

# Risk management in CSSD

Jean-Marc Legentil MBA  
Senior Partner  
Bell Nordic Consulting  
Canada

 Bell Nordic inc.  
Libérateurs de génies  
Igniting Genius

---

In collaboration with  
Richard Marchand MD  
Laboratoire de Santé Publique du  
Québec  
Université de Montréal  
Canada



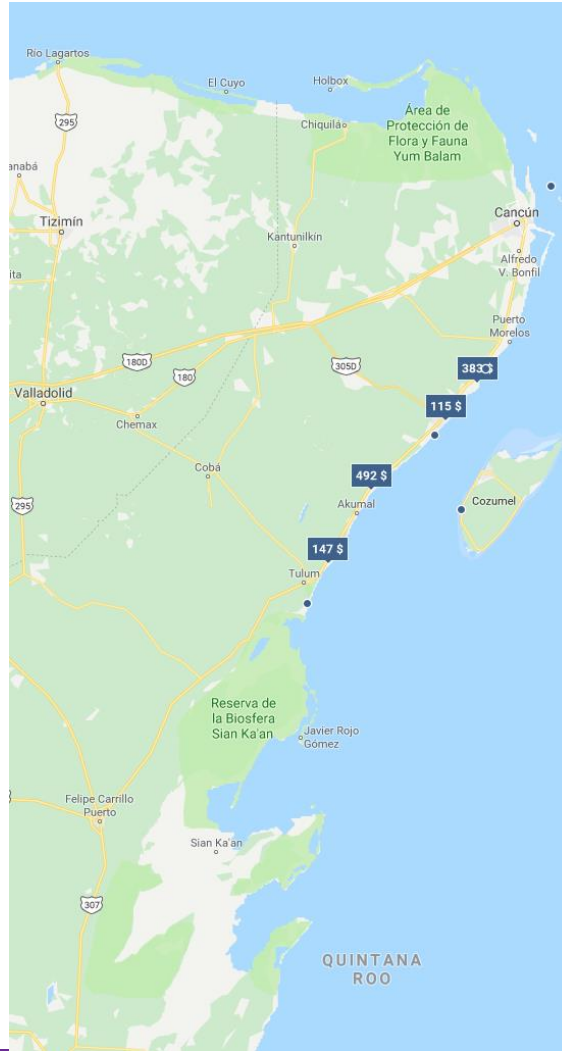


Jean-Marc Legentil



Richard Marchand MD





# Objectives

- Introduce the congress attendees the concept of **risks at the CSSD**
- Introduce the tools and methodologies to be used to manage and reduce risks in a responsible and ethical manner





# Content

## 1. What is risk management

- Defining risk
- Ethic asks us to do what?

## 2. How to identify the risks

- Process mapping
- Identify the risk
- Evaluate the failure mode
- Select the risk priorities

## 3. Mitigate the risk

- Problem solving
- MANAGE the process

## 4. Maintaining the improvements

- Quality Assurance Program



# Content

## 1. What is risk management

- Defining risk
- Ethic asks us to do what?

## 2. How to identify the risks

- Process mapping
- Identify the risk
- Evaluate the failure mode
- Select the risk priorities

## 3. Mitigate the risk

- Problem solving
- MANAGE the process

## 4. Maintaining the improvements

- Quality Assurance Program



A **probability** or threat of damage, injury, liability, loss, or any other **negative occurrence** that is **caused by external or internal vulnerabilities**, and **that may be avoided** through pre-emptive action.

Food industry: The possibility that due to a certain hazard in food **there will be an negative effect to a certain magnitude.**





# WHAT IS A RISK

- Something may happen in the sterilisation process
- Contamination will cause infection
- Risking the health of the patient





# Risk management: a social principle

---

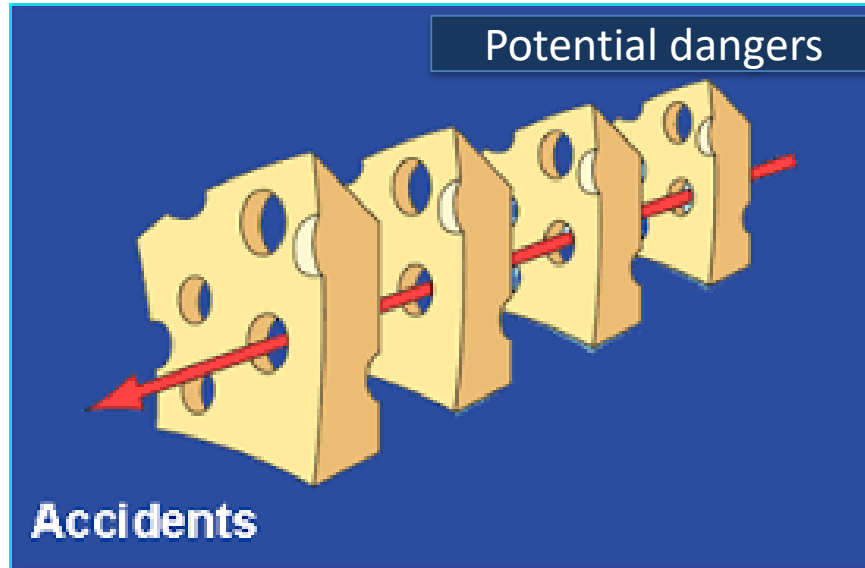
Risk acceptance level varies in time and societies



# Risk management: a social principle

---

Accident in a complex process is a mathematical certainty:  
serious problems WILL occur



# Managing risk in an organisation

...is to evaluate the « **tolerance** » of the organisation and society to the consequences of the possible accidents that may occur so politically and socio-economic acceptable could be made.



# Managing risk in an organisation

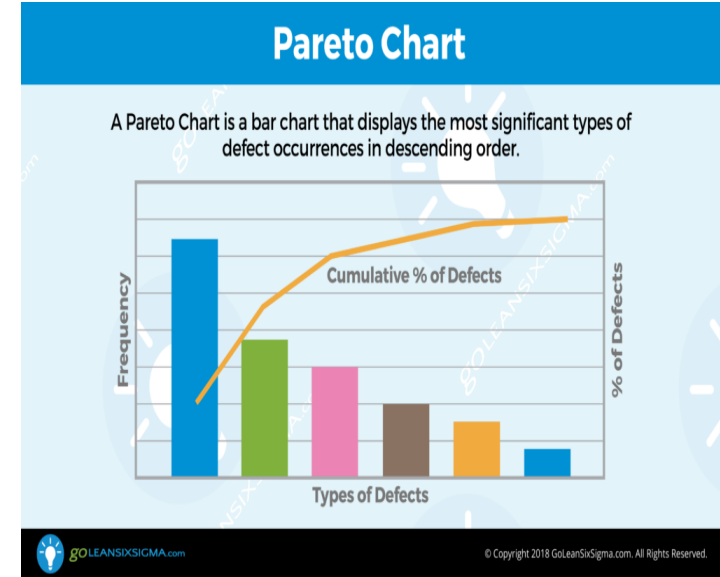
...is to evaluate at what level is a fair limit between what is technically feasible compared to the available resources.





