

Biological Risk Management and Containment

Fermentation Facilities

Containment Laboratory Guidelines

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Record of Amendments to Version 2.1

Date	Page number	Nature of amendment
30/11/24	all	University logo updated
30/11/24	6	Scitrack updated

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1. Who are these guidelines for?

These guidelines are intended for **principal investigators (PIs), designated persons in charge, designated laboratory person (DLPs)**, technical staff and students trained in the safe use of **risk biologicals** in appropriate containment facilities with specific reference to cultures for the purposes of generation of recombinant protein in standalone culture. The room and the standalone culture vessel is referred to as a Fermentation Facility.

Note that fermentations must not exceed the maximum safe capacity for the fermentation vessel as defined by the manufacturer.

2. Fermentation Vessel Placement and Local Rules

The following requirements must be observed:

- Fermentation vessels must be placed and operated within a spill tray capable of retaining the entire volume of the culture media in the event of a spill (i.e. total volumes plus 20% margin of safety)
- Fermentation vessels must be located in areas to allow easy access for cooling water supplies, controlling equipment, maintenance and spill clean up
- Rooms with fermentation vessels must have facilities for handwashing
- Local rules which include manufacturer's instructions and clean up procedures must be posted next to the fermenter.
- A notice or log-book will be readily available to indicate current person using the fermenter and the identity of the culture.
- Sufficient Approved Decontamination Agent (refer to Expert User Guideline on Chemical Decontamination of Liquid Biohazardous Waste) to decontaminate the largest spill must be readily available.

3. Spill Containment and Contingency Plans

Notwithstanding that fermentation vessels are double skinned and capable of retaining with contents, the following additional requirements will mitigate risk:

- Fermentation vessels are placed and operated within a spill tray capable of retaining a volume 20% larger than the maximum capacity of the vessel (i.e. total volumes plus 20% margin of safety).
- Clean up procedures are posted as part of Local Rules posted next to the fermenter.
- Person responsible for each fermentation is clearly identified and will be readily available.
- Sufficient Approved Decontamination Agent to decontaminate the largest spill is readily available.

In the event of a spill, the following procedure will be followed:

- Sufficient approved decontamination agent will be poured onto spill and left for at least 1 hour before any clean up commences.
- The decontaminated spill will be absorbed onto paper towels which are then placed inside bucket and autoclaved.
- Once autoclaved the material is then disposed as medical waste.

4. Training

Fermentation vessels are computer controlled and therefore their operation is quite complex.

The **Principal Investigator** (PI) in charge of the Fermenter will ensure that any person who uses the fermenter has read and understood the manufacturer's instructions and the local rules. The PI may delegate this task to a **Designated person in charge**.

5. Definitions

Designated laboratory person (DLP) means the trained person in each research group who has been given the authority to receive purchase requests made in SciTrack and to make a formal request for a purchase order via PeopleSoft. In containment and transitional facilities DLPs will have additional training to enable them to scrutinise documentation for restricted items and provide support to researchers.

Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager or an appointed delegate.

Principal Investigator (PI): In the context of hazard containment and transitional facilities, a principal investigator is the holder of an independent grant administered by the University and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader." The PI is responsible for assuring compliance with applicable University standards and procedures, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks, they retain responsibility for the conduct of the study.