

Standards and Evaluation Issue:

Documentation Requirements For Controlled Environment Rooms

Part 1 The Basis For Documentation

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 service technician is 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. 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



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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?

Communicate your documentation requirements to prospective vendors. Put them on notice that you consider documentation to be an integral part of the product, every bit as important as the hardware. Your position should be that, without delivery of a comprehensive documentation set, the project is not complete. Prequalify vendors carefully before obtaining pricing. Review samples of a prospective vendor's previously completed documentation packages for clarity and content. Make sure that every bidder regularly provides a standard documentation package that meets your minimum requirements.

The next *C.E.R. TECH NOTES*, Volume 1, Issue 6, details the elements of a comprehensive documentation set.

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Standards and Evaluation Issue: Documentation For Controlled Environment Rooms Part 2 Minimum Documentation Requirements

System documentation is the collection of tables, drawings and other descriptive tools illustrating the design, fabrication and commissioning of a specific Controlled Environment Room (CER).

What is the purpose of documentation?

Comprehensive information about the design and operation of the CER allows the owner/operator to maximize the control and application of the room. See *C.E.R. TECH NOTES*, Volume 1, Issue 5 for more discussion.

Who generates the documentation?

Much of the information comprising a documentation set is time sensitive. The opportunity to effectively collect or generate the data occurs only once, generally when the CER is in design, fabrication, or commissioning. The CER manufacturer is best positioned to produce a complete documentation package. It is important that clients incorporate specific documentation requirements into purchase descriptions and take action to assure that the needed information is documented at the proper time.

What information does the owner of a C.E.R. need?

Load calculations serve as a quantitative basis for system design and proper equipment selection. Detailed calculations should indicate the capacity allowance for each factor affecting chamber

performance.

"As Built" drawings indicate the architectural, mechanical, and electrical elements of the equipment installation, with locations of all fixtures and equipment provided with the room. Information contained in these drawings is gathered at the installation site while the room is being constructed. Any changes to the original plan are shown. The purpose of this process is to provide the client with an illustration of the work in place, as it was installed. Of special concern is the location of concealed piping, ducts, or other work. Future service or renovations of adjacent areas can be accomplished more effectively with this information.

Ladder diagrams of the control system will provide any competent technician the means to solve control system related problems with a minimum of downtime. The drawing should use symbols and drawing conventions recognized by a national standard, so that technicians with standardized training will be able to quickly read and interpret the drawings.

Conductor identification is an often overlooked part of documentation because it is not delivered entirely as a document. When conductors are installed, whether on site or in the manufacturer's plant, they should be uniquely and permanently identified with a symbol that can be traced to other documents that indicate the function of that conductor. The ladder diagram should show the conductor identifiers. A wiring hook-up or

component layout diagram provides a pictorial view of the control panel interior and indicates the identifier for the conductor at each connection, providing a snapshot of all the wiring connections in the control panel. Field installed conductors must be similarly identified when installed and on the "as built" documents and ladder diagrams to complete this portion of the package for the client.

A refrigeration schematic will illustrate the installed components and flow of refrigerant through the cooling system. Additional information, such as design settings for adjustable valves or regulators should also be included.

The parts list should include all the parts installed by the CER manufacturer and indicate the original manufacturer's name and part number. Parts should be assigned alphanumeric tags that identify the part on all documents, such as ladder diagrams and schematics.

The operations manual provides clear description of the following items:

- ⇒ How to start up the system.
- ⇒ How to shutdown the system.
- ⇒ Functions of all instruments, operators, and indicators.
- ⇒ The performance limits of the equipment.
- ⇒ Simple, step by step procedures detailing how to set the controls to attain the

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specified range of environmental conditions.

- ⇒ Emergency shutdown procedures.
- ⇒ Troubleshooting procedures that can help a technician diagnose a problem.
- ⇒ How and when to perform routine maintenance.

Baseline data is a collection of information describing the operational characteristics and unique identification of each unit of equipment integral to the CER. Initially, model, serial, and other identifying data are tabulated on a simple form. This information can be useful in processing warranty service claims or procuring replacement parts. After room performance has been verified and all adjustments are completed, the settings, operating currents, pressures and other pertinent operating data are collected from each piece of equipment, much of it while the unit is running. This provides a "baseline" to which future operation can be compared, and is invaluable as a diagnostic tool.

How does a design professional evaluate documentation performance when considering "equal" vendors?

Require the submission of a sample set of documentation from a recently completed project for

evaluation. Take time to review the submission, determining what is omitted as well as the usefulness of what is included. Ask prospective vendors to provide a sample documentation set and compare the offerings of each for completeness.

Is a compilation of component manufacturers' cut sheets sufficient documentation?

No. Original component manufacturer cut sheets generally have instructions for proper installation, but do not provide any indication of the function of the component as it is applied in the controlled environment room design. The client has purchased a system of integrated components that perform a unique function. The delivered documents must describe the design, function, and operation of the system.

Is post installation testing considered part of the system documentation?

Testing of the completed CER should be considered part of the baseline data and included in the completed documentation. The degree to which a system is tested will vary, depending upon regulatory, safety, validation, or other requirements the client may have. It is important that a testing plan is developed early in the procurement process, so that all vendors can be advised of the

client's requirements. The next issue of **C.E.R. TECHNOTES** will cover post installation testing in detail.

Summation.

The design flows through the documents. Documents validate the design process for the client by showing that a careful and considered path was followed in the selection and arrangement of the componentry and equipment. Secondly, it shows that the design has been checked, loads and equipment selections have been accounted for, and a basis for the incorporated materials and methods has been established.

The production of a useful documentation set may add to the first cost of a CER purchase, but the payback from this small added expense continues for the life of the equipment.

Need more information on this subject?

Contact our office for samples of any of the documentation elements discussed.

Speak with one of our designers about the specifics of any of the documentation elements discussed here.

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Future Topics:

The Case For Tighter Temperature Control, Part 2

Post Installation Testing Of Controlled Environment Rooms

Definitions of Performance Terminology For Controlled Environment Rooms

Risk Management: Refrigerated Storage Of Critical Materials