# Ethic asks for what?

- To do the most with the resources we have
- Thus evaluating the most adverse consequences and to invest by order of importance in reducing the risk, according to the available budget
- Not obliged to eliminate ALL risks at ALL cost
- To deploy every effort to reduce infection risks from CSSD process



# Content

## 1. What is risk management

- Defining risk
- Ethic asks us to do what?

## 2. How to identify the risks

- Process mapping
- Identify the risk
- Evaluate the failure mode
- Select the risk priorities

## 3. Mitigate the risk

- Problem solving
- MANAGE the process

## 4. Maintaining the improvements

- Quality Assurance Program



1- MAP THE PROCESS

2- Identify the risks

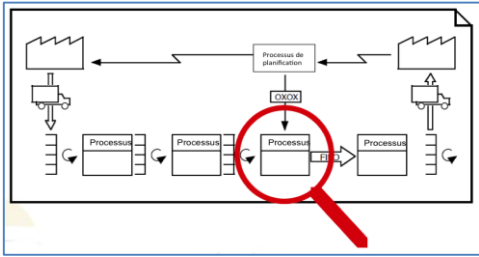
3- EVALUATE THE FAILURE MODE

4- SELECT THE RISKS PRIORITIES

5- MITIGATE THE RISK



# 1- MAP THE PROCESS



## 2- Identify the risks

## 3- EVALUATE THE FAILURE MODE

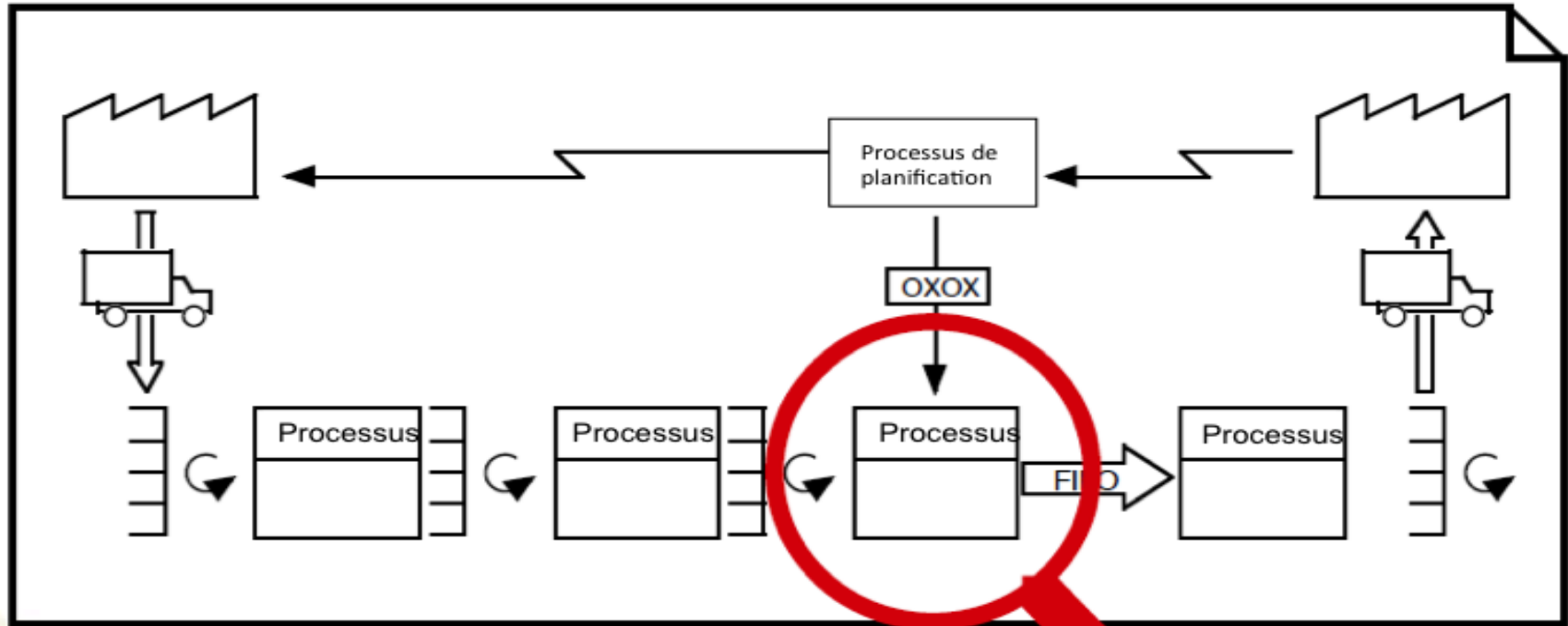
## 4- SELECT THE RISKS PRIORITIES

## 5- MITIGATE THE RISK

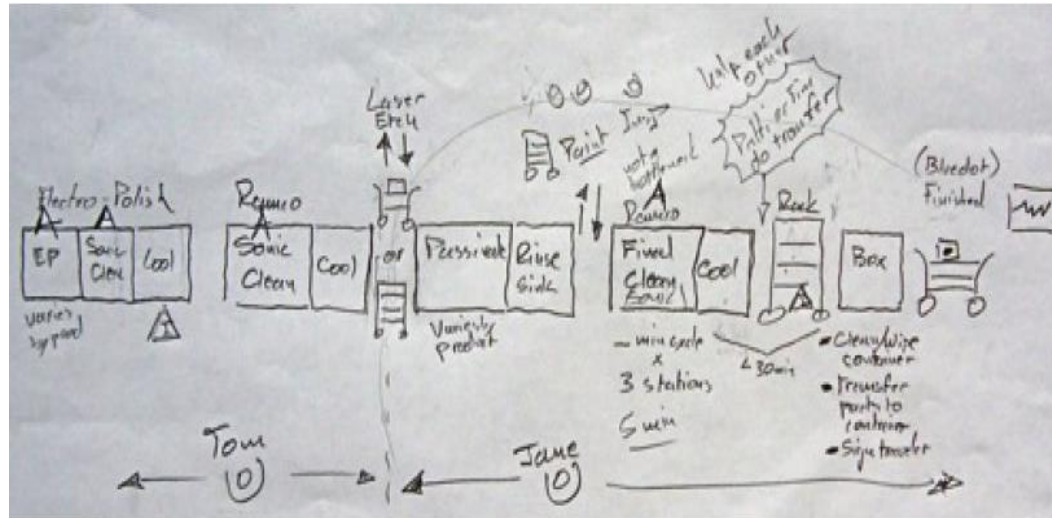




# Mapping the PROCESS

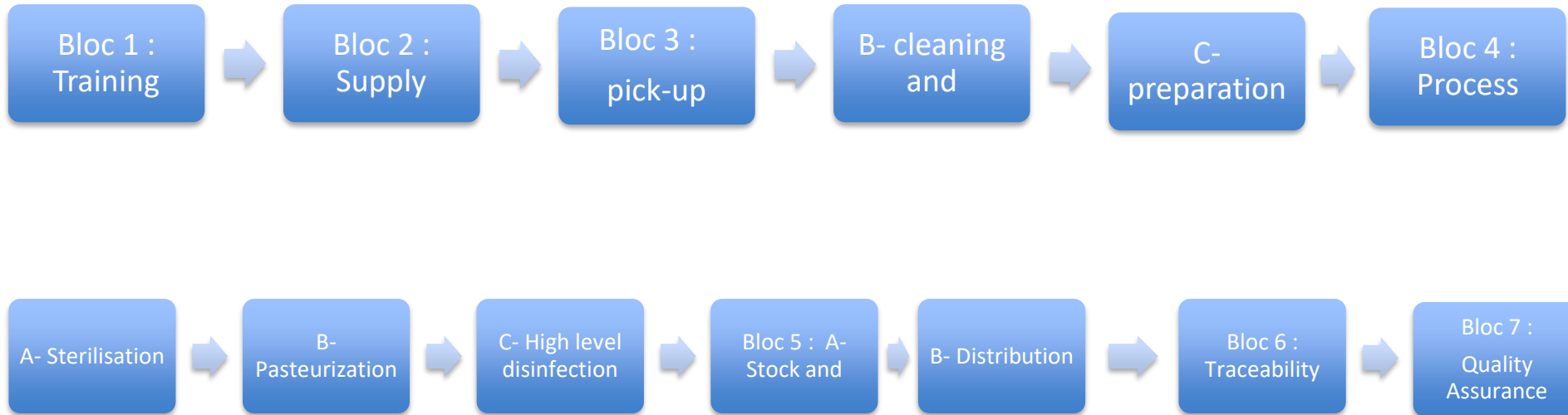


# Process Mapping with the Block Diagram format

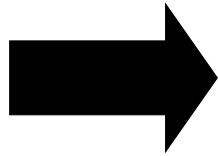


# Process Mapping with the Block Diagram format

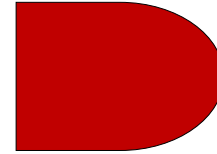
19



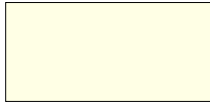
# Symbols to use FOR PROCESS MAPPING



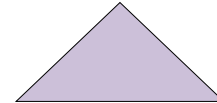
Transport



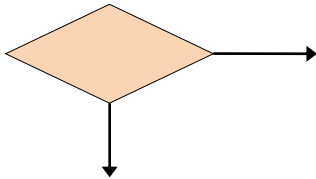
Delay/  
Wait



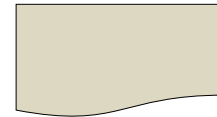
Operation



Inventory



