
The Case For Tighter Temperature Control

CER (Controlled Environment Room) design professionals and users must specify the allowable room temperature variance when considering the purchase or modification of a CER. This basic specification element has an impact on the owner's beneficial use of the chamber which extends beyond the obvious. Carefully combining the stated needs of the end user with other risk reduction strategies and developing a concise overall performance requirement will help meet the stated end user requirements, as well as those they may not have considered.

Assume the end user will be storing biologics in a cold room. When queried about the temperature control requirement, they are likely to indicate a need to maintain temperature at +2°C to +8°C. It is important for the specifier to determine the real import of the end user's stated requirement and how it will impact CER cost and operational features. Clients assign the specifier or design professional the implied task of going beyond merely the end user's stated requirement. After all, why hire a design professional unless they are going to adequately look out for their client's interests by having practical application knowledge and experience far beyond what the client can bring to bear on his own? As a design professional, how can you best serve your client in this particular instance? Continuing with the illustration shows that there can often be more to consider than just repeating the client's requirements in the procurement documents.

Given what the client stated in the example here, you could specify a setpoint of +5°C with a maximum variation of +/-3°C to meet the requirement. Is this the correct performance to specify? Can better performance be provided at little or no additional cost? Will the +/-3°C have an impact on other aspects of cold room operation of which the client is not aware? Let's consider one, only one, aspect of the coincidental effects that temperature control can have on room operation.

Enhancing the requirement to +/-0.5°C provides tangible benefits in system operation and product protection. A narrow variance range allows alarm points to be set close to the normal room operating condition, alerting the operator of an abnormal condition before the product is exposed to damaging temperatures. In our +5°C setpoint example, specifying +/-0.5°C maximum control variance enables alarms to be set at +6°C and +4°C, providing an alarm on the high side with a margin of 2 degrees before exposure of the stored product to unsafe or unacceptable conditions.

An additional benefit can be derived from more accurate temperature control. In the same example with better temperature control, we can operate at a setpoint of +3°C, still within the acceptable product range. Since this room's operation is primarily based on cooling, most failure conditions will send the temperature upwards. By maintaining the room condition near the low end of the acceptable product range and setting alarms

close to the normal room condition, we can increase the length of time allowed to respond to an equipment failure. With a setpoint of +3°C, you can have alarm points as low as +4°C, providing more time to take action and protect the product from damage or loss. Working with the original +/-3°C control specification provides no time to take any action to protect stored product from loss or damage because the alarm setpoints must be set outside the normal control range of the room, which in this example is the same as the safe range for the product.

What increase in control accuracy is appropriate? Certainly it can vary with each project and application. The client, when presented with a comprehensive and unbiased illustration of the trade-off between cost and benefit, can make the selection. At some point, the costs to achieve incrementally better temperature control and its associated advantages will balance with the client's tolerance for risk of loss. This is the level of control that should be specified for the project, along with a requirement for documentation of the as built performance with multi-point testing.

A reduction in the risk of product loss or damage can be attained through the implementation of better temperature control with reduced variance from the setpoint. This will allow enhanced alarm capabilities which provide the operator more time to take action in response to an alarm. There are



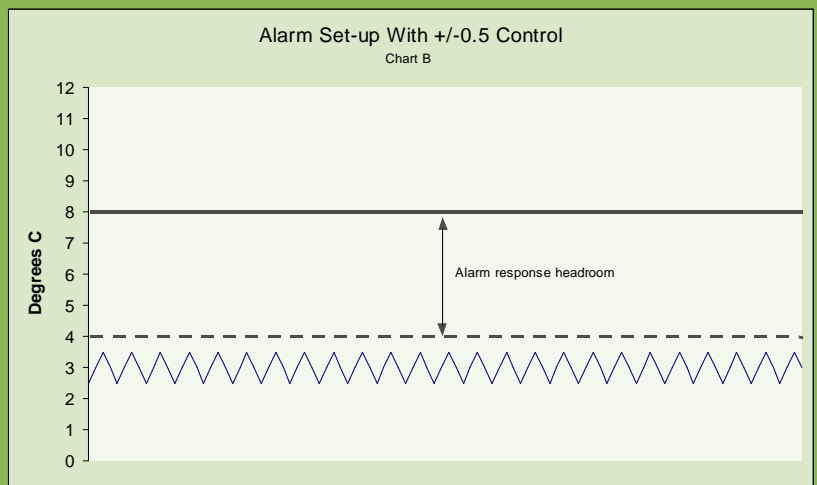
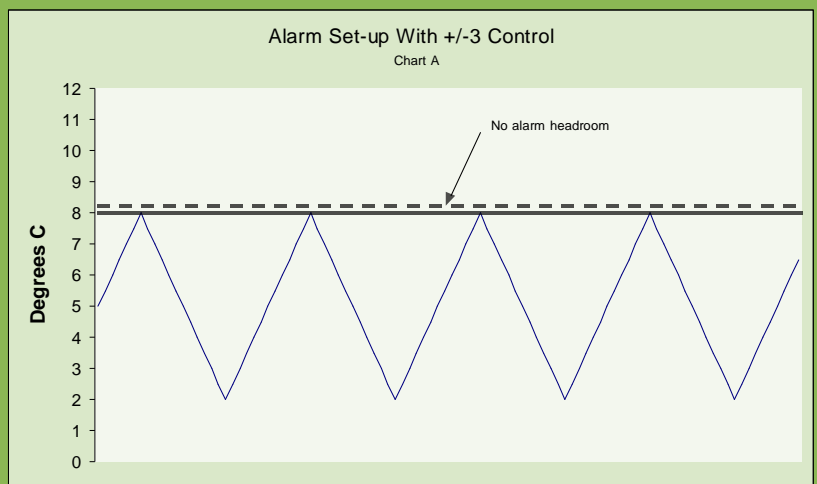
also more complex alarm and monitoring strategies that can be implemented to provide a degree of predictive notification of impending problems.

The two charts show how you can increase the alarm *headroom*, the difference between the maximum tolerable room temperature and the alarm setpoint, by reducing the normal room temperature fluctuation with better control.

The dashed line on both charts indicates the lowest alarm setpoint applicable to the level of temperature control indicated. Chart A shows room temperature control variation ranging over the span of acceptable product temperature, limiting the lowest alarm setting to a point which will notify the operator only that the stored product has already been exposed to damaging conditions. Chart B shows how increased headroom can be attained by controlling the room temperature within a narrower band and setting an alarm point further from the maximum tolerable room temperature.

Earlier notification of abnormal temperature variances, through the application of better temperature control, will lead to a reduction in the risk of product damage or loss. Other operational benefits can also be attained through a combination of better temperature control and more complex alarm strategies.

But how is a specifier to determine what is the best arrangement to include in the project documents? How can a purchaser evaluate proposals amid a storm of sales calls and efforts by various prospective vendors to influence their decision? Most purchasers have, at best, little experience with specifying and procuring this type



equipment, so how is the purchaser supposed to sort out all the technical details necessary to get what they need?

Controlled environment room planners and purchasers can seek out professional unbiased assistance in sorting out what will be beneficial and practical for their particular project. The professional consultant must have no ties to any manufacturer, so as to be completely unbiased. He or she is paid by, and works exclusively for, the purchaser in all matters. Extensive and specialized experience with CER control system design will help the consultant technically evaluate proposals for proper functionality,

assuring the client receives equipment and performance as specified and expected.

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