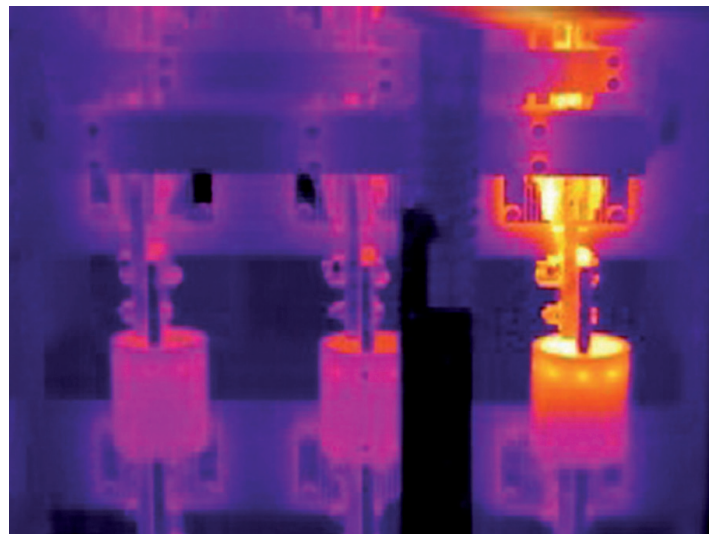




Science & Technology

INSURANCE BROKERS

Protecting Perishable Property



[Redacted text]



[Redacted text]



[Redacted text]



Insurance for your reputation



www.m-f-l.co.uk

MFL Science & Technology Barlow House Minshull Street Manchester M1 3DZ
5th Floor 2 Wellington Place Leeds LS1 4AP T 0113 366 2274
Telephone 0161 236 2532 Fax 0161 236 2583 Email info@m-f-l.co.uk

The Loss Control Services team at Chubb Insurance has compiled a general advisory article on how science-based companies can exercise good risk management in order to avoid the sometimes expensive consequences of malfunctions and power loss. It has been reproduced with the kind permission of Chubb Insurance Company of Europe.

Core principles of risk assessment

A malfunction or loss of power to refrigerators or freezers can be devastating to biotechnology companies. Drug discovery companies as well as contract manufacturing or research organisations are no less immune from risk. Incidents arising from a change in controlled environment can be very costly.

A successful risk management programme integrates a planned approach to minimise the impact of losing critical cell lines or other sensitive property.

Quantify the risk

The first step is to understand the significance of your perishable property and the risks associated with the controlled environments.

Values may range from a few hundred pounds to millions, often requiring months of replacement lead time. This can negatively impact revenue and relationships.

The initial risk assessment should include the following steps:

- Itemise the perishable property stored in each refrigeration unit.
- Identify critical temperature thresholds.
- Determine how long it will take the unit to reach the critical temperature in the event of power loss or other failure (refer to the refrigerator manufacturer guidelines).
- Calculate the replacement cost of

the property, including reconstitution.

- Estimate the impact on operations, business relationships, contractual responsibilities, and ensuing revenue implications if the temperature range is not maintained.
- Evaluate current controls, including maintenance programmes.

Manage the risk

There are always a number of solutions available to manage exposure to changes in controlled environments. Duplication and separation of critical sensitive materials is a key to minimising the impact of the loss of a refrigeration unit. The combination of solutions needed to manage your exposures depends on the risk assessment outcome.

- Duplicate refrigerated contents in multiple refrigeration units.
- Consider storing redundant/duplicate biologic material in a separate refrigeration or freezer unit.



Many companies have multiple freezers. However, on further investigation we often find that the spare ones have insufficient capacity to store additional stocks.

- Ensure that additional freezers and coolers have sufficient capacity to

store all of the contents of a failed unit.

- Place additional refrigeration units on separate circuit breakers.
- Depending on the critical nature of the material stored and the likelihood of a widespread power failure, consider the duplication of critical stock in a separate fire area, a separate building, or at a separate distinct location.