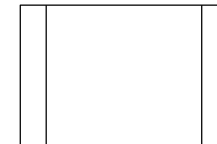
Decision



Document



Beginning  
/End

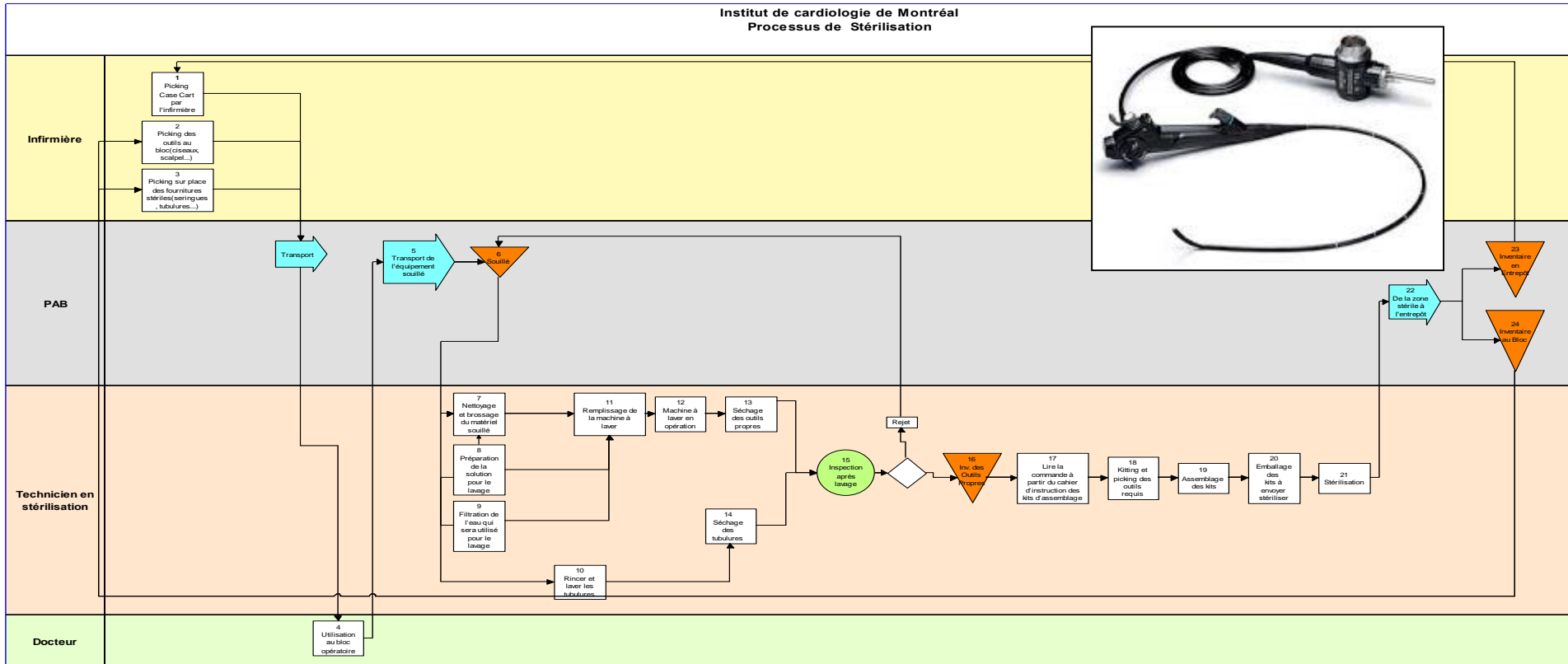


Sub-  
process

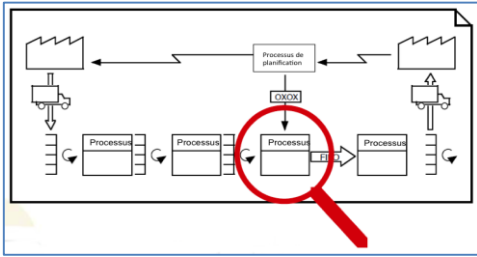




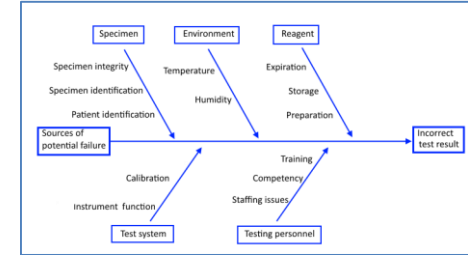
# CSSD completed process map



# 1- MAP THE PROCESS



## 2- Identify the risks



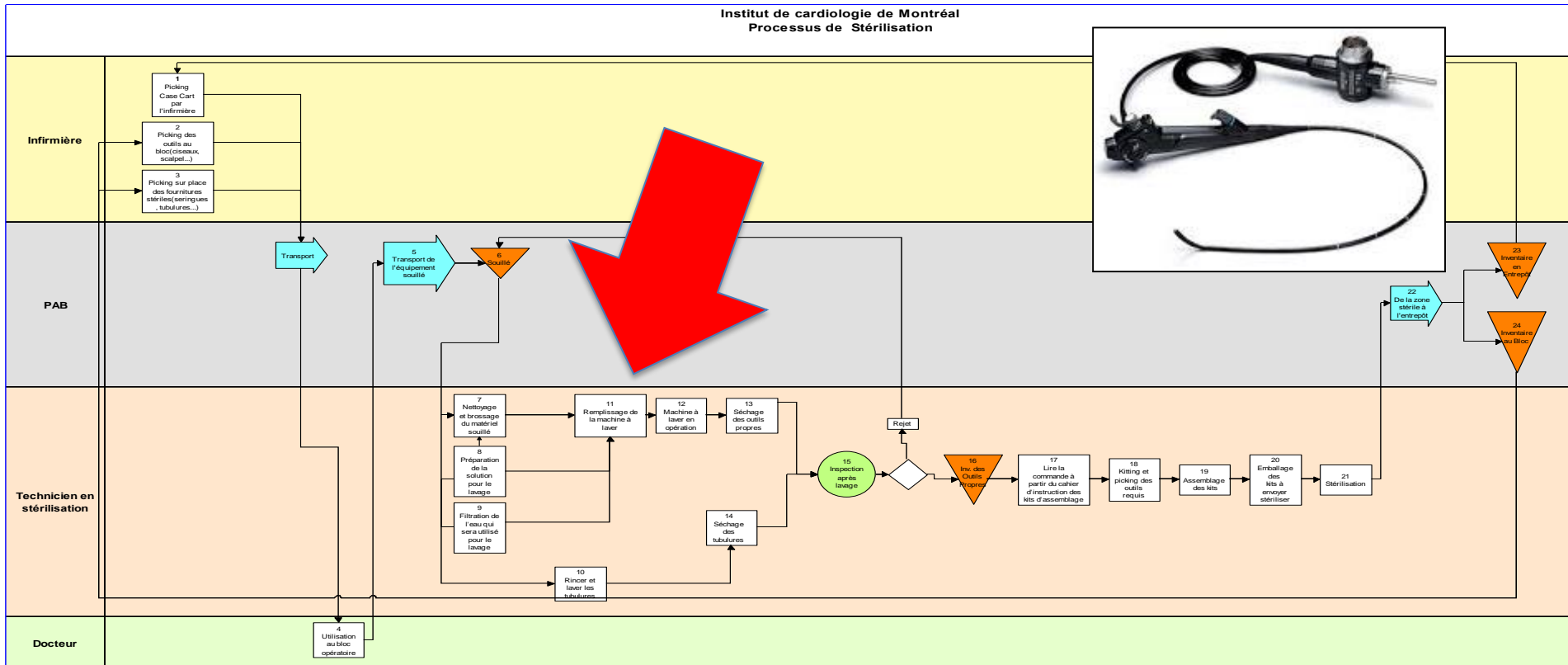
## 3- EVALUATE THE FAILURE MODE

## 4- SELECT THE RISKS PRIORITIES

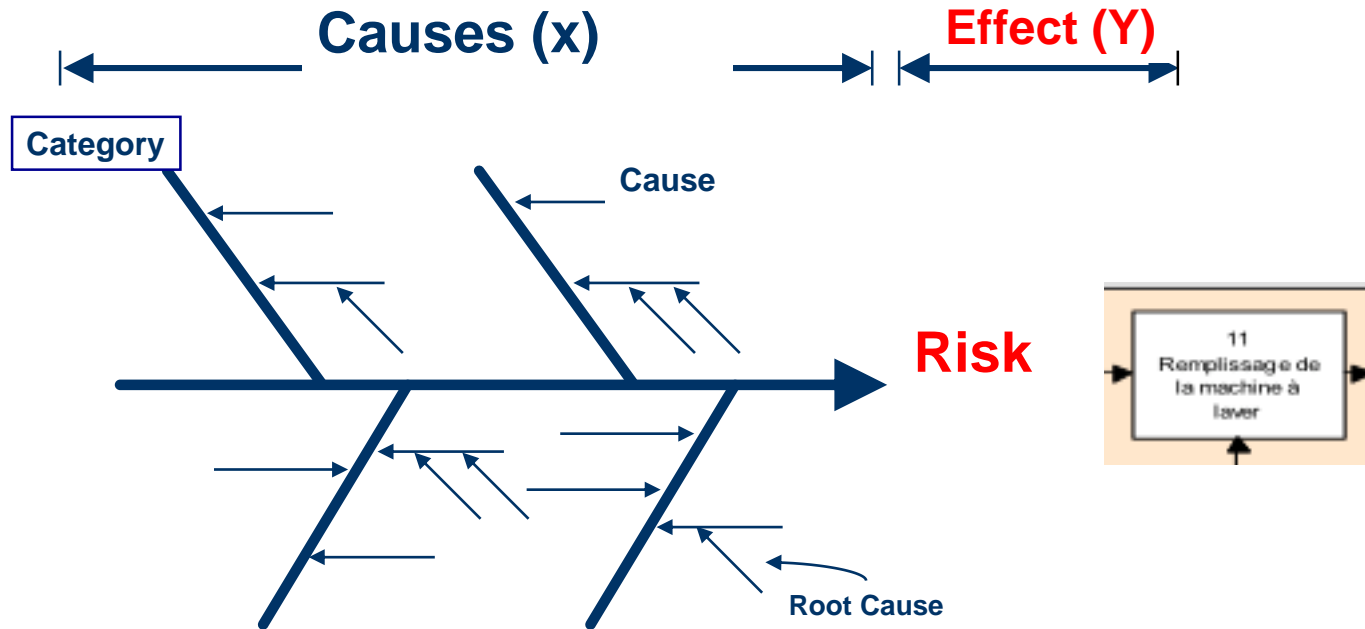
## 5- MITIGATE THE RISK



# Identify the source of errors to prevent them from reoccurring, to invest where it is more effective



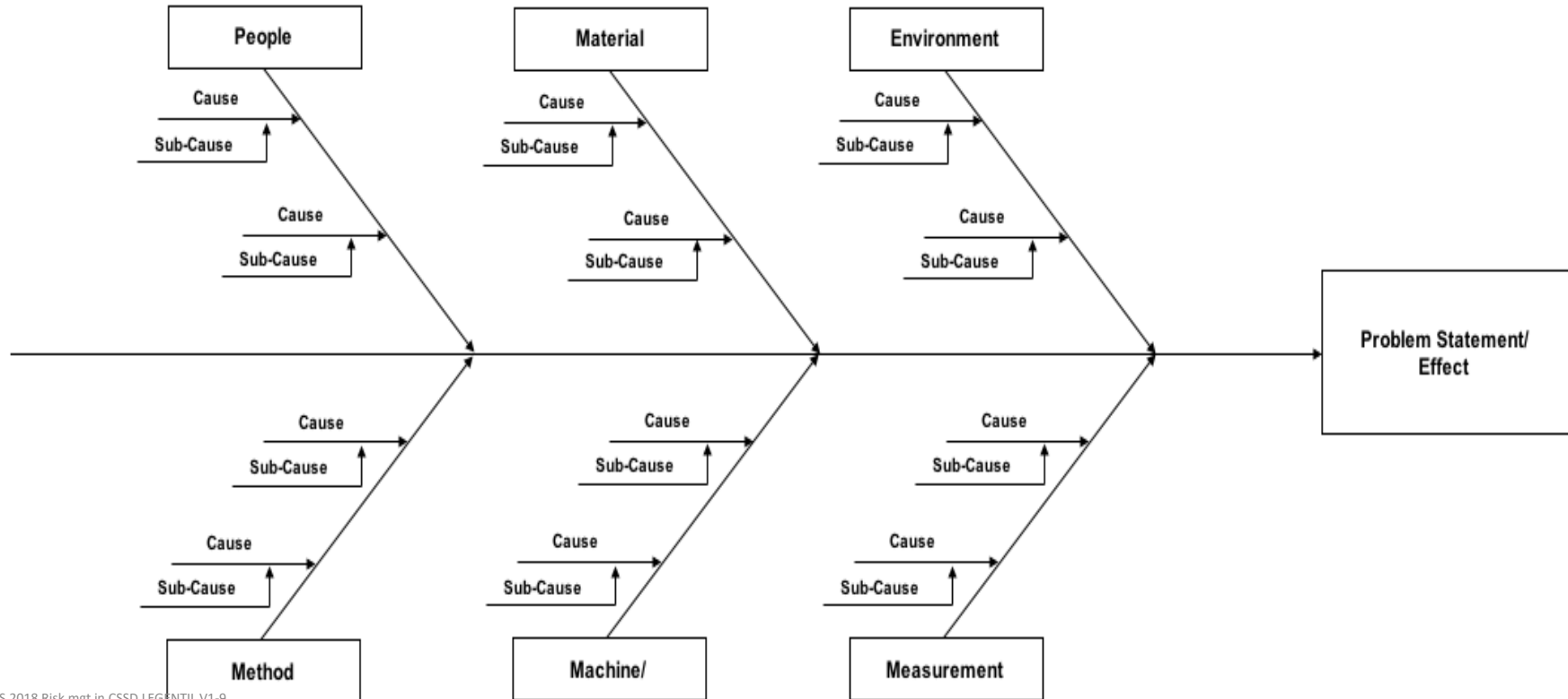
EACH RISK POINT IS ANALYSED WITH A CAUSE AND EFFECT DIAGRAM ( FISHBONE DIAGRAM OR ISHIKAWA DIAGRAM)



## CAUSE &amp; EFFECT (FISHBONE) DIAGRAM

Process/Project Name:	
Date:	
Prepared By:	
