

Background

The Cytotoxic Production Unit (CDP) is equipped with N1000 and N4N2 isolators (JCE Biotechnology®).



⚠ Power supply incidents (ou failures) occurred, causing the isolators to shut down and potentially compromising sterility. Depending on the type of isolator, this resulted in a potential loss of airtightness and/or a shutdown of the air treatment system, thereby no longer ensuring the sterility.

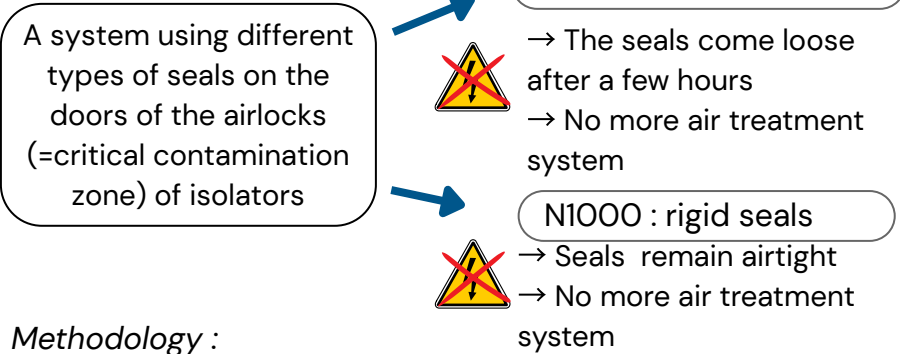
➡ Production could only be restarted after a time-consuming full sterilisation process, directly affecting patients by delaying treatment administration.

Objectif

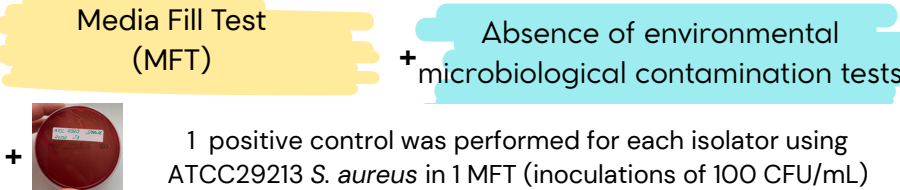
Determine how long the isolators remain sterile after a power outage (or failures, loss of power supply).

Matériel & Méthodes

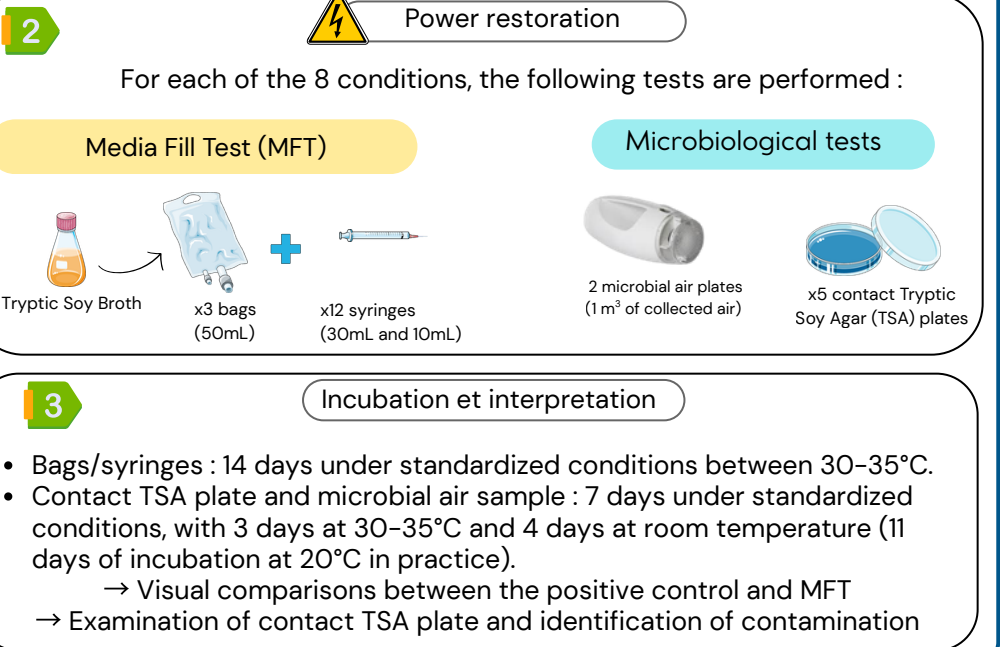
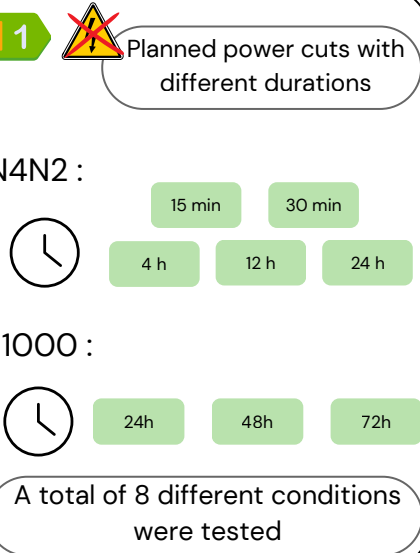
Available at the CDP :



Methodology :



Manipulation protocol :



Results

N4N2 isolator :

Power cut duration	MFT	Contact TSA plates	Microbial air plates
15 min	-	-	-
30 min	-	-	-
4h	-	-	-
12h	-	-	+
24h	-	-	-

Tab 1. Environmental microbiological and MFT results following a power outage on isolator N4N2

- ✓ All MFT tests were negative.
- ✗ Microbial colonies found on environmental agar plates.

N1000 isolator :

Power cut duration	MFT	Contact TSA plates Test 1	Contact TSA plates Test 2 *	Microbial air plates
24h	-	+	-	-
48h	-	-	Unfulfilled	-
72h	-	+	-	-

Tab 2. Environmental microbiological and MFT results following a power outage on isolator N1000

(*) Contact TSA plates were tested positive well beyond the recommended shelf life periods specified in the European Pharmacopoeia for test 1, which led to a second test.

- The following commensal environmental bacteria were found on environmental TSA plates in which there was microbial growth :
- ➡ *S. capitis*, *S. hominis*, *A. viridans*, *K. sedentarius* et *C. suicordis*.

Discussion/conclusion

- Keeping the production process and the isolator environment sterile for a limited period of time.
- Periods of 48 hours and 4 hours have been specified for maintaining sterility in the N1000 and N4N2 respectively.
- Further tests are being considered for the N4N2, for durations ranging from 4 hours to 12 hours.