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# A new integrated approach for risk analysis and performance evaluation of a hospital sterilization service

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**Abstract:** In this work, we are interested in developing an integrated approach that combines simulation and risk analysis in the sterilization service, in order to take into account the effects of risks in the evaluation of the system performance. Our approach consists in creating an operating model of the sterilization service in order to describe the characteristics of the system. This system is subject to a multitude of risks, which can disrupt its operation. To take these risks into account, an analysis was carried out. The risks analyzed are integrated into the operating model in order to obtain a risk model. This model is simulated using a SIM.JS library using a JavaScript programming language. This simulation made it possible to evaluate the system performance in its different behavior modes (normal mode, degraded, reconfigured).

**Key-words:** Performance evaluation, Risk analysis, Sterilization service, Modeling, Simulation

**Mots clés :** Mesure de la performance, Gestion des risques, Service de stérilisation, Modélisation, Simulation

## 1 Context

**The sterilization service** is responsible for the production of sterilized medical devices that are used for surgical operations. Sterilization is the operation of eliminating microorganisms carried by dirty medical devices (AFNOR, 2005). A Medical Device (or MD) is an instrument, equipment, or any other tool used for medical purposes on patients in diagnosis, therapy or surgery. The sterility of a medical device is achieved by carrying out a set of operations necessary to obtain and maintain the sterile state of this device. MD will be sterilized many times during their operating period. The production process of sterile MD is a cyclical process called "sterilization loop". This loop comprises several steps: utilization, pre-disinfection, rinsing, washing, packing, sterilization, and storage. The utilization step corresponds, for an MD, to its passage through the operating room, and to the opening of the packing that contained it. After utilization, these devices are immersed in a product, to facilitate the washing and to avoid drying of the dirt on the material. Pre-disinfected MD are stored in containers and then transported to the sterilization service. The rinsing step is necessary to remove the residues of the pre-disinfectant product on the MD and to avoid the risk of interference with the washing product. This step can be performed in the operating room just after the pre-disinfection or in the sterilization service. The rinsed MD are loaded into washers to remove dirt and obtain clean MD. After the washing, the devices are dried in dryers to prevent the presence of drops of water on the medical devices. In order to maintain the cleanliness of the MD until their use, packing should be carried out as soon as possible after washing. Devices are packed in containers or bags. The sterilization of the MD is done by saturated steam. A daily and / or weekly check of the autoclave parameters like Bowie Dick test validates the good steam penetration. The last step is to store the sterilized MD in a storage area, which must be protected from direct sunlight, moisture and any kind of contamination.

**Impact of risk on the sterilization service.** Sterilization is an indispensable process in the medical field, which is subject to a multitude of risks. Some risks can be very serious, since they affect the lives of staff and patients operated, and can have dramatic consequences. These risks include "transmission of infectious diseases" such as Creutzfeldt-Jakob Disease (CJD), human immunodeficiency viruses (HIV), hepatitis C (HCV) and hepatitis B (HBV). This transmission is due to contamination of MD during surgical procedures and poor sterilization of these

devices. In his work (Cheng, 2013) deals with risk analysis in a sterilization service in a clinic specialized in dental procedures, and he shows a real case of MD contamination. During sterilization, a batch of MD were not properly sterilized and due to inattention at the control department this improper sterilization was not detected and the MD were stored and used in surgical operations. After 4 days, a surgical assistant detected that he had a bag present in the operating room without a sterilization indicator (it is a colored label stuck on the bags and containers to show that they are well sterilized). The latter informed the manager who launched an investigation to find other poorly sterilized bags in stock, and another unsterilized bag was found. An inventory has been set up to determine all surgical operations performed during these days. This inventory shows there were 248 patients who received care during this period and were exposed to contaminations. These patients underwent tests lasting up to 6 months to find out if they were contaminated and some contracted infectious diseases. This example illustrates the consequences that risks can have in sterilization services. Some research works aim at limiting these effects. We can cite, among other, (Talon, 2011) and (Bernard and Lacroix, 2001), who used risk analysis data in order to improve the security and the availability of the service. We can mention also the work of Garrigue (2008) who treats the risk of corrosion of medical devices in the packaging stage at Nantes University Hospital. This analysis shows that this corrosion is due to the waiting time of these devices and to the wet state after rinsing.

