Institute For Thermal Processing Specialists

GUIDELINES FOR VALIDATING ELECTRONIC CHART RECORDERS

Various methods may be employed to validate electronic chart and **the following recommendations are to be considered voluntary guidelines.** While this does not preclude the application of other methods and equipment, these guidelines have been developed by consensus of the Institute For Thermal Processing Specialists and should be given serious consideration for adoption as methodology by individuals validating electronic chart recorders.

1.0 SCOPE

In 1997, the US Food and Drug Administration (FDA) introduced 21 CFR Part 11 regulation to provide criteria under which the FDA will consider electronic records and signatures to be equivalent to paper records and handwritten signatures. This mandatory regulation provides requirements to ensure the accuracy and integrity of electronic records, specific only to records required by the FDA. The scope of the regulation covers both electronic records that will be submitted to the FDA and electronic records that are being kept to meet FDA regulatory requirements. Records generated by a company that are not required under FDA regulations do not need to comply with Part 11.

FDA defines Part 11 Records and Electronic Signatures as "Records that are required to be maintained under predicate rule requirements; that are maintained in electronic format *in place of paper format* and that are relied on to perform regulated activities" and "Electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules."

This document will focus on electronic chart recorders used in the food processing and packaging industry to create and maintain records required by the FDA (e.g., 21 CFR Parts 113 and 114), and hence fall under 21 CFR Part 11.

For manufacturers utilizing food safety plans mandated under the Food Safety Modernization Act (FSMA) and for non-US manufacturers, adopting this validation guidance is voluntary. This guidance, however, may be considered as best practice for any food manufacturing operations that intend to utilize electronic recording systems and would like to ensure that electronic records are secure and cannot be amended without audit trail notation.

2.0 OBJECTIVE

The purpose of this document is to provide guidance on the validation of electronic chart recorders to meet FDA regulation on Electronic Records and Signatures, 21 CFR Part 11. This guidance document will not ensure compliance, but rather intends to outline a validation approach for the food processing industry to use and adapt to meet 21 CFR Part 11 requirements.

3.0 BACKGROUND

3.1 Historically, food processing facilities have used paper chart recorders to record and trend critical processing and packaging data. Over the years, limited advancement has occurred with paper chart recording technology, and the transition to more advanced and reliable electronic systems has been slow despite its many advantages. Paper chart recorders require moving mechanical parts and the purchase of pens and paper on an ongoing basis. Maintenance for these systems can be costly and repetitive. Paper jams and/or skips and dry ink associated with paper-type recorders can lead to data loss, overwriting, and non-conformance with food safety regulations and/or corporate standards. Electronic chart recorders, on the other hand, prevent paper chart recorder associated deviations, and do not have the associated upkeep costs and physical space requirements related to paper storage.

3.2 Reliability is another major advantage of electronic chart recording systems over traditional paper chart recorders. Electronic records stored at multiple data locations prevent loss of critical records, allow for quick retrieval, remote access, and have improved data security and integrity. Process data is more legible in electronic chart recorders since there is the capability to zoom in on data for review. Unlike paper chart data, electronic data can easily be compiled into summary reports, and alarm logs which automatically provide a snapshot of events that occurred during production. Despite the significant advantages, the vast majority of food processing facilities continue to use traditional paper chart recorders as their singular and primary recording device. While the change may appear daunting in regards to proper validation and management of electronic data/records, the benefits of making the switch to electronic chart recording far outweigh the issues involved with continued use of paper chart recording systems.

4.0 OVERVIEW OF 21 CFR PART 11 & FDA PREDICATE RULE REQUIREMENTS

The primary focus of 21 CFR Part 11 is on data reliability and integrity of electronic records and signatures. The aim is to minimize the risk of data loss and manipulation while ensuring electronic systems meet the requirements set forth by the FDA. Table 1 summarizes the main requirements covered under 21 CFR Part 11. It is necessary to understand these requirements prior to selecting and validating an electronic recording and storage system that is claimed by the vendor to be 21 CFR Part 11 compliant.

