

# RENOVATING ISOLATORS AFTER ACTIVITY PRODUCTION INTERRUPTION, A CHALLENGE WHICH GENERATES RISKS



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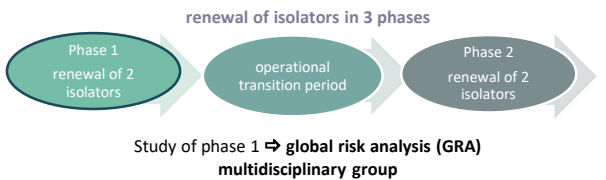


## INTRODUCTION

The Production and Control unit for cytotoxic drugs includes 4 double-posts isolators. The ageing of these isolators leads to an increase in breakdown and curative maintenance operations. In order to guarantee the quality of patient care, a project to renew the 4 isolators has been initiated. It's essential to maintain the production activity during the renovation and the qualification periods. (between 110 and 130 preparations dispensed per days)

- GOALS :**
- anticipate dangerous situations and guarantee the quality of preparations and the continuity of the service by carrying out an *a priori* risk analysis to identify the risks associated with these critical periods (flows deterioration, working conditions, reduction of production capacity).
  - develop an appropriate strategy to control these risks.

## MATERIALS AND METHODS



- 1 - GRA system**
  - identification of dangerous situations
- 2 - GRA scenario**
  - identification of accident scenarios
  - assessment of their criticality by rating their severity (G) and their occurrence (V)
- 3- Management of risk reduction actions**
  - Development of corrective actions
  - Determination of residual criticality

## RESULTS

### 1 GRA system

**Studied system :** Process of preparation of cytotoxic drugs during the first phase of change including a phase of work (T1) and qualification (Q1)  
 → 38 identified dangerous situations

### 2 GRA scenario

38 accident scenarios were listed (Fig.1)  
 → 23 during the work period and (T1)  
 → 15 during the qualification period (Q1)

		G				
		1	2	3	4	5
V	5	1	3	7	2	
	4	1	3	2		
	3	2	2	5		
	2	2	2	1	1	
	1	5	1	1	1	

Fig.1 : Criticality of accident scenarios

	T1	Q1
C1	6	4
C2	8	3
C3	9	8
Total	23	15

17 C3 scenarios  
11 C2 scenarios

### 3 Management of risk reduction actions

- Examples of risk reduction measures :
- Increase in standard preparation stock
  - reorganization of staff/hours during T1 and Q1
  - preparation of non-cytotoxic preparations in the preparatory (Monoclonal antibodies)
  - Outsourcing part of the production

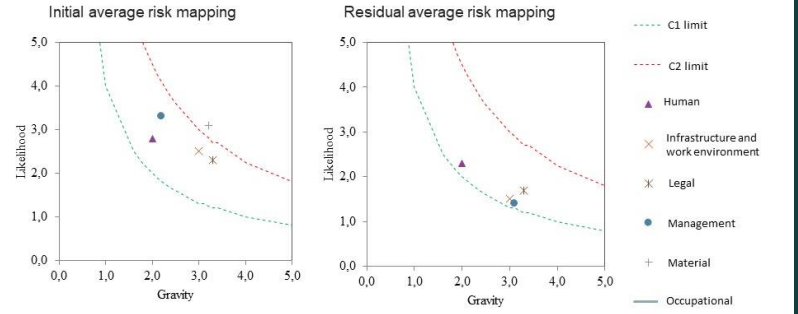


Fig. 2 : Residual risk assessment

## DISCUSSION-CONCLUSION

The GRA enabled us to exhaustively analyze risks associated with this particularly sensitive project and to identify underestimated or even omitted risks. Today this work continues in order to evaluate new risks associated with possible identified actions and to determine risk control indicators for each remaining C2 risks to guarantee preparations, staff and patient safety during this high-risk period.