Despite the importance of risk management in sterilization services, risk analysis is not deeply explored and studied in the literature. Only the works of (Talon, 2011), (Negrichi et al, 2012), and (Negrichi, 2015) conducted a detailed risk analysis in the sterilization services. The first one was a study using a conventional method, Preliminary Risk Analysis (PRA). It is a method for risk analysis related to products and process operations in order to identify hazardous elements (causes of accidents), assessing their consequences and providing remedies for appropriate measures. While the second used a model-based method, which is Function Interaction Structure (FIS) (Flaus, 2008).

Based on these works, we propose a study that allows the analysis of the different risks that can appear in the service of sterilization. This study is carried out in three stages: "risk identification", "risk classification" and "risk grouping"

**Performance Evaluation.** The sterilization service is the subject of several research projects aiming at understanding how the service works and identifying best practices, in order to first measure performance and then try to improve it, as, for example, (Reymondon et al, 2008), (Di Mascolo and Gouin , 2013), or (Delpech, 2016). However, despite the fact that risks are the main causes of performance degradation in any production system, these studies do not consider the risks, and usually simulate the behavior of the studied systems in normal functioning mode. To the best of our knowledge, the only works which take into account risks in performance evaluation of sterilization services are (Negrichi, 2015), (Negrichi et al, 2016) and (Barkaoui 2015). These two studies use different modelling and simulation methods. Negrichi used the FIS method to obtain a risk model, which is then translated into a PTPS Petri Net (Predicate-Transition, Prioritized, Synchronous) for the simulation, while Barkaoui used a model simulated using the Arena software, to which some risks could be added using VBA coding. These two methods show limits when applied to real cases

**Proposed approach.** We are interested here in developing a new approach that addresses the performance evaluation of sterilization services by taking into account the impact of risks on the flow and performance of the studied systems, even on real cases. Our approach is based on 2 phases. The first one is the description of the analyzed system by representing the different steps, resources, inputs/outputs, the different risks that can appear in the service and the integration of these risks in the model in order to obtain a risk model. The second phase is the simulation of this risk model with a SIM.JS simulation library using a JavaScript programming language that will then give us performance indicators. We focus here on the first phase, i.e. the model, which is detailed in section 2. Section 3 gives an idea of the other stage.

## 2 Model

Our objective is to create a model that gathers all necessary information about the sterilization service: the different process steps, inputs/outputs, resources used, as well as the various risks that may appear and disrupt the system operation.

### 2.1 Functional model

The functional model describes the different steps of the sterilization service, defines the input / output entities and the necessary resources.

*Entity:* MD come from the operating room, in containers, containing each a given number of MD, after each operation. These MD will go through the sterilization process to be reusable. In order to maintain traceability, the containers of the same operation will be treated together during the steps: pre-disinfection, rinsing, washing and drying, and from the packing, these containers will be mixed. "Operation" is the input entity corresponding to the first steps. From the packing, the entity will become "Container". For example, during the pre-disinfection all the containers of the same operation are pre-disinfected all together, the same thing goes for the following steps. While from the packing step, the containers for all operations are put together and the medical devices that are in the containers will be packed. This assumption has been taken also in (Barkaoui, 2015) and (Di Mascolo and Gouin, 2013). To pursue this approach, we assumed that packing is only done in containers, while it can be done in bags.

*Resource:* A resource is a way to get what you want. In a production system, a resource can be human, material or informational. The material resources are all the equipment (machine, tools) used to accomplish the tasks of the system by human resources (personnel) thanks to the information data (document, guide ...). The resources can be either support resources that are necessary in the activity of transforming input entities into output entities without undergoing transformations such as the washers, which means that there will be consumable resources such as the detergent.

This model is based, at first, on a functional view that describes the system, its composition and its architecture. It is created by the decomposition of the system into elements in order to facilitate the reading and the understanding of the operation. This view allows us to build a first model with a "normal" behavior mode. This is the mode where everything works normally without any faults. Fig 1 illustrates this functional view.