Table 1: 21 CFR Part 11 Requirements	
Part 11 Requirement	**Main Points**

Data Security and Data Access	• Electronic records must be protected to enable accurate and easy retrieval throughout their retention period.
	• System access must be limited to the authorized individuals.
	• System must be capable of performing operational system checks, authority checks, and device checks.
	• System must have appropriate controls over:
	  o Distribution of and access to documentation for system operation and maintenance.
	  o Revision and change control procedures to maintain an audit trail.

Audit Trail and Record Traceability	• System must use secure, computer-generated, time stamped audit trails to independently record the date and time of operator actions/entries. • Audit trails are necessary when users are expected to create, modify, or delete regulated records during normal operation. • Persons who develop, maintain, or use electronic systems must be properly trained to perform assigned tasks. • Adherence to written policies holds individuals accountable for actions performed under their electronic signatures.
Copies of Records and Record Retention	• System must be able to generate copies of records in both human readable and electronic format suitable for inspection, review, and copying by the FDA.
Electronic Signatures	• Each electronic signature must be unique to each individual. • Before assigning an electronic signature, the identity of an individual must be verified. • Persons using electronic signatures must certify that their electronic signature is a legally binding equivalent to their handwritten signature. • Identification codes and passwords used for electronic signatures must be periodically checked and/or revised to ensure authenticity.
Validation	• *"Systems used to create, modify, and maintain electronic records must be validated to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records*" (21 CFR 11.10(a)).

In addition to 21 CFR Part 11 requirements, food companies that intend to manufacture low acid or acidified food products for the US market must ensure that FDA predicate rule requirements are met. Table 2 summarizes the FDA predicate rule requirements for Low Acid Canned Food (LACF, 21 CFR Part 113) and best practices for Acidified Foods (AF, 21 CFR Part 114) as they relate to critical factors recording.

Table 2: 21 CFR Part 113 Requirements and 21 CFR 114 Best Practices

21 CFR Part 113	Main Points
Temperature Indicating Device (TID)	• The TID shall be the reference (official) instrument for indicating the processing temperature. • The TID is a standalone device.
Temperature Recording Device (TRD)	• There shall be an accurate TRD for each product sterilizer. • The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, a known accurate TID. • The chart shall have graduations that do not exceed 2 °F within the range of 10 °F of the processing temperature. * • Each temperature chart shall have a working scale of not more than 55 °F per inch within the range of 20 °F of the desired product sterilization temperature. * • The graduation shall not exceed 2 pounds per square inch on the working scale of not more than 20 pounds per square inch per inch (situations where product to product regenerator is used). * • A lock, or a notice from management shall be posted at or near the recording device that provides a warning that only authorized persons are permitted to make adjustments.
Critical Factor Recording	• Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes. • Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; for example in aseptic systems such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour. • Clock times on recording-temperature charts should correspond to the time of day on the written processing records to provide correlation of these records.
Record Keeping and Record Review Requirements	• Recording charts shall be identified by date, system # etc. so they can be correlated with the written record of lots processed. • Copies of all processing and packaging records shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible

Table 2: 21 CFR Part 113 Requirements and 21 CFR 114 Best Practices	
21 CFR Part 113	**Main Points**
	location for at least an additional 2 years. • A qualified representative of plant management shall review all processing and packaging records within 1 working day after the actual delivery of the process for completeness and ensure that the product received the scheduled process. The records, including the charts, shall be signed or initialed and dated by the reviewer.

** If for any reason, electronic records are printed as official thermal processing records for regulatory review, then the graduation scale requirements must be met.*

This validation guidance document is developed to assist the end user in meeting United States FDA regulatory requirements. It is the responsibility of the end user to ensure compliance with other local regulations and corporate standards, where applicable.