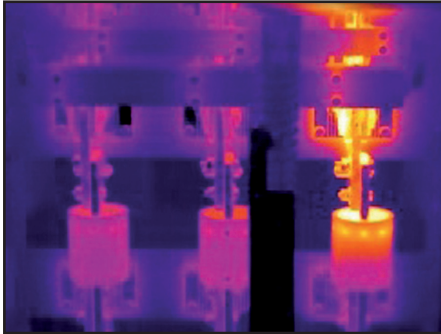
Maintenance of power supply

Spoilage incidents often come from power supply issues. Many incidents stem from procedural short-comings, such as contractors turning off the electrical power without realising the consequence for spoilage. An even more common mistake is moving the refrigeration unit from one side of the room to another and forgetting to plug it in again. Consider the following best practices to avoid these common mistakes:

- Hard wire refrigeration units into the wall rather than via a plug and socket.
- Good contractor selection and close supervision is essential for any business.
- Highlight critical issues as part of their orientation process. Unless told, a contractor may not differentiate between a refrigerator full of cell lines and a refrigerator containing food. To minimise this exposure, consider a process specific permit system.
- Use infrared thermography to scan for abnormal operating temperatures in electrical and mechanical systems. This inspection technique is conducted on energised equipment to identify hot spots. Early detection of problems provides the opportunity to address hazards with an inexpensive correction that can prevent equipment failure.
- Where the preservation of sensitive stock is critical, the provision of a reliable backup power supply must be a high priority. Generators need an auto-start mechanism and must have sufficient fuel to last until either power can be restored or alternative arrangements made for the storage of the refrigerated materials. In addition, it is imperative that scheduled

maintenance and regular load-testing take place on the generators.

- Voltage surge protection should be considered for either the building as a whole or for critical refrigeration units. This is also key to protecting your property against the effects of a lightning storm.



Carrying out a routine infrared thermography inspection with one of our clients highlighted a damaged fuse that cost a few pounds to repair – imagine the cost if the fuse had blown and loss of power had ensued.

Provision of alarms and emergency response mechanisms

In the event of a refrigeration unit failure, it is important that early detection of a change in temperature is achieved so that corrective action can be taken. Manual monitoring at scheduled times is only as reliable as the individual taking the measurement. An automatic alarm connected to a central monitoring station is generally more reliable.

If an automatic dialler type alarm system is used, it is imperative that the dialler does not stop calling the responder list until a person is reached. It is not enough for the dialler to accept a voice mail or answering machine and stop dialing. Most dialler systems require the responder to put in an access code to ensure that a person actually received the alarm.

Another factor to consider is the type of alarm response. Your emergency response plan should ensure that an engineering response and solution can be achieved within the critical thaw times identified. Communication of the plan to

all relevant parties is extremely important.

Fire department pre-planning

Fire personnel are trained to shut down power on arrival at a site. Pre-planning with the fire department could avoid this. By letting them know there is temperature-sensitive property on site, they can be trained to maintain electricity to critical areas, thus minimising damage.

Liquid Nitrogen Dewars

Liquid nitrogen dewars provide different exposures than refrigerators and freezers and require some different solutions. They are not reliant on the electrical supply and are portable and flexible, which is why they often contain critical stocks and raw materials.



One company stored more than £3 million of cell lines in each of four dewars. None were alarmed for temperature or low liquid nitrogen. In addition, all dewars were stored in the same room within the facility. The loss of the contents of any one of these would have created significant issues for the company. During a routine visit, this situation was identified and resolved in order to protect years of accumulated research and development investment.

However, the very low temperatures involved often give a false sense of security. Although temperatures may be low, the critical thaw temperature is also likely to be low.

Consider the following controls to help reduce your exposure to risk:

- Ensure the temperature alarm is set low enough to ensure an emergency response in an appropriate time frame.
- Make sure you include low liquid level alarms to ensure that manual refilling liquid nitrogen operations are completed, especially as human error usually plays a large part in any loss.
- It is worthwhile having a liquid nitrogen auto-fill system to support manual procedures in place.
- Liquid nitrogen back-up tanks should be available that are large enough to store all stock when needed.
- As with conventional refrigeration appliances, duplication between units and sites should be strongly considered.
- The benefits of focusing on risk management are clear – you will significantly reduce your exposures and prevent or minimise disruptions to your business. Moreover, good risk management strengthens customer and shareholder confidence.

This document provides general advice only. It is offered as a resource to be used together with your professional insurance advisors in maintaining a loss prevention programme. No liability is assumed by Chubb or MFL for the information contained in this document. Chubb refers to the insurers of the Chubb Group of Insurance Companies. This article has been reproduced with the kind permission of Chubb Insurance. McParland Finn Ltd gives no warranty as to the accuracy of the information contained herein nor accepts any liability arising there from.

For further information, contact:

Mark Philmore ACII, Director

Direct Dial: 0113 366 2359

Fax: 0161 236 2583

Email: markp@m-f-l.co.uk

Web: www.m-f-l.co.uk