

ISHAGE 2001 – TECHNICAL BREAKFAST 1& 16
STORAGE and CRYOPRESERVATION of CELL PRODUCTS

General Issues in the Storage of Cryopreserved Products

A cell processing laboratory must provide for and develop policies and procedures to address the following:

Storage Condition & Duration – must decide on the storage conditions and equipment to be utilized and take into account the duration of storage.

- Mechanical vs Liquid Nitrogen Storage Banks
- Liquid vs Vapor Phase Storage
- Storage Temperature
- Quarantine Storage
- Volume and # of Containers
- Short-term vs Long-term storage

Storage Space (Facility) – the storage facility is the room(s) that contain the storage bank(s). The storage facility must have the following characteristics:

- Lockable and limited access
- Proper lighting and ventilation
- Floor supports to handle the heavy weight load
- Floor material (epoxy resin) resistant to cryogenic temperature
- Emergency power outlets
- Ergonomic layout of equipment for workflow and safety
- Safety built-in – for example: oxygen sensor, cryogenic gloves, eye protection

Monitoring of the Storage Facility and Equipment – must be able to maintain and document desired storage conditions. Must be able to detect and respond to equipment problems, failures or other emergencies. Need to have the following:

- (24 / 7) monitoring
- alarm checks, validation and audits
- procedure for alarm response
- emergency / disaster plan
- back up storage

Inventory System – must have a system that expedites finding and accounting for specific cell products in the storage facility. The inventory system utilized must be auditable and safeguarded from unauthorized and unintentional modification or destruction. Back up or redundant systems are “typical” and recommended. Sample inventory methods are:

- Card System
- Worksheet System
- Computerized Spreadsheet System
- Computerized Database System