- Store the groups of medical devices

To be more accurate, we decided to define sub-functions for each function. Later, we added, to each function and sub-function, the resources that are connected to them. The following table (see table 2) shows the result of our structuro-functional modeling. For each sub-function (example S.01.F01: Prepare Pre-disinfection baths) we can identify the required resources (input resources) and the impacted one's (output resources). The obtained model was then integrated in X-Risk<sup>1</sup> software.

S01.Pre disinfect and transfer the medical devices		
Name	Required Resources	Impacted Resources
S01.F01:Prepare pre-disinfection baths	S01.R01:Pre disinfection Chemicals S01.R03:baths S01.R10:Information on medical devices to pre disinfect S01.R11:Information on the composition of the pre disinfection solution S01.R16: Sterilization staff S01.R17:Surgical block staff	S01.R06:Pre-disinfection baths prepared
S01.F02:Put medical devices in the baths	S01.R02:'Dirty' medical devices S01.R06:Pre-disinfection baths prepared S01.R12:Soaking duration> 15 min S01.R13:Information on the capacity of trolleys S01.R16: Sterilization staff S01.R17:Surgical block staff S01.R20:Tracking sheet	S01.R07:Medical devices soaked in baths
S01.F03:Place the baths in the trolleys	S01.R04:Trolleys S01.R08:Baths placed in the trolleys S01.R13:Information on the capacity of trolleys S01.R16: Sterilization staff S01.R17:Surgical block staff	S01.R08:Baths placed in the trolleys

**Table 1: Extract of structural-functional view of the sterilization service (from X-Risk software).**

## 2.2. Dysfunctional modeling of the sterilization service

After completing the structuro-functional modeling of a sterilization service, we proceeded to the definition of dangerous phenomena, and then to the identification of failures.

### 2.2.1. Identification of dangerous phenomenon

A dangerous phenomenon is characterized by the fact that it generates damage to a target (function or resource). It may appear during normal operation of the service, while manipulating dangerous elements (displacement of dangerous chemicals, presence of high temperature), or appear unexpectedly (explosion, fire ...).

Based on this definition and on the visits that we made to sterilization services, we have identified the various dangerous phenomena that exist. For each dangerous phenomenon, we have identified the degraded function, the source of danger, the causes, the targets and the effects.

<sup>1</sup> Software based on the FIS approach

The identified dangerous phenomena's information (degraded function, source of danger, causes, targets and the effects) were then included in the model. The following table shows an extract of the PHA table that is automatically generated using the information related to dangerous phenomena's integrated in our model.

Preliminary Hazard Analysis					
System	Source(s)	Phenomenon generating damages	Target(s)	Causes	Effects
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.R05</a> : Elevator	<a href="#">S01.DP01</a> : Work accident (transport), degradation of the physical state of staff	<a href="#">S01.R17</a> : Surgical block staff <a href="#">S01.R16</a> : Sterilization staff	<a href="#">S01.R05.FM01</a> : Failure of the elevator; <a href="#">S01.R03.FM01</a> : Pre-disinfection baths non functional	<a href="#">S01.R17.FM02</a> : Injuries; <a href="#">S01.R16.FM02</a> : Injuries; <a href="#">S10.F01.FM01</a> : Decrease in production capacity, with no impact on customer services
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.R16</a> : Sterilization staff <a href="#">S01.R17</a> : Surgical block staff	<a href="#">S01.DP02</a> : Cross-contamination of medical devices washed together with medical devices contaminated or contamination of washing equipment	-	<a href="#">S01.R16.FM04</a> : Lack of vigilance or control of information concerning the identification of kreusfel Jacob disease	<a href="#">S03.R01.FM04</a> : Contamination of washers; <a href="#">S09.DP04</a> : Contamination of the patient
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.R02</a> : 'Dirty' medical devices	<a href="#">S01.DP03</a> : Injuries sterilization staff while receiving or washing medical devices	<a href="#">S01.R16</a> : Sterilization staff <a href="#">S01.R17</a> : Surgical block staff	<a href="#">S01.R16.FM03</a> : Improper handling of medical devices	<a href="#">S01.R16.FM02</a> : Injuries; <a href="#">S01.R17.FM02</a> : Injuries
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.R01</a> : Pre disinfection Chemicals	<a href="#">S01.DP04</a> : Work accident: eye and lung irritation skin causing work stoppages, degradation of the physical state of staff	-	-	<a href="#">S10.F01.FM01</a> : Decrease in production capacity, with no impact on customer services

Table 2: Extract of dangerous phenomena table (from X-Risk software).