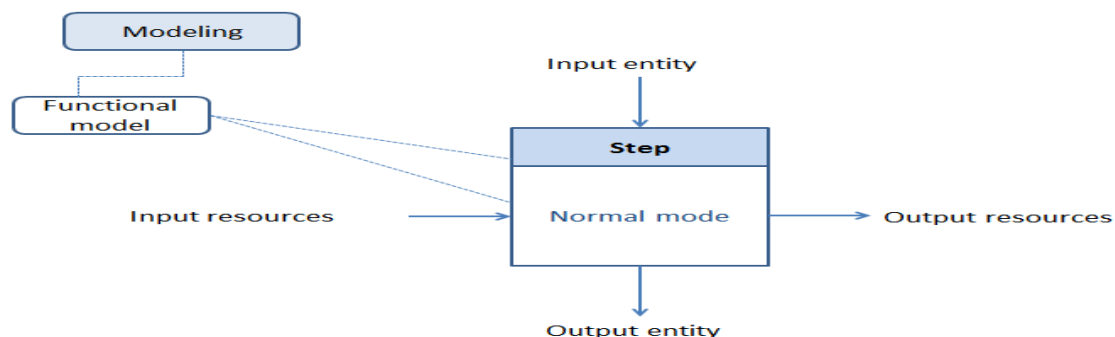


Figure 1: functional view

For example (see Fig 2) to ensure a good washing, this function requires a material resource "the washer", a human resource "operator" that will load the MD into the washer and check parameters of the washer (cycle time, temperature), as well as an information resource "patient card". This card gathers all the necessary information

on the patient operated in order to keep a traceability. The input entities are the rinsed devices and the output entities are the washed devices.

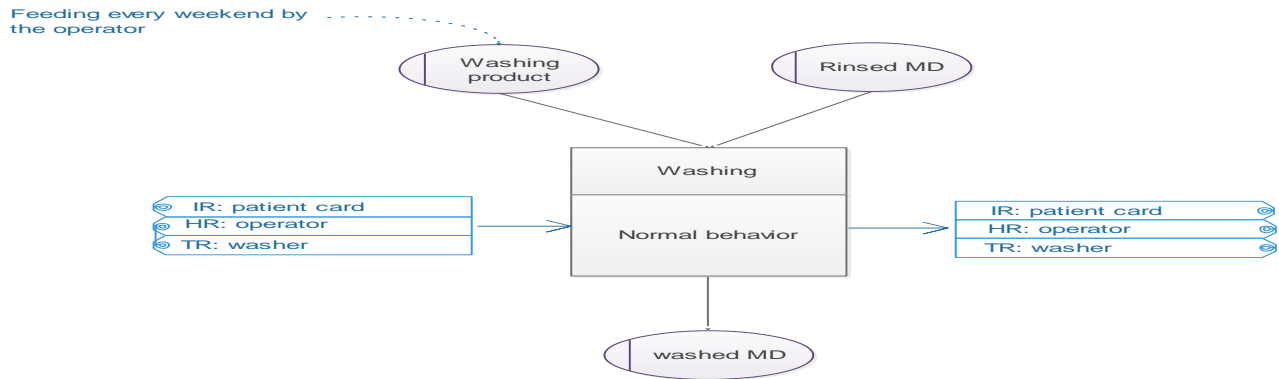


Figure 2: functional view for the washing step

This mode describes the operation of the system without taking into account the risks that may appear and disrupt the system operation. For this purpose, a risk analysis will be carried out in this service in order to create a risk model with other behavior modes.

## 2.2 Risk analysis

**Risk identification.** In order to analyze the various risks, several studies have been carried out in the field of the sterilization service. The study conducted by (Talon, 2011) made it possible to identify the different dangerous situations, the dreaded events resulting from these situations, the causes which allowed these dangerous situations and their consequences to appear. For each situation he assigned the gravity, likelihood, criticality and the solutions. The study led to the identification of 348 hazardous situations, including 230 with high vulnerability to danger. These 348 hazardous situations led to 364 risk scenarios. Also (Negrichi, 2015) carried out a field study in the sterilization department of Grenoble public Hospital to analyze the major dangers existing in the service. This analysis was carried out through various discussions with the staff and managers of the sterilization service, by analyzing the complaint files received from the operating room and the link sheets received with the MD. From this study, Negrichi was able to identify 177 dangerous phenomena.