Notes:	

# Categories for the Cause and Effect Diagram ( 5M's)



# Process Mapping with the Block Diagram format

26

Bloc 1 :  
Training

Bloc 2 :  
Supply

Bloc 3 :  
pick-up

B- cleaning and

C-  
preparation

Bloc 4 :  
Process

A-  
Sterilisation,

B-  
Pasteurization

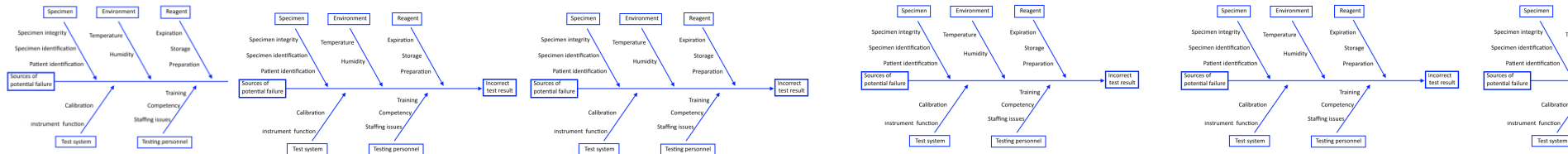
C- High level  
disinfection

Bloc 5 : A-  
Stock and

B- distribution

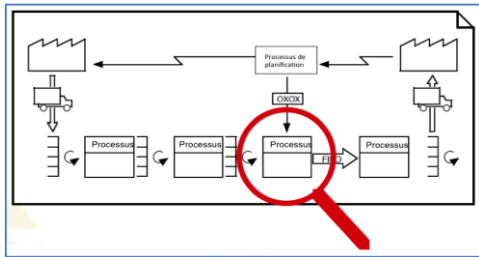
Bloc 6 :  
Traceability

Bloc 7 :  
Quality  
Assurance





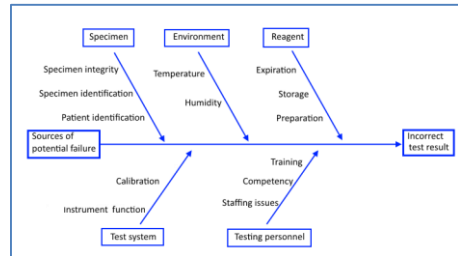
# 1- MAP THE PROCESS



## 2- Identify the risks

216=6X6X6

3-Evaluate the failure mode:  
 $RPN = S \times O \times D$



## 4- SELECT THE RISKS PRIORITIES

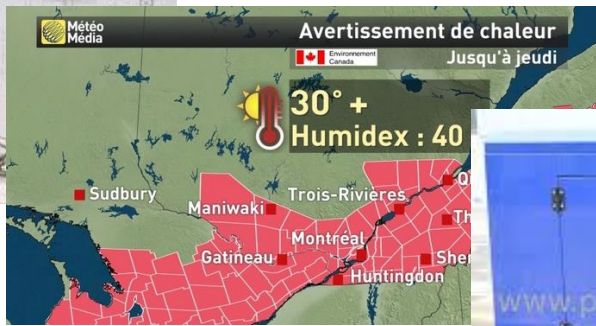
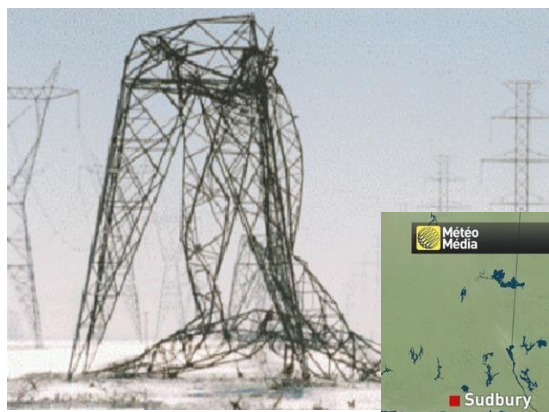
## 5- MITIGATE THE RISK



