CONSULTING AND TECHNICAL SERVICES FOR ALL FACETS OF CONTROLLED ENVIRONMENT ROOM OWNERSHIP

Risk Reduction in Controlled Environment Room Operation

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 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 the design and material related risk can be achieved by applying quality control procedures during manufacture and installation of the CER. Careful review of the design submission may reveal some shortcomings of the proposed design that can be corrected prior to installation. Thorough commissioning and testing of the completed system provides further assurance that system function is correct and reliable. The 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 correcting them can reduce or eliminate their contribution to future equipment failure. But, while these methods are effective, their total impact is relatively small, related 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. As a practical substitute, qualitative analysis of the potential failure points will determine the elements to consider for risk reduction. Experience with other CER installations, designs, and operations will help the involved individuals produce a more useful set of results. Many clients could benefit from outside professional assistance in this process, since their experience and knowledge is generally limited to anecdotal accounts.

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 or professional consultant 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 likely departs from the owner's view of failure, defined in terms of the environmental conditions to which the product is exposed. A statement such as, "The freezer temperature exceeding –10^{O}C" may sum up a client's criteria for failure. The consultant's task is to use the broader definition proposed here and 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 this additional time with responsive control system activity, and it is possible to avoid loss of product due to equipment failure. This is certainly to the

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client's advantage.

Consider a freezer room operating at -20^{O}C with a maximum allowable temperature of -10^{O}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.*

There are many methods of monitoring system performance, most of which require specialized knowledge of CER operation and control processes for proper implementation. It is uncommon for a specifiers or purchasers to have the expertise or experience needed to delineate the wide array of failure conditions and responses. Vendors may not be especially helpful in this area, being driven hard by the market to deliver environmental performance at a competitive price. Purchasers of controlled environment rooms must make risk reducing features and designs part of the "minimum acceptable requirements" if wide vendor interest and effort is to develop in the industry. A major first step in risk reduction for many clients may be an admission that they do not possess the needed knowledge or time to complete the analysis and implement the solutions through an exhaustive vendor search and procurement. Short-cutting the process will significantly reduce the amount of benefit received.

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 overall procurement objective is to reduce risk, with a controlled environment being one aspect of the full scope of risk reduction.

Increased control complexity and costly hardware may 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 after the fact.

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 another CERTS article.

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