

## A Basis For Controlled Environment Room Documentation Requirements

Controlled Environment Rooms (CERs), have a long life cycle, often 15 to 20 years. During this time numerous components and subsystems will need repair, modification, and replacement. There will likely be several, if not many, different operators and users of the equipment. Safety and regulatory evaluation of the equipment and its performance will be conducted numerous times. New operating, maintenance, and safety procedures will be implemented in response to changing governmental and internal requirements. These and other factors demand that each CER is delivered with a comprehensive documentation set which empowers the client with information necessary to maintain useful, cost effective ownership of the controlled environment room.

### What constitutes “useful, cost effective ownership”?

A CER is a customized tool performing a specialized function necessary to a process operated by the client. In order to gain “useful” ownership, the client must be afforded the ability to efficiently perform any task necessary to keep the room performing at its rated capacity and range. Complete and concise documentation of the assembly and initial performance of the room is essential to providing the owner with this ability.

**Cost effective** means maximizing the benefit derived from an expenditure, or minimizing the cost to perform a needed task. In the case of the CER, the client needs the power to manage and maintain the equipment in the way most advantageous to his interests. Only a good documentation set can provide this advantage by “uncoupling” the client from the manufacturer as the only source of information necessary for repair, maintenance, training, and performance evaluation tasks.

### What tasks will require

### documentation?

The primary task, of course, is service support. Troubleshooting a problem will involve examination of control circuits and mechanical equipment to determine if they are functioning properly. On the electrical side, the service technician must answer many, if not all of the following questions....  
What are the controlling circuits? What are their functions? How are the functions of the various control circuits interlocked or interrelated? Where are the conductors located or connected? Which conductor of the many that may be connected to a piece of equipment is the correct one to check? What voltage, current, or resistance should be present in the circuit to verify proper operation? How can the control components be identified and located in the control panel?

Without clear and careful documentation of the electrical assembly of the CER, you are left with 2 alternatives....figure it out for yourself, or call the factory. Neither of these alternatives is likely to be cost effective because of the slow rate of information exchange. There are huge inefficiencies resulting from a failure of the manufacturer to generate and provide the client with information essential to ownership of the CER. Lacking needed documentation, the client and service technician are at the mercy of the collective memory of those individuals with the manufacturer who may have been involved with the initial design or installation of the CER. Their memory may be incorrect or incomplete. They may no longer be employed by the company. The company may be out of business. In any event, the service technician spends an inordinate amount of time seeking information that would have been readily available in a complete documentation set. The wasted diagnostic man-hours, demoralizing and frustrating effects of not having

the needed information to do the job right, excessive equipment downtime, and the postponement of production or other work related to the operation of the controlled environment room can be avoided with good documentation.

Imagine the same service operation, this time with a documentation set providing the means to answer the questions previously raised. The technician will review the documents and begin checking the control circuits in a systematic manner. If unable to diagnose the problem, he may call the factory, where they have copies of the documents, providing a common vehicle for discussing the problem. The technician can indicate his findings, the factory can suggest other things to check, all in the context of documents which are a common reference for all parties. Communication is quick, concise, and productive. Once the problem is diagnosed, repair is generally uncomplicated. If replacement parts are needed, the documents indicate precisely the information needed to procure them. The amount of time spent to repair the room is minimized, resulting in substantial savings in technician diagnostic time alone. Over the 20 year life of the equipment, this process will be repeated numerous times. The value of the documentation increases with the age of the equipment. The life cycle cost savings potential from complete documentation is very large.

The potential for benefits exists on the mechanical side also. Controlled environment rooms can have unconventional operating characteristics which are necessary to achieve their specified performance range. Often, a special arrangement of valves or other devices is employed to perform a necessary function. Service technicians unfamiliar with a



particular controlled environment room may incorrectly diagnose a problem and perform unneeded repairs due to a misinterpretation of design intent or system performance. Again, documentation to the rescue in the form of mechanical schematics, a sequence of operation, and baseline start-up data.

Documented performance and baseline data, derived when the room is commissioned by the manufacturer, can be compared to measurements made by the technician to quickly determine if a piece of equipment is operating at its original level of performance. This reduces service inefficiencies by helping the technician to focus on what is not performing as specified. Schematic drawings and a sequence of operation description get the technician up to speed quickly on how the system works. Again, without the documentation set, downtime and service costs will be higher each and every time the unit needs service.

Generally, a controlled environment room is “demonstrated” when it is turned over to the owner. A representative of the manufacturer will familiarize those attending with basic procedures for setting the temperature and alarm points, silencing and responding to active alarms, and often some basic maintenance procedures. Little of this information is retained by the operators over time because CERs require only infrequent interaction between the operator and control system. Nothing less than clearly written procedures for all the interactive tasks with the control system will provide the client with the ability to beneficially operate the room, train new operators and service technicians, and provide validation and safety training materials for management.

It is not uncommon for a client to encounter a requirement to modify an existing controlled environment room. If a solid documentation package was delivered with the original room installation, you have everything you need to determine the feasibility and cost effectiveness of modification. Without the needed documentation, the modification project begins with a high level of uncertainty because, from a

technical standpoint, you don't know what you are modifying. Your first task will be to collect and organize the information that would have been delivered with the original documentation, had there been any. Anyone who has ever reverse engineered a CER in the field will know the true value of up front, complete documentation. It is almost priceless in some cases. Obviously, without a good set of documents to begin the redesign of the room, it is not possible to minimize the time to complete the project, and the probability of error due to incomplete information increases greatly.

Over the life of a controlled environment room there can be any number of issues which can be resolved by the possession of a good set of documents. The drawings, text, labeling, and listings that comprise a complete document set are a solid indicator of the commitment of the manufacturer to its client. They are an indicator of intrinsic quality, the quality every client desires, but finds difficult to specify with words in a purchase description. A vendor that does not provide a useful documentation set will provide lower first cost, but not an equal product. A documentation set shows the essential elements of the design and its implementation through carefully completed procedures. Through this set of papers, the owner is uncoupled from the manufacturer for service and parts, allowing the owner to select whatever means are in his own best interest to maintain and service the equipment. These documents allow the client to truly own the equipment.

How do you specify all the necessary elements of a documentation package? How can you be assured of receiving them after the CER is installed? What procedures can be used to evaluate documentation package submittals?

The first step in obtaining a complete documentation set is to accept the premise that the documentation is every bit as important as the hardware in your procurement activities. It will be necessary to devote the man-hours necessary to obtain these items from the vendor because most do not provide a complete documentation set in the normal course of business.

The ability to communicate the requirements to vendors and review their submissions before and after delivery of the CER will require technical skill, experience with CER design and operation, and, most importantly, the desire and willingness to wade through the process. In the midst of a major procurement, all the attention is on the initial equipment cost and the current schedule. It is easy to neglect items that, while you acknowledge they may be important, have no current urgency. This line of thinking will cost the owner of the CER for the life of the equipment through service and maintenance difficulties.

Those entering the design or procurement phase for a controlled environment room should carefully consider how they will obtain the documentation needed to have control of this substantial asset investment for its projected 15 to 20 year life. If a thoroughly qualified individual cannot be tasked within the organization to work through the documentation specification, review, and certification, consider contracting outside assistance with at least this portion of the project. The one time cost of the technical service personnel will easily be returned many times over in the future through reduced service and maintenance man-hours.

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