SEVERITY

OCCURENCE

DETECTION



# EVALUATING THE RISKS: FMEA

(failure mode and effect analysis)

$$RPN = S \times O \times D$$

Risk Priority Number=  
Severity  
X Occurrence  
X Detection



# Failure Mode and Effect Analysis

$$RPN = S \times O \times D$$

RPN	SEVERITY	OCCURRENCE (probability)	DETECTION challenge	Interpretation
1000	10	10	10	Major & imminent
10	10	1	1	Major but rare and immediately detectable
75	5	5	5	Low risk
50	1	10	5	Will occur but with little impact
240	5	8	6	Important risk

Scale from 0 to 10



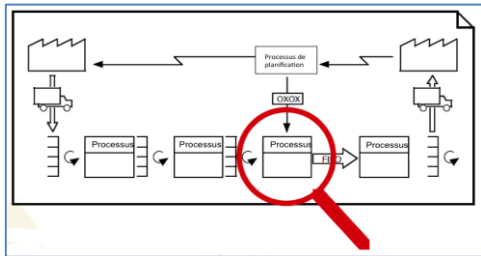
## Example

$$RPN = S \times O \times D$$

	severity	occurence	detection	RPN
Power failure	1	3	9	27
Earthquake	9	1	1	9
Infectious agent	5	9	9	405
Sharp object	4	9	10	360
Mechanical failure	3	3	9	81
Contaminated contrast agent	7	4	8	224
Toxic liquid	7	4	6	168
Burn	6	6	2	72
Electrical shock	5	1	6	30



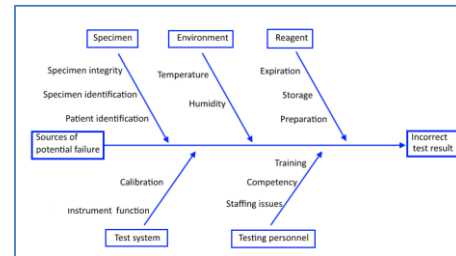
# 1- MAP THE PROCESS



## 2- Identify the risks

216=6X6X6

3-Evaluate the failure mode:  
RPN = S X O X D



## 4- SELECT THE RISKS PRIORITIES

Pont critique	Mode de monitoring	Mode de mitigation	Mécanisme de suivi	Mécanisme de documentation