5.0 APPLICATION OF ELECTRONIC CHART RECORDERS IN FOOD MANUFACTURING AND PROCESSING FACILITIES

There are several options for using electronic chart recorders on food processing and packaging machines in place of paper chart recorders. The option selected depends on facility needs, company commitment, and overall readiness to invest in an integrated electronic recorder and data storage system that is 21 CFR Part 11 compliant.

5.1 **Option 1:** Electronic chart recorders may be used as a backup recorder to paper chart recorders. An electronic backup (i.e., secondary recorder) can assist in alleviating issues with paper charts that automatically result in process deviations (i.e., paper jams/skips, dry ink, pen adjustment, paper replacement). This option is a good choice for facilities that intend to gain experience with electronic chart recorders, or, that are considering to implement/explore electronic records in the future. In situations where the secondary electronic data is printed and used in place of the paper chart, the recorder must be set up such that it meets all predicate rule and relevant sections of 21 CFR Part 11 requirements. This printed record must be reviewed within one working day to meet predicate rule requirements. If the primary chart recorder fails, and the secondary electronic chart recorder is used to make decisions about the disposition of the product, it becomes the primary recorder, which must satisfy all the regulatory requirements previously mentioned. A disadvantage with this option is that two (2) separate devices must be maintained and configured to receive input signals from the same or identical field devices. In such situations, the plant should clearly define the primary chart recorder that will be utilized for regulatory review of thermal processing records.

5.2 **Option 2:** Electronic chart recorders may also be installed in place of paper chart recorders with the ability to print, review, and sign-off on the printed records in compliance with applicable regulations (including relevant sections of 21 CFR Part 11) and/or corporate standards. Daily printouts can be used as the legal production records provided that the predicate rules are satisfied. This option appears to be a preferred choice for facilities who have experience with electronic records because it allows for the option of going fully electronic in the future. Some of the issues associated with paper chart records are avoided with this option. However, in absence

of a system that is validated to be 21 CFR Part 11 compliant, the validity and life span of electronic records can be questionable once paper records are printed for regulatory review.

5.3 **Option 3:** The third option is a fully integrated electronic chart recording and data storage system that is 21 CFR Part 11 compliant. This option completely eliminates the need of paper records for recordkeeping. A thorough 21 CFR Part 11 validation of the chart recorder setup and associated integrated systems and network (if applicable) should be completed following procedures outlined in this guidance document.

6.0 ELECTRONIC CHART RECORDING SYSTEM VALIDATION APPROACH

Prior to use in production, the entire system should be validated to ensure that it meets Part 11 requirements. The electronic chart recorder itself is just one part of the system that needs to be validated. The data server, data management system, data access & security, and signal distribution from sensor to recorder will also be included in the electronic chart recording system validation. System validation starts prior to the purchase and installation of the system and covers the series of activities that must take place over the validation life cycle of the system. This includes developing a validation plan, establishing a User Requirement Specification (URS), generating documented evidence of the validation, and continued verification to ensure that the system remains in its validated state. A detailed system validation strategy can guard against unnecessary issues at a later stage.

Validation is mentioned briefly in 21 CFR Part 11. However, it does not specify or describe in detail how validation should be carried out. The following sections outline a validation approach for Part 11 compliant electronic chart recording systems to be used in food manufacturing and processing facilities.

7.0 VALIDATION PLAN

First, a plan for carrying out the validation should be created. The validation plan should be developed by person(s) knowledgeable of 21 CFR Part 11 requirements and preferably with project management experience. Senior Management should sign-off on the plan and have awareness of the activities, timeline and objective of the validation as early as possible in the project. Acceptance and support from Senior Management at an early stage is critical.

