



Critical Coverage

400

300

200

100



Recognising and responding to the common causes for the deterioration of stock contained in a controlled environment is vital in the long-term battle for cost and operational efficiency. Keith Gallois and Gerry Heffernan of Chubb Insurance report

Keith Gallois is a Senior Loss Control Representative at Chubb Insurance and an Associate of the Chartered Insurance Institute. Keith has over 16 years' experience of managing risk for multinational clients, with the last five of these specifically targeted towards the biotech and medical device industry. As well as providing risk management advice to Chubb's life science clients, Keith's role also embraces active risk management relationships with this industry sector as a whole.



Gerry Heffernan leads Chubb's Life Science Specialty Group in the UK and Ireland, and is a Senior Life Science Property Underwriting Specialist. Gerry has over 20 years' commercial underwriting experience, and for the past seven years has focused on the biotech and medical device industry. Through client interaction he has helped to develop policy wordings that target the unique and varied exposures faced by biopharmaceutical customers.

Wouldn't you rather be in control of the risks that face your business instead of hoping that your insurance policy will cover you in the event of a disaster? Property loss incidents within the biopharmaceutical sector are fairly infrequent, whereas losses arising from a change in controlled environment – mostly malfunction or loss of power to fridges or freezers – are comparatively high. The storage of refrigerated stock is a key exposure faced by most contract manufacture or research organisations, and the successful management of this exposure needs to form part of any integrated risk management programme.

ASSESSING THE RISK

To understand the risks you face, the first thing you need to do is carry out an initial assessment of the risk exposure. You need to evaluate how business-critical the contents of the refrigeration units are. Values may range from a few hundred pounds if contents are stored there merely to extend shelf life, to hundreds of thousands of pounds and months of valuable time to replace, impacting your revenue and your client's research and development operations. An initial assessment should include the following questions:

- ◆ What perishable property is stored in each refrigeration unit?
- ◆ What are the critical temperature thresholds and how quickly could these be reached? The refrigerator manufacturer guidelines should outline how quickly the unit would lose temperature if power failed.
- ◆ What is the replacement cost of the property, including reconstitution?
- ◆ How well could the company maintain production if one or more units do not keep the contents at the required temperature and what would be the customer relationship and revenue implications?
- ◆ What current controls exist and how are these checked, implemented and kept up-to-date?

MANAGING THE RISK

There are always a number of solutions available to manage your exposure. The combination of solutions needed to manage your exposures depends on the outcome of the risk assessment.

Duplication of Refrigerated Contents

We are all told not to put all our eggs in the same basket and this is a saying we should stick to in business – the duplication and separation of critical business components is key to mitigating the risks you may face. The key questions you should be asking yourself to minimise the risks you face include:

- ◆ Can the biologic material stored in a refrigeration unit be separated, and/or duplicated and stored in an additional refrigeration unit on a separate power supply?
- ◆ Do your spare units have capacity to store all the contents of your other refrigeration units? If not, consideration should be given to purchasing additional capacity.
- ◆ What would happen if the premises were lost in a major incident such as a fire? You should consider the duplication of critical stocks in a separate fire area, or better still separate building.
- ◆ What would happen if a change of temperature occurred to all of your stocks, for example in a local or wide area power failure? The business impact could be critical and therefore duplication of stock should be considered at a location well away from the premises. On 14th August, 2003 there was a blackout in the Eastern United States: it affected 50 million people and took three days to restore power to the whole area. The financial impact was around \$6 billion. 2003 also saw large blackouts in London, Denmark, Sweden and Italy.

Maintenance of Power Supply

Most claims received due to change in temperature generally arise from power issues. Many of these stem from procedural

short-comings, such as contractors turning off the electrical power to the site without realising that in doing so the refrigeration units are starting to thaw. An even more common mistake is moving the refrigeration unit from one side of the room to another, and then forgetting to plug it in again! Ways to avoid these simple yet common mistakes include the following:

- ◆ The wiring of refrigeration units into the wall, rather than via a plug and socket is a relatively simple procedure and avoids the scenario of the plug being removed.
- ◆ The control of contractors is always critical in any business environment. As part of their induction process, critical issues need to be highlighted. Unless told, they might be unlikely to differentiate between a refrigerator full of cell lines and a refrigerator containing a pint of milk and a packet of sandwiches. Good contractor selection and close supervision is critical. To minimise exposure, consideration should be given to a process specific permit to work system.

The maintenance of electrical systems is key to minimising risk, and therefore procedures and controls should be put in place to ensure this. Carrying out an infra-red thermography inspection should also be considered – ask your insurer if they can do this as part of your insurance package.

Where the preservation of stock is critical, the provision of a suitable generator must be a high priority. Generators need a suitable 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 takes place. Whilst the installation of a suitable generator is preferable and may be looked upon more favourably by your insurer, if cost is an issue, you could consider hiring a portable unit. Contract terms for the generator hire should be scrutinised, comparing installation guarantee times against critical thaw times. Consideration must also be given to ensuring a method of connecting the generator to the building electrical installation. The cost of hiring a generator is around £400-£500 a week. Voltage surge protection should also be considered for either the building as a whole or for critical refrigeration units. This is key to protecting your stock against the power of an electrical storm.

Provision of Alarms and Emergency Response Mechanisms

In the event of a refrigeration unit failure, it is important that early detection of a change of temperature is achieved so that corrective action can be taken. Manual monitoring at scheduled times is better than nothing, but is only as reliable as the individual taking the measurement, which, outside normal hours of operation, is usually a contract guard. An automatic alarm linked to a central monitoring station could therefore be far more reliable. Another factor to consider is the type of alarm response. Your emergency response plan should endeavour to make sure that an engineering response and solution can be achieved within the critical thaw times identified. Communication of the plan to all relevant parties is critical. Solutions to avoid these risks don't always need to cost thousands of pounds. Often the solutions can be simple and cost

little. Some companies have a contract with an ice supplier to supply ice at short notice in the event of a unit failure. Many others make use of bottled gases, supplying a fixed period of coolant.

Fire Brigade 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, where possible, in the event of a fire to maintain electricity to critical areas thus minimising damage.

Liquid Nitrogen Dewars

Liquid nitrogen dewars provide different exposures to refrigerators and freezers and could require some different solutions. They aren't reliant on the electrical supply and are portable and flexible, which is why they often contain critical stocks and raw materials. 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. Controls to consider in order to help reduce your exposure to risk include the following:

- ◆ Ensure your temperature alarm is set at a low enough temperature to ensure an emergency response in an appropriate time-span.
- ◆ 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.
- ◆ Duplication between units and sites should be considered.

BEST PRACTICE

The solution or range of solutions that a biopharmaceutical contract manufacturing or research company should employ will be dependent on the risk exposure present. The benefits of focusing on risk management are clear – you will significantly reduce exposure and prevent or minimise disruption to your business and/or your client's business. Moreover good risk management strengthens customer and shareholder confidence. By taking into account some of the areas highlighted, and demonstrating the importance and integration of risk management within your business, you can also enter into a stronger relationship with your insurer and reap the rewards. These may include: securing the correct and widest coverage available for your business, thus ensuring your own peace of mind; more control over your insurance programme; lower deductibles across some areas and less likelihood of a loss developing, thereby avoiding or minimising interruption to your business.

Having in place good risk management controls and procedures, and an insurance company that really understands the risks you face, are two clear ways to ensure that you really have got it covered! ◆

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