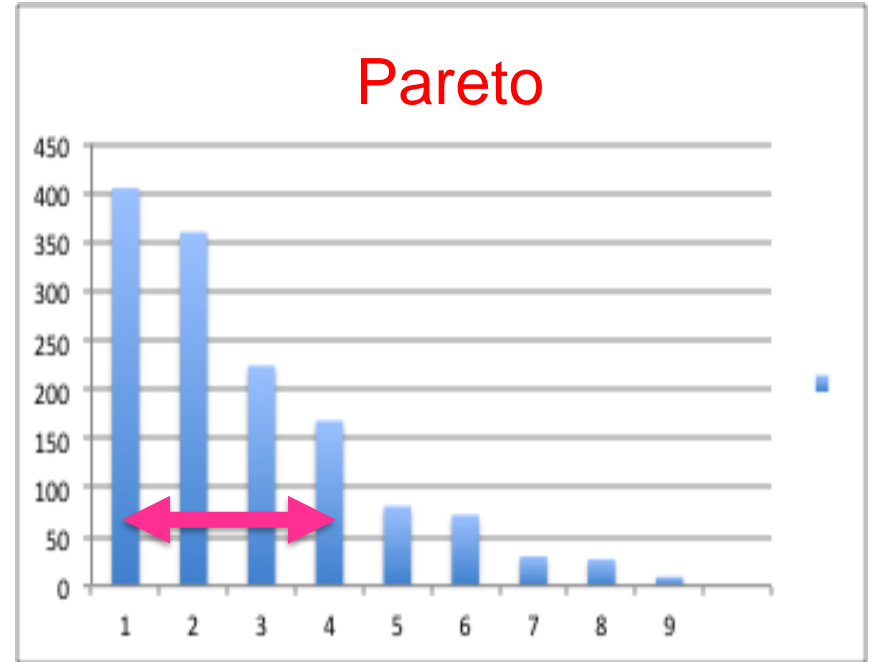
## 5- MITIGATE THE RISK



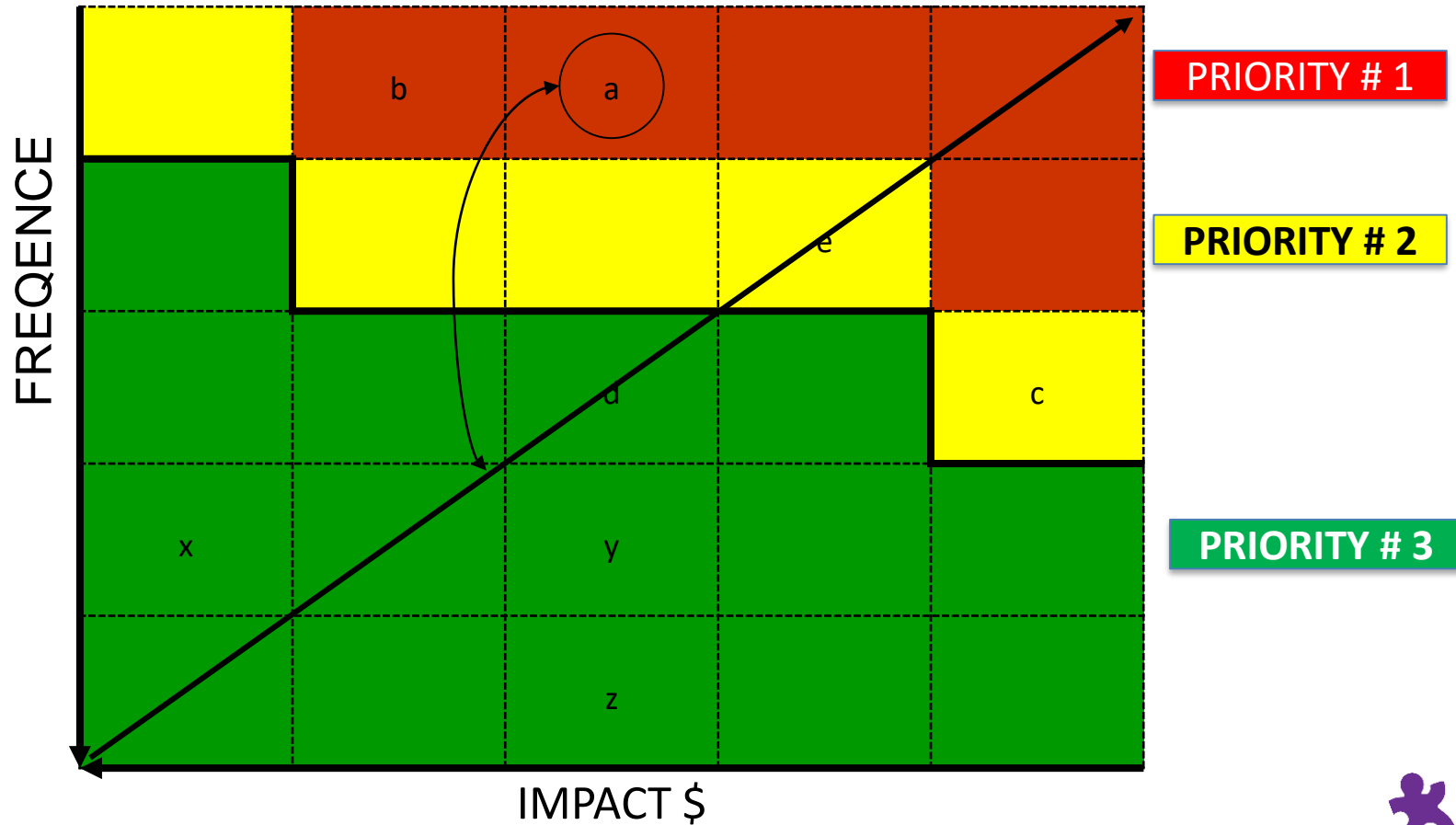


# RANKING AND PRIORITIZING RISKS

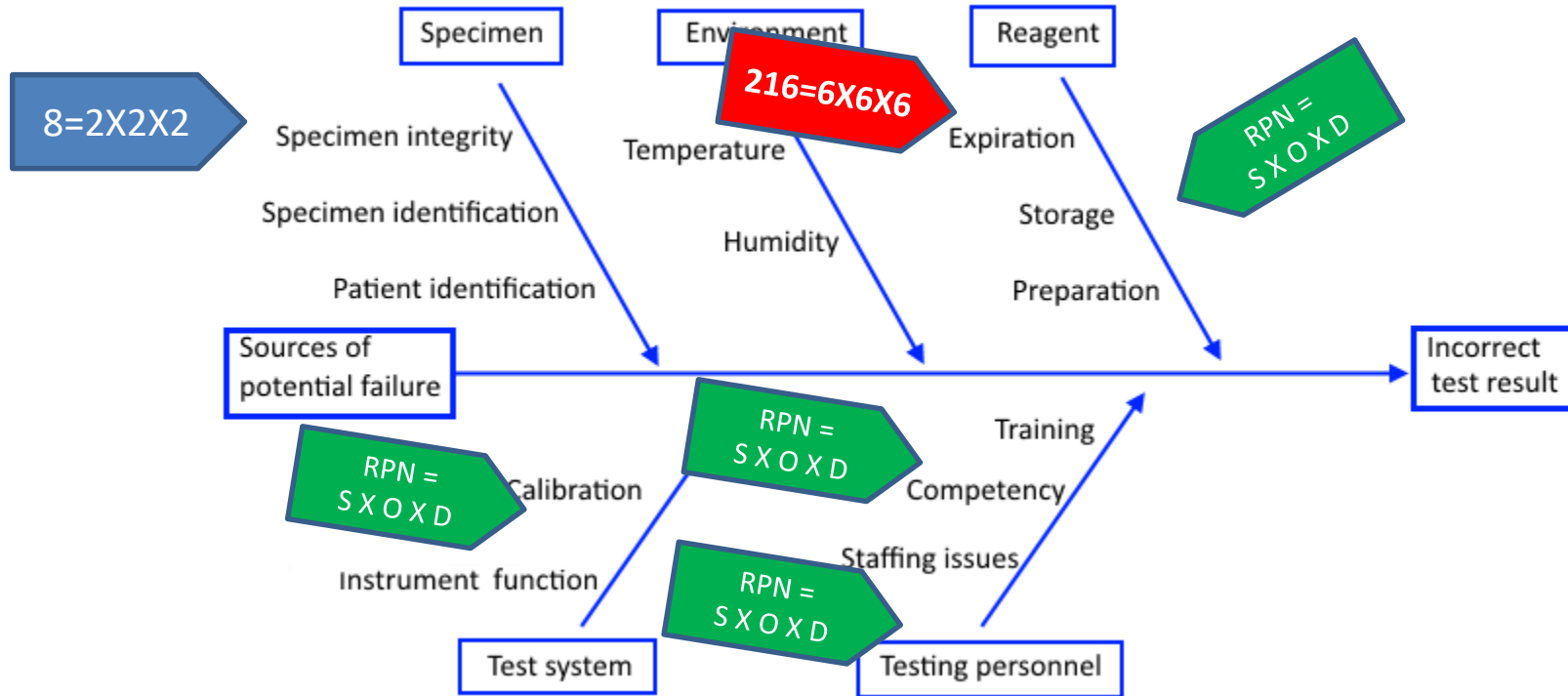
1. Infectious agent	405
2. Sharp object	360
3. Contaminated contrast agent	224
4. Toxic liquid	168
5. Mechanical failure	81
6. Burn	72
7. Electrical shock	30
8. Power failure	27
9. Earthquake	9



# PRIORITIZING RISKS



$$RPN = S \times O \times D$$



# Content

## 1. What is risk management

- Defining risk
- Ethic asks us to do what?

## 2. How to identify the risks

- Process mapping
- Identify the risk
- Evaluate the failure mode
- Select the risk priorities

## 3. Mitigate the risk

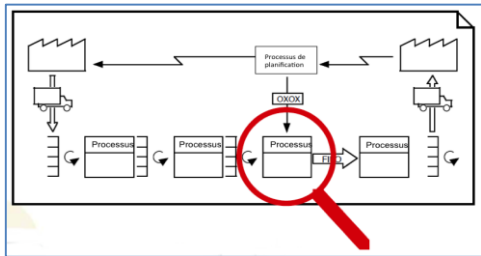
- Problem solving
- MANAGE the process

## 4. Maintaining the improvements

- Quality Assurance Program



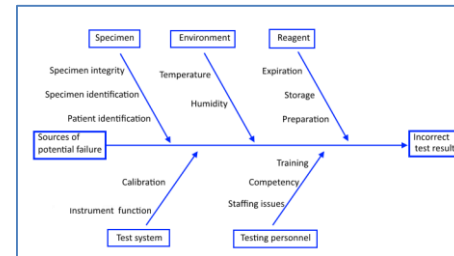
# 1- MAP THE PROCESS



## 2- Identify the risks

216=6X6X6

3-Evaluate the failure mode:  
RPN = S X O X D



## 4- SELECT THE RISKS PRIORITIES

Pont critique	Mode de monitoring	Mode de mitigation	Mécanisme de suivi	Mécanisme de documentation