The validation plan should clearly define the following:

1) Validation Study Scope
2) Cross-functional Team Roles and Responsibilities
3) Risk Assessment
4) Validation Activities & Timeline

7.1 *Validation Study Scope*

The scope of the validation should clearly outline what is and is not part of the project. This includes outlining which food processing equipment will be affected, which electronic chart recording system will be purchased or paper chart recorder will be replaced by the electronic chart recording system, and which critical parameters must be electronically trended. Signal distribution is fundamental to determining a validation approach in electronic systems and should also be defined in the scope. The signal(s) going to the electronic chart recorder may be coming from a Programmable Logic Controller (PLC) system or directly from the transmitter of the field device (e.g., Resistance Temperature Detectors (RTD), manometers, flow meters etc.). A direct connection from the sensor to the chart recorder (as shown in Figure 1, Option A) is the simplest option since the raw signal from the RTD transmitter is connected

directly to the input card of the chart recorder. This option precludes the use of hardware that may interfere with the reliability of the signal and/or the use of unsecured third party hardware and software that interpret the raw signal. If a control module such as a PLC system is necessary, it should be placed in the same current loop as that of the chart recorder. The use of a separate transmitter, analog input card, PLC, and analog output card as an interface between the RTD and chart recorder (Figure 1, Option B) is possible, but it creates additional complexity, requiring that the PLC system be secured and validated in addition to the validation work for the chart recorder. For the purpose of this validation guidance, the focus will be on signal distribution directly from a field device (e.g., an RTD/sensor) to the chart recording system (Figure 1, Options A or C). For Figure 1, Option C, a dual probe with two independent transmitters is used to transfer a signal from the field devices to the analog input cards of the PLC and recorder.

Regardless of the option selected, the network and server configured to the chart recorder for data storage, retention and retrieval must also be within the scope of the Part 11 validation. Piping and Instrumentation Diagram (P&ID) should be included for any of options selected. Also, proper change control will need to be implemented when using any of the 3 options.

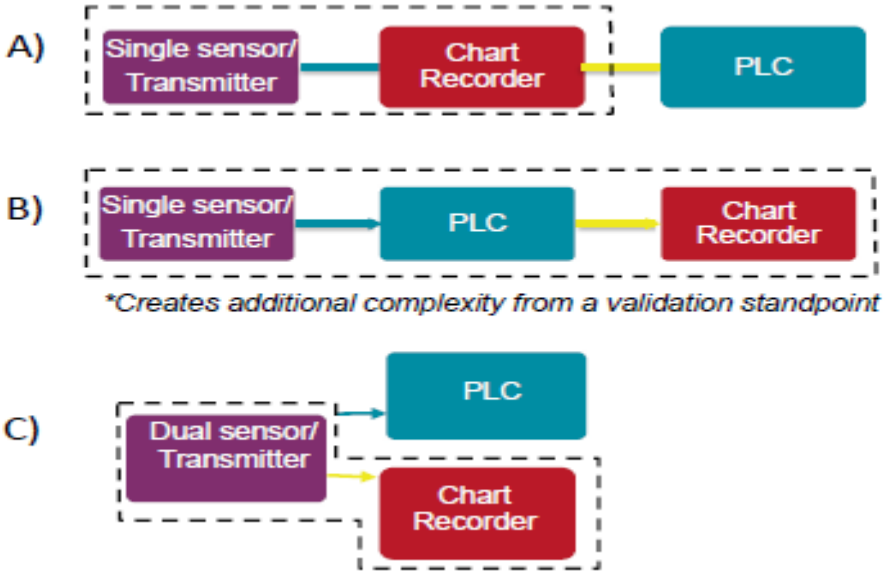

Figure 1: Signal Distribution (Note: area within dotted line represents Part 11 validation scope)

7.2 *Roles & Responsibilities of the Cross-Functional Team*

The roles and responsibilities of the cross-functional team members should also be detailed in the validation plan. The validation team should include representation from Process Authority, Food Safety, Engineering, Quality, Maintenance, IT and the Equipment Supplier. See Table 3 below for example validation team roles and their responsibilities. The team members and responsibilities may vary from facility to facility, however each of the following duties should be accounted for within the team. A consultant or consulting group may be responsible for some of the roles and responsibilities of the validation team.

