

REFRIGERATED STORAGE IN THE PHARMACEUTICAL INDUSTRY

ALLIANZ RISK CONSULTING



This Tech Talk examines why refrigerated storage losses occur and offers mitigation tips to minimize loss and damage.

AT-A-GLANCE

- Refrigerated warehouses in the pharmaceutical industry are not only subject to fire hazards. Loss of refrigeration and lack of effective emergency response procedures can also cause large losses.
- Technical redundancy, preventive maintenance, temperature monitoring and emergency response procedures can prevent losses.
- Refrigeration systems supplying high value and business critical goods should be treated as safety critical.

INTRODUCTION

Refrigerated storage is widely used in the pharmaceutical industry. The stored goods often represent high value products such as finished goods, business critical intermediates, strategically important buffer stocks, and/or mother cell banks. The common denominator, in most cases, is that the stored goods must be maintained within a precise temperature range since they are sensitive to temperature fluctuations. Loss of refrigeration may not only cause high monetary losses, but may also cause undesired production and supply chain disturbances or increase the business risk exposure through the loss of a buffer stock.

WHY DO LOSSES OCCUR?

Allianz Global Corporate & Specialty's (AGCS) experience shows that losses typically occur when there are flaws in between layers of protection. Several large monetary losses in the pharmaceutical industry have occurred when loss of cooling (e.g. caused by machinery breakdown, loss of power, etc.) is combined with poorly managed alarm and response procedures.

The following are some examples of losses in the pharmaceutical industry which could cause large monetary losses:

- **Power outage in a refrigerated warehouse:** The Building Management System (BMS) was not supplied with emergency power and the warehouse's high temperature alarm was not transferred to an around-the-clock monitored location.
- **Miscommunication:** An operator forgot to close the door of a deep freezer warehouse. The high temperature alarm was received at the gate house and emergency response was ordered. Due to miscommunication, the response never came.
- **Breakdown of a refrigeration system control unit during plant shut-down:** Multiple high temperature alarms in the refrigerated warehouse were received at the same time as a result of the plant shut-down; there was no alarm priority list and the cold store alarm was simply forgotten.
- **Change in temperature limits and miscommunication:** Due to the breakdown of several air-conditioning units, the temperature in a refrigerated finished products warehouse rose to more than 8°C (46°F). Detrimental temperature was above 5°C (41°F), whereas the alarm temperature was set to 7°C (45°F). Changed storage conditions and alarm procedures were not effectively communicated between all parties.
- **Power outage causing loss of cooling in a deep freezer storage:** After a power outage, the emergency generator was started manually, but broke down when the site was unmanned during a national holiday. The stored goods were exposed to detrimental temperatures during the six hours it took to repair the generator.

In all of the above mentioned losses, high value goods were involved and all losses could have been prevented if there were effective alarms, redundant systems, and/or effective emergency response procedures in place.

ALLIANZ RISK CONSULTING (ARC) RECOMMENDATIONS

In an effort to minimize the damage that may occur from refrigerated storage losses, Allianz Risk Consulting has developed recommendations to primarily address refrigerated storage areas containing high value and process or business critical goods. The recommendations may, wholly or partially, be valid for all types of refrigerated storage areas where one wishes to reduce risk. The recommendations also apply to stock in refrigerated areas at third party locations which are under the care, custody and control of the building owner and building operator. Level of redundancies, layers of protection and emergency response times should always be carefully analyzed.



Proper refrigeration storage will reduce the risk of damage to refrigerated goods.

Please note that this Tech Talk does not address hazards related to fire, explosion, construction materials, chemicals or structural design. The following list of recommendations is not all-inclusive and should be used as a guide, taking into consideration specific refrigerated storage areas and business needs:

1. General

- a. Properly designed and well-insulated refrigerated storage can maintain the required temperature for up to 24 hours. This should be considered when designing the storage area.
- b. Cooling compressor units should be redundant (n+1) in order to cope with a single unit breakdown for a longer period of time. If redundant cooling compressors are not present, an insulated cold media buffer tank can act as a short term back up.

