

Controlled Environment Room Minimum Documentation Requirements

System documentation is the collection of tables, text, drawings and other descriptive tools illustrating the design, fabrication, operating processes 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. Cost and time savings accrue through the use of the documentation to streamline service, maintenance, training, and validation operations.

Who generates the documentation?

Much of the information comprising a documentation set is time sensitive. The opportunity to efficiently 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, provided they have demonstrated previous experience with the process. Outsourced technical services are an alternative to manufacturer provided documents and can provide better control over the form and substance of the collected and generated information. In either case, it is important that clients incorporate very specific documentation requirements into purchase descriptions and take action to assure that the needed information is produced at the proper time.

What information does the owner of a CER 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.

Ladder diagrams of the control system will provide a 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 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 at a specified performance condition. This provides a “baseline” to which future operation can be



compared, and is invaluable as a diagnostic tool.

How can a purchaser evaluate vendors' ability to comply with specified documentation requirements?

Require the submission of a sample set of documentation from a recently completed project for evaluation. Have a qualified and experienced individual 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 prospective vendors can be advised of the client's requirements. Alternatively, the testing can be outsourced to a firm of the client's choosing, providing a professional and unbiased assessment of CER performance.

What documentation is appropriate for software based control systems, such as those with a PLC?

Programmable Logic Controllers (PLC) can provide many

improvements to CER operations. They do, however, create some new issues for owners and their maintenance and validation crews. It is not possible to discern the sequence of operation of a PLC based system through an examination of equipment drawings, or even the physical equipment. Most of the functions exist completely in the software, carefully protected by the manufacturer from user access.

It seems understandable that manufacturers need to protect their logic from unethical upload and pilfering by competitors. But, are these fears realistic, and how do they weigh out when balanced against a customer's interest in being able to examine and evaluate what they have purchased, to see if it will meet their specific needs? How can the purchaser accept a design based upon logic that is not subject to examination and review with respect to how it functions? How are the client's interests protected against software failures? What happens to the equipment owner if the CER manufacturer goes out of business?

Purchasers of software based systems should have access to the source code anytime they want it. They should expect to cooperate with manufacturers in a reasonable manner in order to protect the source code from unauthorized distribution. Negotiations or discussions between buyer and seller may be needed to find a suitable arrangement that serves the needs of both parties.

From the purchasers standpoint, access to the source code and the ability to download a new source code version to the system are essential. It is unrealistic to completely evaluate a complex program prior to purchase, but a written description of the performance logic for each network in the program should be provided by the manufacturer. In fact, good programming practice and in house technical training by the manufacturer would dictate that they already have network by network descriptions of how the software works. This will allow a submittal review of the CER functions to determine if there is compliance with project specifications.

The ability to take control of the software and the system in the event the manufacturer goes out of business or abandons the platform should be delivered to the client with the equipment.

It will take considerable technical knowledge of controlled environment room operation, as well as PLC programming, to determine if the information provided by the manufacturer is suitable for the client's needs.

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.

CER purchasers should provide for a careful and thorough review of the submitted documents, by in-house personnel if qualified and available, or by outside professionals that can demonstrate suitable experience and knowledge of CER operation and design. This will help assure that the delivered system meets the purchase requirements and the owner can exercise control over the equipment to meet their needs over its expected useful life.

The production of a useful documentation set may add to the

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