

Climate Technologies, Inc.

21516 Laytonsville Road, Laytonsville, MD 20882
Phone 301-548-0700 FAX 301-548-9038

Volume 1, Issue 4

**Useful information for architects, engineers,
and operators of controlled environment rooms**

Design and Application Issue: Risk Reduction in Controlled Environment Room Operation, Part 1

Controlled environment rooms (CERs) protect a product or process from certain conditions which would cause their deterioration or destruction. When the environmental conditions are not maintained, the client suffers a loss. The loss may be a direct monetary one or a loss of time and opportunity. CER operators bear the risk derived from the probability of system failure. Underlying sources of this risk fall into four categories: defects in materials or workmanship, design defects, service interruption, and normal wear.

Maintaining a constantly controlled environment depends upon the coordinated operation of many mechanical, electrical, and electronic devices. Malfunction of any critical device can destroy thousands of dollars of material or nullify countless man-hours of work. Electrical power, chilled water, deionized water, or building HVAC can be essential for CER operation. There is additional exposure to loss from the interruption of these services which can have the same result as component failure.

How do you reduce this risk? A substantial reduction in design and material related risk can be achieved by applying quality control

procedures during manufacture and installation of the CER. Thorough commissioning and testing of the completed system provides further assurance that system function is correct and reliable. This risk associated with design, material, and workmanship defects will naturally decrease over time. As the system accumulates operating hours, the "bugs" will become evident and can be eliminated as risk factors. But, while these methods are effective, their total impact is relatively small, related mostly to issues removed from the pool of risk factors after a single detected occurrence. There remains a continually increasing exposure to general equipment failure through service interruption or component malfunction and wear. The greatest reduction to this lifelong risk factor is accomplished in the design phase by incorporating features and functions which will detect and respond to events which can lead to product loss.

Accurate probabilities of the occurrence of malfunction for field built-up systems are not available. The customized nature of field installed equipment, arranged and configured for a specific location and purpose, makes useful sampling impossible. As a practical

substitute, qualitative analysis of the potential failure points, based upon client and designer experience, will determine the elements to consider for risk reduction. A thorough analysis will likely generate a frightfully long list of potential failure scenarios. The client's level of risk aversion will help shorten the list, with the probability of some occurrences being judged too remote for consideration. Other risk factors may be handled through structural or procedural changes within the organization, such as maintenance team response to certain alarms or the installation of a back-up electrical generator. There will, however, be failure modes that are deemed probable and costly enough to warrant the application of an automatic control response. These are the elements of risk that the CER designer can most effectively reduce with control and equipment enhancements.

Strictly for the purpose of this discussion, let us define a failure as a change in equipment performance preceding the occurrence of unacceptable environmental room conditions. This departs from the owner's normal view of failure. Generally, a CER operator will

Continued on next page



More on risk reduction for controlled environment rooms

define failure in terms of the environmental conditions to which the product is exposed. A statement such as, "The freezer temperature exceeding -10°C " may sum up a client's criteria for failure. Using the broader definition proposed here will target the events that precede undesirable environmental conditions. Early detection of failure conditions reduces risk by lengthening the time allowed for reacting to an impending emergency. Combine the additional time with responsive control system activity, and it is possible to avoid any loss of product due to equipment failure.

Consider a freezer room operating at -20°C with a maximum allowable temperature of -10°C . Monitoring room temperature will certainly provide useful information, but there are additional monitoring points that will provide early warning of an inevitable rise in temperature before it occurs. In this example, monitoring operation of the refrigeration system will indicate whether cooling is being accomplished or if the mechanical system is not performing in accordance with its commissioned rating. Without proper cooling system performance, the room temperature will rise. It may rise quickly, in the case of a complete failure of the compressor to operate, or it may occur slowly, in the case of a slow refrigerant leak. In either case, more response time and a reduction in the exposure to loss is achieved by detecting the conditions

that precede the rise in temperature.

Begin the process of risk reduction with a framework of three design objectives.

- 1) *Identify the failure modes that are judged likely to occur, or will have unacceptable impact, regardless of probability.*
- 2) *Devise a method for detecting those conditions at their earliest occurrence.*
- 3) *Endow the equipment with an automatic predetermined response that reduces the impact of each failure condition.*

It is not unusual or unreasonable for a client to lack the expertise or experience needed to delineate the wide array of failure conditions and responses. Do not hesitate to enlist outside help. Some good sources of information are free. Consult with in-house service personnel, outside service contractors, and owners or operators of similar equipment. Controlled environment room vendors can be a good source of information but may tend to limit their contribution to items included in their standard product offering.

Successfully completing the process requires thoughtful consideration of all the things that can go wrong with the system. Instead of thinking about the positive aspects of a new piece of equipment, try thinking of how it can damage or destroy valuable material. It can be

difficult, but keep in mind that the procurement objective is to reduce risk. Increased control complexity and costly hardware will be part of the risk reduction solution. These enhancements are unlikely to provide discernibly better environmental control, but that is not your objective here. Assume the environmental conditions will be achieved and develop or evaluate a design based upon its potential for effectively detecting and responding to improper equipment operation.

A control and hardware solution for risk reduction can be viewed as an insurance policy with a one time premium, the original purchase price. The benefit derived from the added expense is the avoidance of loss, not just recompense for it.

Inevitably, the analysis of risk in equipment operation leads to the issue of whether redundancy should be provided for portions of the operating equipment and instruments. This is the next logical step in risk management for controlled environment rooms and the topic of the next issue of *C.E.R. TECH NOTES*.