## 5- MITIGATE THE RISK



# Risk mitigation

1. Identify the critical points
2. One critical point may apply to many risks
3. Monitor each critical point
4. Suggest mitigation mode in case of problems at each critical point
5. Implement follow-up mechanism with proper documentation





# HOW TO RECORD MITIGATION MODES

Critical point	Monitoring mode	Mitigation mode	Follow-up mechanism	Documentation mechanism
Sterilization temperature	Reading temperature from integrated thermometer probe	1-Certified maintenance and calibration program With sticker showing next calibration date 2- At a specified interval, internal temperature recorded on printer output is compared to external readout and recorded in a logbook	Calibration logbook follow-up is audited	Calibration program is integrated in the quality assurance program from Accreditation program



# IMPROVE DAILY

IMPROVEMENT OPPORTUNITY		
Problem _____		
Name _____ Date _____		
Related to which True North Metric (circle) Safety Quality People Financial Stewardship Customer Satisfaction Unit Specific		
Suggestions _____		
_____		
_____		
_____		
OWNER		
Who	What	By When
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

IMPROVEMENT OPPORTUNITY		
Name: <u>Dr Sandelbach</u>		Date: <u>8/11</u>
What is the problem? <u>No Cordis central line in department</u>		
Why is it happening? <u>??</u>		
Potential Solution: <u>locate</u>		
True North Impact: (Circle one) <u>Safety</u> <u>Quality</u> <u>Customer Satisfaction</u> <u>People</u> <u>Financial Stewardship</u>		
Owner: <u>Peter</u>		
Who	What	By When
<u>located &amp; leave in dept</u>	<u>8-20 follow up - staff - PI</u>	<u>communicated with PI</u>
Done Date: <u>① 8/16</u>		



## PROCESSUS

## Production alimentaire

**DÉFI :**

Atteindre Max. 2 erreurs / sem

d'ici le 31 décembre.

CONDITION CIBLE:

Condition cible :

Atteindre 4 erreurs de  
commandes d'ici 3 sem.  
(1<sup>er</sup> mai). en maintenant  
le nouveau menu.

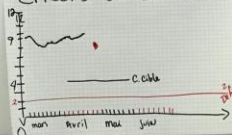
2X2 COMPLÉ

CONDITION ACTUELLE:



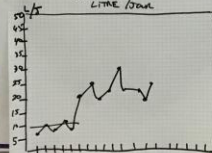
MESURE DE MONITORAGE

## Erreurs de Commandes



MESURE DE MONITORAGE

GAS PILLAGE  
LITRE / TON



## CYCLES D'EXPÉRIENCES

[illegible]

2X2 EN



OBSTACLES / OPPORTUNITÉS D'AMÉLIORATION

FRIGO

- l'élément principal est une doublette ou un quadruplet qui donne un point de vue sur le caractère des personnes
- l'usage du conditionnel permet de voir la réalité
- l'ironie est une manière de se moquer de soi-même, de la situation, de la vie
- le point de vue est toujours subjectif, le point de vue personnel est souvent plus intéressant que le point de vue objectif
- l'ironie : le point de vue sur la vie
- l'ironie permet d'expliquer les actes des personnages, ses faits et gestes, de les juger
- l'ironie
- les traits les plus forts (une de la mort, du mal) dominent le point de vue
- l'ironie permet de juger, de se moquer, d'être plus ou pas digne
- une ironie est un dialogue
- l'ironie permet de juger



# Content

## 1. What is risk management

- Defining risk
- Ethic asks us to do what?

## 2. How to identify the risks

- Process mapping
- Identify the risk
- Evaluate the failure mode
- Select the risk priorities

## 3. Mitigate the risk

- Problem solving
- MANAGE the process

## 4. Maintaining the improvements

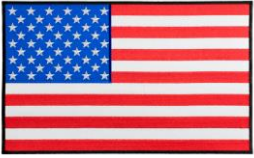
- Quality Assurance Program



# Risk management method

HACCP (Hazard Analysis and Critical Control Point)





# HACCP and ISO 13 485



## Identification and analysis of risks

(Over and above a documentation system)

1. Identification of **critical control points**
2. Establishing **critical limits** for each point
3. Establishing **monitoring** procedures for each critical point
4. Establishing **corrective actions**
5. Establishing **audit procedures**
6. Establishing **documentation procedures** (Record Keeping)






# Risk management and standards

---

- Standards contribute to risks reduction
- But limiting ourselves is not taking in account the **expected unexpected** events
- So, up to what level should we go beyond the standards to prevent the identified risks?





**THANK YOU!  
GOOD LUCK!**

## Jean-Marc Legentil

Jean-Marc Legentil is the President of Bell Nordic Consulting from Canada.

Mr. Legentil has begun his career with Johnson and Johnson and Abbott Laboratories where he was plant manager for sterile products. After 14 years in the industry, Jean-Marc started a consulting firm in 1990 dedicated to training and consulting in the areas of operation management, innovation and continuous improvement to service and manufacturing organizations, healthcare and social services. The main projects he works on are continuous improvement and process review for regional and university hospitals in Canada. He is Master Black Belt (Sensei) in methodologies such as Kaizen, Lean and Six Sigma. His publications of methodologies in French and English addresses the implementation of quality systems and continuous improvement/process review.

In the community, Mr. Legentil is well known for teaching classes and seminars for over 30 years at HEC Montreal and ÉTS, an engineering school. He is President of the board of a training center for nurses: CFP des Métiers de la santé CSMB. His recent speeches on Lean in the CSSD were to AQRDM in Canada, WFHSS in Sao Paulo, Brazil and Antalya, Turkey and Lean in the OR at the JAOM congress in Tokyo, HSCN in Toronto and at GISEH in Quebec. Now in beautiful Mexico City with WFHSS in 2018!

Email : [jean-marc.legentil@bell-nordic.com](mailto:jean-marc.legentil@bell-nordic.com)

Phone : (514) 497-1542



 **Bell Nordic inc.**  
Libérateurs de génies  
Igniting Genius

100, boul. Alexis-Nihon, suite 410  
Saint-Laurent, Québec H4M 2N9

## Dr Richard Marchand

- Dr Marchand completed his training in medicine in 1980 at the University of Montreal. He obtained his speciality certification in Internal Medicine in 1984 and in Microbiology and Infectious Diseases in 1986. He directed the Cellular Immunology Lab. at Ste-Justine Hospital in Montreal and the Flowcytometry Unit at the University of Montreal from 1989 to 1997.
- Since 1997 he is in charge of the Microbiology lab. of the Department of Medical Biology at the Montreal Heart Institute, where he also practices Infectious Diseases.
- As an Assistant Professor of medicine and an Associate Professor at the Ecole Polytechnique of Montreal (Engineering school), he directs several student to Master and Ph.D. degrees.
- His research interest are in the fields of sterilization, disinfection of medical devices, and biocompatibility issues.