- c. Reliable emergency power should be provided for a minimum of 24 hours power outage.
- d. The refrigeration units should have an auto-defrost feature to ensure that the unit's temperature does not fall outside defined limits during the defrost cycle.
- e. Procedures should be in place to verify the temperature range is acceptable for the product. Changing temperature settings should result in a formal management of change process to ensure all necessary adjustments are made.

2. Location and Access

- a. Site refrigerated warehouses in an environment where the ambient temperature does not affect the temperature control within the unit. This normally means an external environment of between 10°C (50°F) and 32°C (90°F).
- b. Distribute goods to separate independent storage areas to reduce exposure to a single loss event. Monetary value and replacement time/value should be used as guidance.
- c. Restrict access to the refrigerated storage area to authorized personnel only. Maintain records of staff and goods movements.

3. Maintenance and Calibration

- a. Ensure only qualified and authorized personnel work on the refrigeration systems, and that preventive maintenance is conducted regularly.
- b. In order to prevent unintended operator errors, clearly label all equipment related to the refrigeration, including electrical supplies. Provide warning signs that turning off this equipment will result in a shutdown of the refrigeration.
- c. Ensure to have a 24-hour emergency contract with the provider of the refrigeration equipment. Emergency response by qualified maintenance should be available according to a specified response time.
- d. Test temperature alarm systems monthly and test/maintain uninterruptible power supplies (UPS) or alternative emergency power supplies per manufacturer's guidelines.

4. Temperature Monitoring and Alarms

- a. Provide redundant and independent temperature and humidity alarms. A back-up power supply (UPS) should be available for the alarms.
- b. Arrange for local audible and visual alarms at the freezer / cooling unit.

- c. In addition, transmit the temperature and humidity alarms to a continuously attended location. The following features should be considered:
 - The entire alarm transmission and receiving unit needs to be connected to an emergency power supply.
 - Clear instructions and updated emergency contacts need to be provided for the alarm center personnel (e.g. guards). These include prompt notification of the relevant utility operator and manager on duty.
 - The utility operator should investigate the reason for the loss of cooling (i.e. machinery, refrigerant leak, electrical power, etc.) and proceed according to the written contingency plan.
 - The alarm center should have an alarm priority system in case of multiple alarms. Temperature alarms should be treated as critical alarms. Alarm center personnel should be instructed to continue calling staff on duty (list) until a response is received.
- d. Cooling compressor and refrigeration unit performance should be connected to a Utility Management System (UMS) (i.e. facility and/or building, facility management system (FMS), BMS, etc.) with an alarm to the utility operator on duty in case of temperature deviations.
- e. Temperature and humidity devices should be calibrated at least annually.
- f. The margin between normal and detrimental storage conditions should be set at such a level that emergency actions can be taken before the goods become damaged.
- g. Regularly make audits of temperature/control procedures. Findings and action plans should be recorded.



Only authorized personnel should be allowed access to the refrigerated storage area.

5. Emergency Procedures

- a. In case of refrigeration failure, restrict access to the storage area to contain the cold air inside the room. Each time the door is opened, valuable cold air is lost.
- b. Maintain a formal contingency and emergency plan to relocate storage in the event of equipment failure. At a minimum, the plan should:
 - Include alternative warehouses that could be used.
 - Specify how temporary coolers/freezer trailers or containers could be obtained.
 - Provide time frames for response.
 - Specify critical temperatures.
- c. Training of personnel and exercises should be performed regularly (at least annually).
- d. In case of changed storage conditions (temperature/humidity), configuration and/or layout, ensure to update/revise:
 - Emergency response and continuity plans.
 - Guard, utility operator and officer on duty instructions.
 - List of alarm priority/procedures.

6. Plan Review

ARC can assist in the process of designing and building a refrigerated storage unit by conducting plan and procedure reviews in order to help reduce risk.

For further information, please contact ARC. For any insurance claims, please contact your insurance broker or AGCS.

QUESTIONS OR COMMENTS?

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Tech Talk is a technical document developed by ARC to assist our clients in property loss prevention. ARC has an extensive global network of more than 100 property risk engineers that offers tailor made, customer focused risk engineering solutions.

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