Table 3: Cross Functional Team Roles & Responsibilities	
Department Representative	**Roles & Responsibilities**
Process Authority / Food Safety Manager	• Outlines validation requirements/expectations from Corporate Standard and/or Regulatory perspective (i.e., 21 CFR Parts 11, 113, 114, 117 etc.; Statement of 21 CFR Part 11 Compliance from the Supplier). • Reviews and approves validation plan and activities. • Ensures proper documentation of qualification and validation results. • Provides guidance and approval on selection of e-chart recorder. • Provides guidance on information that must be recorded on e-chart recorder (e.g., critical process parameters, operator initials and comments, product & equipment ID, alarms, data collection and transfer rate etc.).
Engineering Manager	• Acting Validation Project Manager – develops validation plan, activities, etc. • Serves as key engineering resource. • Manages project cost and timeline. • Provides Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) documentation templates to the cross-functional team. • Responsible for compiling validation documents and/or creating the validation report in collaboration with other cross-functional team members.
Quality Manager	• Provides oversight on implementation to meet local/predicate rule requirements (e.g., 21 CFR Part 113, etc.). • Verify e-chart recorder setup (e.g., critical parameter recording, operator initials, product & equipment ID, data transfer frequency, e-data archiving, extraction, security, e-signature compliance etc.). • Verify audit trails and storage of audit trail records with active/archived records. • Responsible for record review, defining access right and levels, identifying authorized users, and establishing record keeping and record retention requirements. • Challenge alarms and document accuracy of critical sensors, if e-chart recorder is setup to generate alarms. • Responsible for creating applicable SOPs for e-chart recording system operation, recordkeeping and record review, electronic signatures, change control, etc. • Provides applicable training for operators and record reviewers. • Responsible for driving the Change Control process. • Handles user password violations and ramification.

Table 3: Cross Functional Team Roles & Responsibilities	
Department Representative	**Roles & Responsibilities**
Maintenance Manager	• Provides technical support necessary during installation, operation and performance qualification. • Set up data transfer frequency in e-chart recorder internal & external memory and to the server, set up e-chart recorder display configuration, setup alarms, if applicable. • Challenge and document e-chart recorder for electromagnetic interference (i.e., cell phone, Walkie Talkie, high voltage motors, etc.). • Responsible for training operators on specific requirements and features of electronic chart recorder.
IT Manager	• Provides IT support for software and hardware installation, communication, storage, archiving and retention of electronic data. • Assists in setting up data access, data retrieval, data archiving, security and integrity requirements as it relates to server system and software. • Configures network server (company vs. local server)—filename format, server name, network path, directory name, IP address, etc. • Setup software remote access for authorized users. • Set up printer as a backup. • Handles user password requirements and management.
Equipment Supplier	• Technical support to address questions on recorder functions, data security and integrity, system installation and use. • Provide statement of compliance to Part 11 requirements. • Provides Functional Specification and Operator's Manual. • Provides troubleshooting support during IQ and OQ activities, as needed. • Communicates any changes to firmware, hardware and software (version updates, etc.) to the end user.

7.3 *Risk Assessment*

As part of the validation plan, a risk assessment should be conducted. The risk assessment, created with input from the validation team, should take into account any and all factors that may affect data reliability, accuracy and security in an electronic recording system. This assessment will aid in selection of the appropriate electronic chart recording system (i.e., Part 11 compliant-able hardware and software, recorder make and model, etc.) and create an awareness around the risk areas that should be evaluated prior to beginning qualification activities.

Example risks include (but are not limited to) the following:

- Selecting Part 11 compliant recorder (hardware & software).
- Open system vs. closed system server.
- Data backup (recorder internal/external memory, server backup).
- Server capacity and record retention duration.
- Data signal flow (refer to Figure 1).

- Impact of future firmware, hardware or software version updates.
- Network/connection failure and impact of a power outage.
- Plant network/separate server to be used.
- Environmental conditions (humidity, temperature).
- Time/clock synchronization to real time and other system clocks; also taking into account daylight savings time.
- Potential electromagnetic and heavy equipment (i.e., motor and pump) interference.
- Compliance with applicable predicate rule requirements (e.g., 21 CFR Part 113, 114).