Another study carried out by (Ben kahla, 2011) on the management of the risks in operating rooms of the Sahloul Hospital of Sousse has identified 53 risks. This identification includes risks that are part of the sterilization service. Based on these works, we have collected all the potential risks that can appear in sterilization services in an Excel sheet, and we added to that a set of risks that we have proposed and that had not been identified in previous works. This study allowed us to identify 538 risks.

**Risk classification.** The previous step allowed us to identify a significant number of risks that can appear in the service and disrupt its functioning. In order to organize these risks, we define a classification that allows grouping these risks according to classes. The classes must cover all the particulars that may be related to the sterilization service. For this we propose a classification into 5 classes:

- *Equipment:* covers all the risks associated with the equipment used during the manufacturing process (washer-autoclave-dryer-sink).
- *Entity:* covers all the risks related to medical devices
- *Human:* covers the risks related to the staff who work in the sterilization service, as well as the patients.
- *Material:* covers the risks associated with the material used to ensure the correct functioning of the functions (washing product, packing, etc.).

- *Environment*: covers the risks associated with the indoor environment of the system, such as work space and risks related to the external environment of the system.

In order to classify all these risks, we have started to sort the risks according to the classes. All the risks belonging to the same class are put together, for example all the risks that are related to the material, like autoclave failure, overloading of the scrubbers... are put together.

**Risk grouping.** After classifying the risks we noticed that some have the same impact on the production system; for example (electrical failure + absence of steam homogeneity + presence of the leak... = autoclave out of order). This grouping made it possible to reduce the number of risks from 538 risks to 45, which will facilitate their integration in the model and their simulation. Among these 45 risks, there are risks that can propagate from one stage to another, and others can be detected.

*Propagation of risks.* Let us consider the risks that can propagate from one stage to another and cause other risks. For example, if the medical devices are contaminated and the operator has not detected their contamination, the washer will be contaminated. So all the devices that pass through this washer will be contaminated too. This propagation can affect the performance of the service and may have negative effects on the health of staff and patients who may be contaminated by diseases.

*Detection of risks.* This concept, which was not considered in previous papers, as (Negrichi, 2015) and (Barkaoui, 2015), allows to detect the fault and to change the configuration of the system to prevent its propagation. Consider, for example, a medical device that has not been properly dried. Once detected, the device returns to the drying zone to repeat the step and ensure that this has been done in accordance with the standards in order to avoid corrosion of the device.

In order to analyze all the risks, we have determined for each risk the possibility to propagate and to be detected or not. This analysis made it possible to classify and group the risks according to their impact on the system in order to reduce their number. This grouping helps us integrating the risks in our model, to obtain a risk model.

### 2.3 Risk model

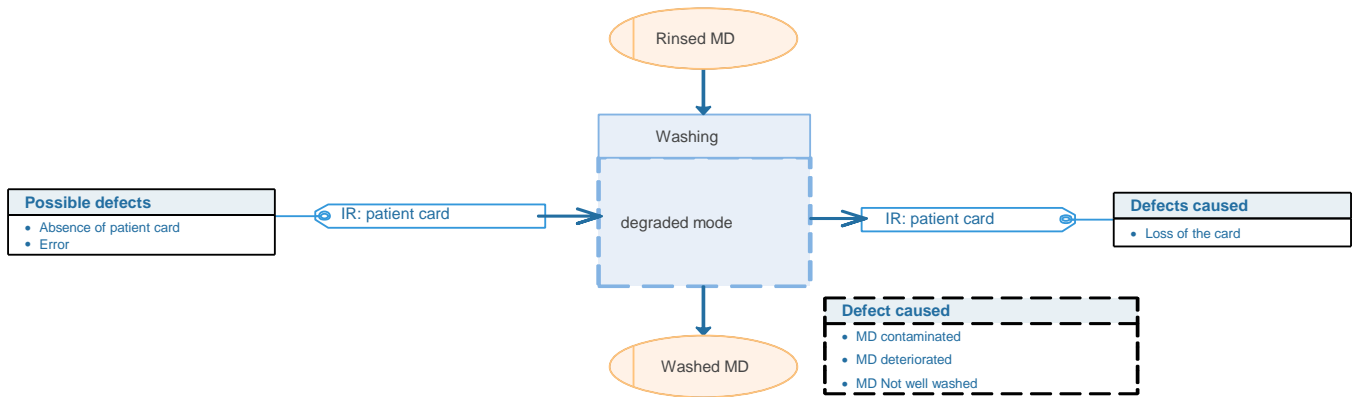
We recall that the model analyzed in the first part just describes the normal functioning of the sterilization service, whereas the risk model is a descriptive model allowing the representation of the system by integrating all the risks that may appear during its operations. This model must include a description of the behavioral mode of the analyzed system once the risks appear.