### 2.2.2. Identification of failures:

A failure is defined as an abnormal state of a resource or a function. This alteration results in an effect which is identified as a failure mode

The identification of all failures in the sterilization service requires a long period of time. This time is necessary to interview the staffs, read technical documents, review working procedure. In order to reduce this time, we used the failures defined in a previously performed risk analysis. To our knowledge the work of [Talon, 2011] is the most exhaustive risk analysis in a sterilization service. Talon's work consists in a risk analysis conducted in the sterilization service of the Bichat Hospital in Paris, using the conventional method PHA. This work presents also the advantage of being exhaustive, since it was conducted by a sterilization specialist. We decided to rely on the failures defined in Talon's work.

For integrating the failures in our model, we needed to define, for each identified failure, its cause, the degraded function and the possible path of propagation of this failure in the system. This information was added to the model. Table 3 represents an extract of the FMECA table automatically generated using our FIS model.

Failure Mode Effect Analysis				
System	Function	Failure/Fault mode	Causes	Effects
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.F02</a> : Put medical devices in the baths	<a href="#">S01.F02.FM01</a> : Deterioration of DM during the pre-disinfection	<a href="#">S01.R01.FM01</a> : Unsuitable chemical pre-disinfection	<a href="#">S01.DP05</a> : Non functional medical devices delivered to customers services ; <a href="#">S01.R02.FM01</a> : Corrosion
<a href="#">S01</a> : Pre disinfect and transfer the medical devices	<a href="#">S01.F04</a> : Transfer the trolleys to the sterilization service	<a href="#">S01.F04.FM01</a> : Over due in delivery of medical device to the surgical block	<a href="#">S01.R16.FM32</a> : Lack of communication; <a href="#">S01.R16.FM33</a> : Lack of training; <a href="#">S01.R17.FM21</a> : Lack of communication; <a href="#">S01.R17.FM22</a> : Lack of training	<a href="#">S01.DP06</a> : Overdue during delivery of medical devices to the sterilization service
<a href="#">S03</a> : Wash the medical devices	<a href="#">S03.F03</a> : Wash the medical devices	<a href="#">S03.F03.FM01</a> : Washing of medical devices using a nonsuitable process	-	<a href="#">S03.DP01</a> : Deterioration of medical devices during treatment
<a href="#">S03</a> : Wash the medical devices	<a href="#">S03.F03</a> : Wash the medical devices	<a href="#">S03.F03.FM02</a> : Deterioration of medical devices during washing	<a href="#">S03.R02.FM01</a> : Nonsuitable cleaning chemical	<a href="#">S03.DP05</a> : Delivery of non-functional medical devices

Table 3: Extract of failures mode table (from X-Risk software).

### 3. Advantage and possible use of the developed FIS model

The main idea behind the model driven method is the formalization of the risk analysis data into a model. This representation in a model form, allows organizing the data in a data base form. This gives more flexibility to add, to use, and to update data, unlike the presentation in a table form offered by classical methods, which becomes difficult to handle as the number of identified failures grows.

The model also ensures the reconstruction of existing cause-effect relationships between events. For example, figure 4 shows that the “staff injuries” can be caused by “transportation accident”, which is initiated by “non respect of the transportation recommendations”. It can also be caused by “parts projection” which is triggered by “autoclave explosion” that can be caused by “temperature or pressure regulation failure”.

This model can accurately describe the reality of occurrence of accidents, where the accident appears as the result of a succession of events. This architecture is very important to implement, in order to view all potential propagation of failures and to highlight the interactions that allowed this propagation.

From a quantitative point of view, the defined cause-effect architecture can be used to calculate the probabilities of occurrence of any event. In fact, the probability of occurrence of an accident is the result of a succession of events, so this probability can be automatically calculated from the probability of its initiating events. For example the probability of occurrence of “staff injuries” accident (see figure 4) depends on the probability of occurrence of its initiating events, which are “transportation accident” and “parts projection”. These, in turn, depend on the probability of occurrence of their initiating events which are “non respect of transportation recommendations”, “Temperature regulation failure” and “Pressure regulation failure”. Therefore by incorporating the probability of occurrence of all initial events, we can automatically calculate the probability of all the resulting events. Note that classical methods only offer probability estimation, which are not very accurate. This leads to a more accurate evaluation of accidents probabilities based on cause-effect relationship.