Based on the risk assessment, a more robust User Requirement Specification (URS) should be established.

7.4 *Validation Activities & Timeline*

A summary of validation activities should also be written into the validation plan. This includes:

- User Requirements Specification
- Functional Specification
- Design Specification
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Development of Validation Report
- Change control program for continued verification

See Figure 2 below for a validation life cycle diagram. These items will be discussed in greater detail in the following sections.

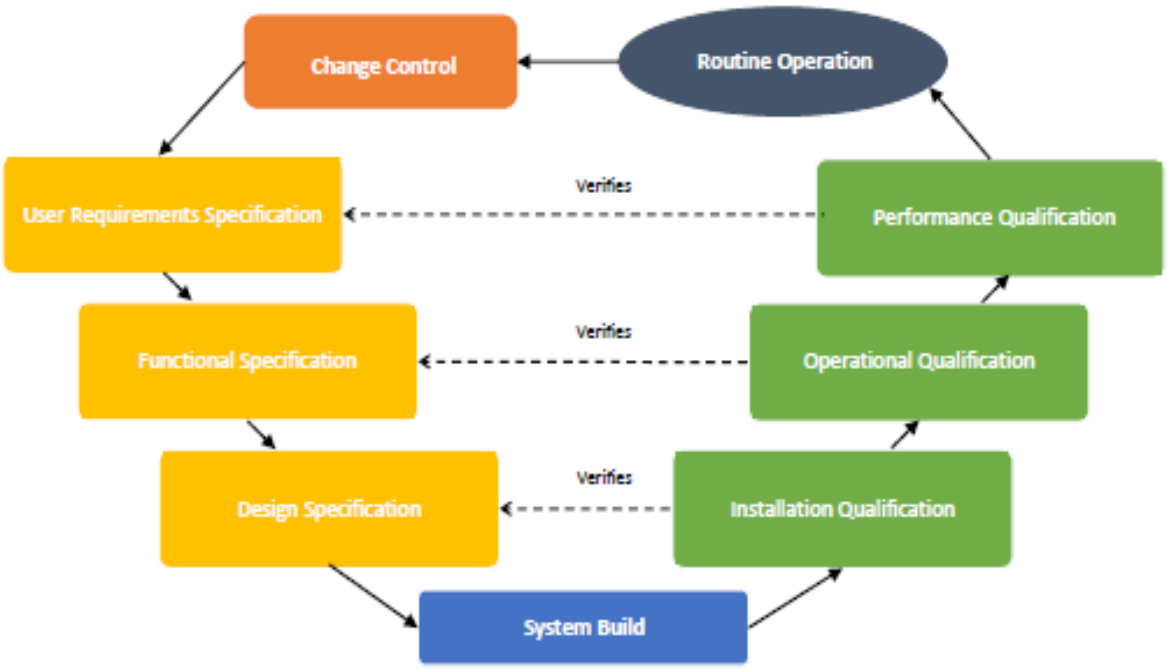

Figure 2: Validation Life Cycle Diagram.

An approximate timeline for the activities should also be devised as part of the validation plan. The Validation Lead/Project Manager should be in charge of managing the validation timeline and communicating any changes to the cross-functional team.

8.0 USER REQUIREMENT SPECIFICATION (URS)

Taking into account the risks determined from the Risk Assessment, a User Requirement Specification (URS) document should be generated. This is the most important document involved in the validation process as it sets out to define system requirements from the end user's point of view in selecting the appropriate electronic chart recorder. The URS should clearly describe required items (i.e., user needs and regulatory musts) and wants for the electronic recording system. This includes Critical Control Points (CCP) and Critical Factors (CF) that must be continuously recorded as well as operational requirements. All cross-functional team members should be involved in the URS approval process.

Below in Table 4 is an example list of some "musts" and "wants" for a Part 11 compliant electronic chart recording, data transfer and storage system.