**Dysfunctional view.** The dysfunctional view aims to represent all the risks that can happen in a system. These risks can reach a function when it does not fulfill the purpose for which it is intended with the desired quality or a resource when it has a degradation that does not allow it to perform its service to a function, or an entity when is degraded and change its main characteristics.

Based on the study of the risk analysis carried out, we created this dysfunctional view by integrating the risks into the functional model. For this, we consider the 45 risks grouped into five classes. Our modeling of risks will depend strongly on the classification that we have made, but also on the degree of degradation associated with the occurrence of the risk as well as the frequency of occurrence of the risk. This means that not all risks have the same impact on the performance and production system operation, for example, the impact of medical devices contamination by a CJD does not have the same effect as the lack of materials, the first will have effects on personal and patient life whereas the second does not have serious effects. These risks are represented in the risk model according to two behavior modes, the degraded mode and the reconfigured mode.

**Degraded mode.** It is the mode in which at least one of the resources cannot function normally; it can be the technical resources TR (machine, tool) human resources HR (staff), informational resources IR (document, patient card) or entities. The degraded mode is not only related to resources and input entities. It can also reach the resources and the output entities, i.e. the resources or the entities can have modifications caused by the function itself, which modifies their characteristics at the exit.

*Example of degraded mode (see Fig 3):* Let us consider the information resource "patient card" in the washing step. This card gathers all the necessary information of the operated patient in order to keep traceability in the system. In normal mode, this card is always present in all the process steps, and information are correct. For the degraded mode, this card can have defects which can be either in the entry of the function, like the absence of the card and thus, the operator does not have the necessary data on the patient (is it contaminated by a disease or not ...), or at the exit of the function (the card is present at the entry but is lost after the consultation). For the entity: at the entrance of the washing stage we have rinsed MD which are in good condition. This function can cause defects on the entities that will appear at the output, for example the MD can be destroyed due to improper use of the washer, or contaminated by other DM that are already contaminated or by washer himself...

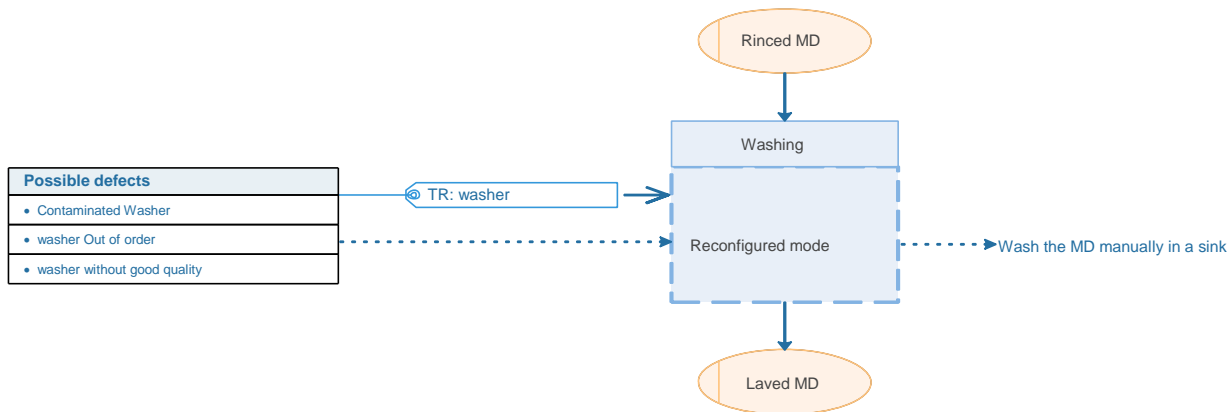


**Figure 3: Example of a degraded mode**

Based on the functional model and the carried out risk analysis, we determined all the degraded modes that can occur in a production system within the sterilization service.

