Assessment of the microbiological impact of an isolator failure on the working environment

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COM23-27086

Context

- High-risk preparations are carried out in vacuum isolators in controlled area
- Isolator failure ➔ Maintenance of sterility in the working environment ?

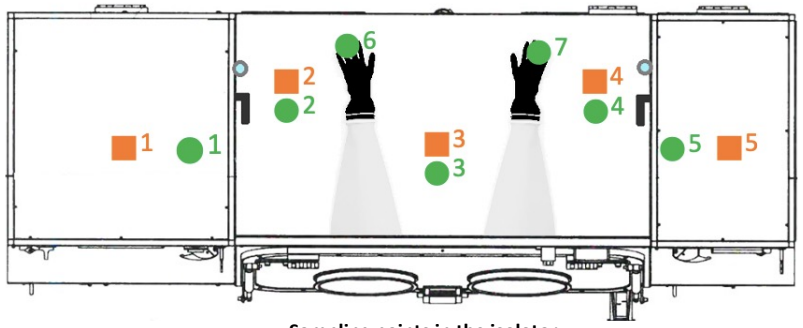
Objectives

1) Define the various problems or situations that can lead to the failure of an isolator and prevent them through the implementation of appropriate actions
2) Determine the microbiological impact of an isolator failure on the working environment

Materials and methods

Brainstorming : identification of potential causes of an isolator failure → Implementation of 2 Ishikawa diagrams to structure and classify into 6 categories → Rating failures using a FMECA → Assessment of the microbiological impact of an isolator failure

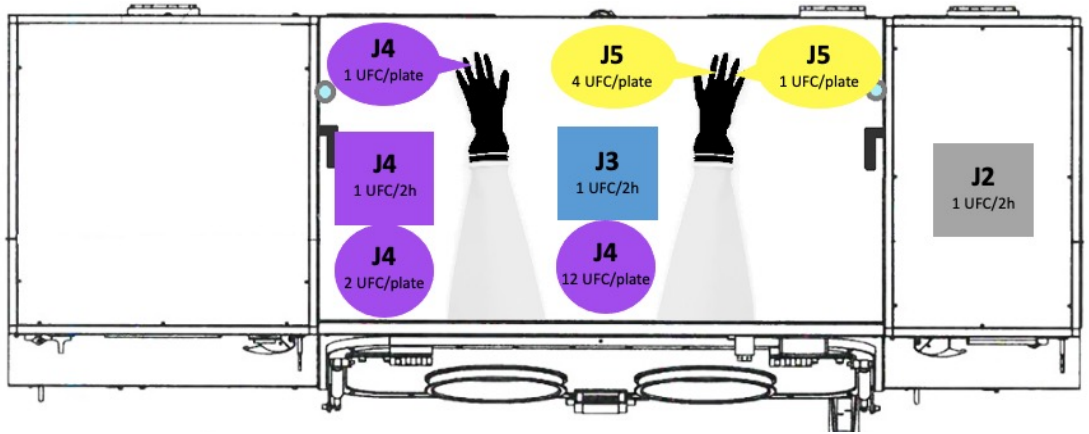
- ➢ Voluntary switch off of an isolator and environmental monitoring for 5 consecutive days with simulated activity ;
- ➢ Use of settle plates and contact plates with TSA medium ;
- ➢ Incubation at 22,5 ± 2,5 °C for 3 days and at 32,5 ± 2,5 °C for 2 days ;
- ➢ Reading results by UFC count and identification of the microorganisms involved.

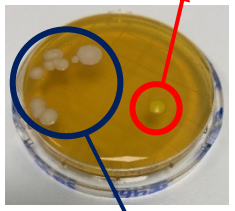


Sampling points in the isolator
■ = settle plate [sedimentation time = 2 hours]
● = contact plate

Results

✓ Growths detected during microbiological impact assessment :





Micrococcus sp.

Staphylococcus sp.

Additional information on the 29 identified failures and the microbiological impact assessment

Conclusion

- ✓ Identification and quantification of potential risks associated with an isolator failure ;
- ✓ Assurance of being able to finish the current work session when a failure occurs.