Table 4: User Requirements Specification

Musts	• Comply with 21 CFR Part 11 requirements (hardware and software). • Able to meet predicate rule requirements (e.g., 21 CFR Part 113 chart graduation scale requirements). • Good chart resolution for charts not under predicate rule requirements. • Monitors, records and trends specified CCPs/CFs for each mode of operation. • Provide an audit trail for changes in data unless data encrypted. • Provide an audit trail for comments that are either added or edited. • Enable secure electronic signature with password control. • Measure, store and record information that must be displayed on the recorder (e.g., Date, Product code, Equipment number, Operator initials, signature and comments, etc.). • Server setup (open vs. closed system). • Meets maximum number of process parameters that needs to be trended. • Specific data measurement and recording frequency to the recorder and to the server (e.g., every second/minute). • Chart recorder memory card storage space. • Time synchronization capability (between systems, daylight savings etc.). • Intranet/internet connectivity. • Remote access and configuration capability. • Others based on risk assessment, as necessary.
Wants	• Trends non-critical process parameters. • Ability to display trends in different chart formats (i.e., strip vs. circular). • Printer set up at recorder. • Alarm setup in case of out of spec recording or process deviation.

Using the information gathered in the URS, an electronic chart recording system should be selected and purchased with the appropriate approvals. It is a good practice to involve the electronic chart recorder supplier early in the validation process to obtain the appropriate technical support and expertise (see Table 3 for Roles and Responsibilities).

Upon purchase of the electronic chart recording system, the supplier should also provide a written statement of Part 11 compliance or certification. The statement of compliance will serve as proof that the electronic recording system is capable of meeting all the provisions of 21 CFR Part 11 (e.g., the system is able to be validated) prior to moving forward with the validation.

9.0 FUNCTIONAL SPECIFICATION (FS)

After an electronic chart recording system is selected, a Functional Specification (FS) should be provided by the system supplier. The FS describes major components and functions of the electronic chart recording system. It should contain descriptions of the System Display, Operational Overview, System Set-up Options, Process Instrumentation, List of Hardware & Software, User Interface, System Networking, Data Security & Storage, Data Monitoring, and Data Recording and Reporting. This document should also contain the methods for verifying that the requirements of the URS have been met. All the functional requirements ("Musts" and "Wants") from Table 3 should be addressed by the FS and satisfied by the chosen electronic chart recording system.

10.0 DESIGN SPECIFICATION (DS)

A Design Specification should be provided by the electronic recording system supplier as well. This technical document describes how the system is configured and programmed to perform the functions identified in the Functional Specification. The DS will assist in verifying the correct installation of the electronic chart recorder.

11.0 ELECTRONIC RECORDING SYSTEM QUALIFICATION

Once the validation plan is in place, electronic recording system qualification may begin. The qualification activities ensure that the system meets the requirements set forth by the end user. Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) are the 3 qualification phases that must be completed. These activities should be planned for in advance as they require test protocols and templates to be generated and used during the qualification process. The protocols and templates serve as documented evidence that the validation has been completed and the system is installed and operating as expected.

12.0 INSTALLATION QUALIFICATION (IQ)

The first qualification phase, Installation Qualification, confirms the design specifications of the electronic recording system. This verifies that the system hardware and software have been built, installed and connected properly. P&ID diagrams, component lists and system manuals should be collected and verified during this phase.

The IQ protocol and documentation templates should be developed by the end user with input from the recording system supplier. The protocol should describe the verification and qualification tests that are to be performed upon installation of the recording system. In each section of the IQ protocol, responsible parties should sign-off and date the tasks completed. At a minimum, the Installation Qualification should cover the following:

12.1 **System Installation** – The chart recorder installation, both hardware and software, must be verified as per supplier and corporate requirements. For the entire system, this includes

electrical and mechanical drawing verification, as well as checking the critical equipment installation against supplier manuals and other specifications. In the protocol, these check-offs will ensure each component of the system is installed as required. Refer to Table 5 below for an example.