**Reconfigured Mode.** The difference between the degraded mode and the reconfigured mode is the detection of the fault. The reconfigured mode allows the system to be reorganized once a fault has been detected, in order to avoid the propagation of the fault or the shutdown of the system. This reorganization is done through a change of the resource using another resource, which was not programmed. For example, see Fig 4, during the normal operation of the washing step, the medical devices are loaded into the washer for a defined period, in case of a defect detection such as contamination of the washer and to prevent the propagation of this contamination, washing will be done manually in sinks.

After defining these system behavior modes: normal mode, degraded mode and reconfigured mode, we can start building our new model "the risk model".



**Figure 4: Example of a reconfigured mode**

**Presentation of the risk model.** Our risk model combines the various behavior modes of the system and gives an idea about system functioning in its normal state as well as the different risks that may arise in operation with different classes by providing solutions for the reorganization of the system in case of risk detection.

The originality of this model is its simplicity, ease for reading and quick understanding of the system functioning in its various behavior modes.

Based on this formal model we can create our risk model by combining in the same model all the different modes illustrated in Figures 2, 3, and 4.

### 3. Simulation and Performance indicators

The risk model presented in section 2 is used to model the studied system behavior. This model is the core of the performance evaluation for our system. In order to determine the performance indicators of this service, we simulated our risk model using a SIM.JS library, a multiagent framework allowing to simulate discrete event systems using a JavaScript programming language. For this purpose, we started by identifying our parameters:

- *entities*: staff of the sterilization service; they are the active actors of the system.
- *resources*: the resources used are the facilities and the buffers :
  - facilities: materials used (washers, autoclaves, dryers, pre-disinfection tanks, etc.).
  - buffers: stocks in which we store the MD. These devices are queued to consider the waiting time.

Based on these main parameters and on our model we could code our program to model and simulate the sterilization service. We began by the normal mode, to which we added the other two modes.

We simulated the sterilization service studied in (Di Mascolo and Gouin, 2013), using the same real data (number of washers/autoclaves, capacities, process duration, MD arrival process...) and compared the obtained results with other approaches, especially, the one in (Di Mascolo and Gouin, 2013), which does not consider risk, and (Barkaoui, 2015) and (Negrichi, 2015) which consider risks with different modelling and simulation methods. We could thus observe the impact of risks on the performance (sojourn time, resource utilization rate, buffer levels, number of cycles (autoclaves and washers)...), which are degraded. We also observed the impact of the arrival of a contaminated operation: this contamination is propagated to one washer, and then to the other operations washed in the same washer, until the contamination is detected.



## 4. Conclusions and future research

We proposed an integrated approach combining simulation and risk analysis to consider the effects of these risks in assessing system performance. To do this we started by creating a model of the system representing the sterilization service process in its normal mode. Subsequently, a risk analysis was carried out in the sterilization service in order to determine all the risks that may appear in this service. These risks are classified into 5 classes and grouped according to their impact on the system in order to reduce the total number of risks and facilitate work. These risks are integrated into the functional model in order to obtain a risk model, making it possible to represent two other behavior modes, the degraded mode and the reconfigured mode.

The approach, including the simulation, has been tested on the sterilization service. Nevertheless, with improvements and updates, it can be used in any production system, since the formal model we propose is based on the common structure of a production system.

Some improvements could be done: in our approach the detection of a failure is carried out as soon as the failure appears, whereas this detection can be carried out at any time;. Therefore it is necessary to generate an event which will trigger the moment when this detection will be carried out, either as soon as the failure appears or a certain time after its appearance. Another aspect that is not taken into account in our approach concerns urgent requests: sometimes, urgent DM have the priority to pass in the sterilization cycle without entering the queues.

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