Furthermore, and as seen in [Talon, 2011], risk analysis can be an extremely long process. The formalization of this analysis as done in this work is the first step toward the capitalization of the data. This makes it easy to be reused and updated for future risk analysis. For example, for the resource “autoclaves” used to sterilize the DM, we defined all possible failures in our model. If in another analysis we find the same resource, we can immediately import this resource, with its failure modes from the existing model, rather than defining it another time.

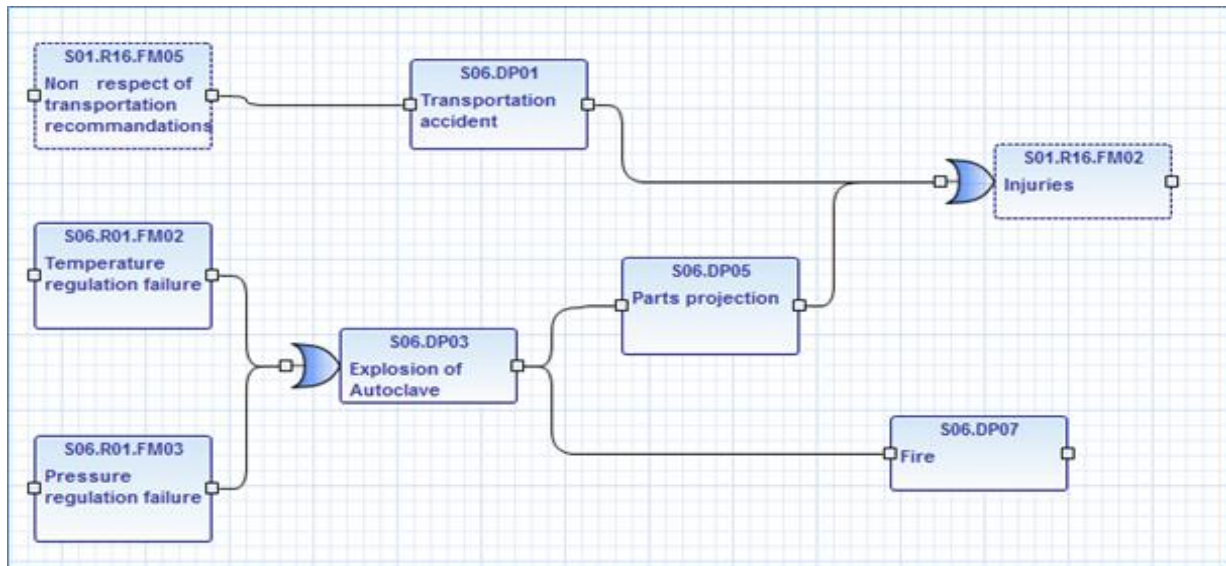


Figure 4: Extract from the cause-effect chain that leads to staff injuries (from X-Risk software)

## Conclusion

In this work, we conducted a risk analysis in sterilization services, based on a model driven approach. We started the analysis with the development of a structuro-functional model of a sterilization service. Thereafter, we performed a dysfunctional modeling, by integrating dangerous phenomena and failures that may occur in this service, and by adding, for each dangerous phenomena and failure, its related information (degraded function, source of danger, causes, targets and the effects)

Our analysis has shown that model-driven approaches can overcome some of the limitations of conventional methods. They present an important flexibility to manipulate data (add, delete and update) and a good capability to accurately describe the reality of occurrence of accidents (cause-effect relationships, probability computation), which are basic elements for the relevance of risk analysis results.

The risk model can also be used for performance evaluation in a degraded mode. The idea is to use a discrete simulation model in degraded mode using the risk model as a data base to retrieve risk information. Indeed, several works were conducted for improving the performance of sterilization services [Di Mascolo et al. 2006], [Di Mascolo et al. 2009], [Ngo Cong, 2009]. But these studies do not take into account the failures that can occur in the sterilization system. Note that other recent approaches use multi-agent simulation with the FMECA classical method to simulate degraded mode [Ben Kahla 2011]. It would be interesting to combine our risk developed model with a simulation model, in order to be able to simulate the behavior of the sterilization service in a degraded mode.



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