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Microbial contamination of isolators: from risk analysis to decision-making flowchart

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INTRODUCTION

How to deal with microbiological non-compliance of production equipment is a difficulty for the teams and regularly leads to delays and heterogeneous decisions.

A Preliminary Hazard Analysis (PHA) was carried out in our chemotherapy preparation unit to determine possible areas for improvement.

METHOD

- Multidisciplinary working group (pharmacists, operators)
- 8 meetings between march and october 2021
- Two scales were definied to evaluate **initial and residual criticality**
- After the implementation of the corrective actions.

→ Identify, analyze, prioritize, and assess the risks associated

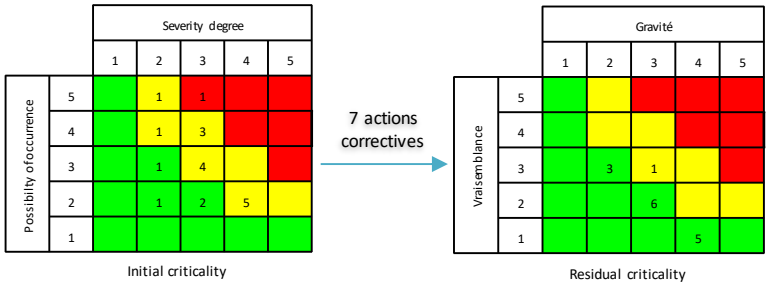
RESULTS

Hazard mapping → 3 phases identified: Sampling conditions | Continuation of activity | Preparations made from the positive sample

6 main dangers
10 specific dangers
20 basic dangers
→ The phase with most dangerous situations is the sampling conditions

28 priority situations
18 scenarii developed

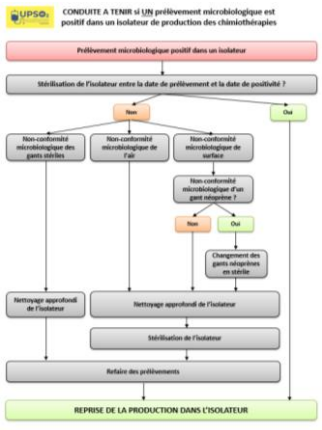
Priority 1	Priority 2	Priority 10
15	9	4



7 corrective actions

- **Creation of a decision-making flowchart** on what to do in the event of a positive microbiological sample from an isolator
- Simplification of sampling procedures
- Acquisition of a second oven
- Uptading of the check-list of action in the ZAC
- Creation of a summary table of the type of agar used and sampling frequencies
- Creation of an e-mail alert
- Validation of sterility test on preparation by media-fill test

Flowchart



DISCUSSION - CONCLUSION

This PHA made it possible to review the possible situations and propose a decision logigram describing the action to be taken in the event of a non-compliant microbiological result, allowing for faster and more consistent decision-making. A re-evaluation of the effectiveness of this new procedure is planned one year after its implémentation.