

Risk analysis Freezer Challenge

This document provides a format for a risk analysis regarding participation in the Freezer Challenge. It helps laboratories to take a risk-based approach to freezer disposal in accordance with ISO 15189:2022.

Fill in the fields below and adjust to the local situation where necessary.

Process / Activity	Mogelijk risico	Probability (low/medium/high)	Impact (laag/middel/hoog)	Controls	Residual risk	*Risico score (Kans x Impact)
Sample Removal	Removing relevant material too early	Low	High	Compliance with current retention periods and approval of management	Low	
Cleaning up freezer inventory	Loss of traceability	Waist	Middel	Digitale log + protocol voor registratie	Low	
Transport of removed material	Unsafe device removal	Low	Low	Use certified waste treatment process	Low	

*Risk score (Probability x impact)

Green (1–3) = low risk, usually acceptable.

Yellow (4–6) = medium risk, needs attention.

Red (7–9) = high risk, measures required.

Note: This risk analysis must be approved by the quality officer and recorded in the quality management system. Always document who performed the analysis and when it was revised.