Table 5: System Installation

System Installation Criteria	Drawing/ Specification Reference	Installation Verified?	Signature and Date
Piping and Instrumentation Diagram	P&ID dated 1/1/2016; Title: P&ID Aseptic Line; Drawing Number: 123456	Yes	
Hardware Technical Manual	Supplier Name Manual	Yes	
Software Technical Manual	Supplier Name Manual	Yes	

12.2 **Hardware and Software Connections** – Hardware and software connections related to the monitoring and recording of critical factors must also be checked and documented for proper installation. For hardware, this includes wiring for signal transmission, signal distribution verification, signal channel configuration, panel and instrument connections, server connections (independent server or shared), memory card presence and storage limit, and confirmation that the environment is suitable for the system (e.g., power supply, relative humidity, room temperature). The local plant network that will be utilized for data archiving should be set up and network configuration, IP address, server name, network path, directory name, data transfer frequency, maximum data storage capacity, file formats for future data retrieval should be confirmed as well.

On the software side, server connections, system security deliverables, procedures for assigning usernames and passwords, and other critical software capabilities for the record reviewer must be verified. How the system is setup during Installation Qualification dictates the testing that will be completed during Operational Qualification. See Table 6 for example Hardware and Software Connection tests to be included in the IQ protocol.

Table 6: Hardware and Software Connections

Device Specification	Tag #	Description/ Location	Manufacturer/ Serial #	Wiring/ Signals Verified?	Signature and Date
Temperature Sensor Wiring & Configuration	TE-1	Product Temperature RTD – Hold Tube Inlet	ABC Co. #11111	Yes	

Table 6: Hardware and Software Connections					
Device Specification	**Tag #**	**Description/ Location**	**Manufacturer/ Serial #**	**Wiring/ Signals Verified?**	**Signature and Date**
Server Connection	NA	Shared or standalone? connection to hardware and software	BBD Co. #11112	Yes	
E-Recorder Set Up (Mechanical Installation)	TAG-123	Installation as per Vendor Manual, sensor signal and channel configuration, display configuration	BCD Co. #11113	Yes	
Memory Card	NA	Location, Storage Size	DCD Co. #11114	Yes	
Uninterruptable Power Supply (UPS)	TAG-456	Server and/or e-recorder back-up?	ABCD Co. #11115	Yes	

12.3 Input/Output (I/O) Checks – After hardware and software connections are set up and verified, I/O checks (also known as functional checks) should be completed. I/O checks test all critical field devices for proper operation. These functional checks also verify that electrical output signals to all critical devices are functioning properly. Such checks should be documented as seen in Table 7.

Table 7: Functionality Checks					
Device Specification	**Tag #**	**Description/ Location**	**Manufacturer/ Serial #**	**Functionality Verified?**	**Signature and Date**
Temperature Sensor	TE-1	Product Temperature RTD – Hold Tube Inlet	ABC Co. #11115	Yes	
Pressure Transmitter	PT-3	System Pressure PTD – Hold Tube Outlet	ABC Co. #11116	Yes	

Table 7: Functionality Checks					
Device Specification	**Tag #**	**Description/ Location**	**Manufacturer/ Serial #**	**Functionality Verified?**	**Signature and Date**
E-Recorder	TAG-123	Critical Factor Data Recording	BCD Co. #11117	Yes	

12.4 Calibration Verification – All critical sensors and transmitters that are to be recorded must be verified for calibration after the electronic chart recorder is installed and periodically thereafter. Also, signals from the same sensor should display the same value on the HMI/Display device as on the recorder. These results must be documented. For example, the following critical sensors should be verified for calibration on an aseptic system: Hold tube exit temperature, product flow rate, pressure differential, final heater temperature, timers, CIP parameters, etc. See Table 8 below for example documentation.

Table 8: Calibration Verification					
Device Specification	**Tag #**	**Description/ Location**	**Manufacturer/ Serial #**	**Calibration Verified?**	**Signature and Date**
Temperature Sensor	TE-1	Product Temperature – Hold Tube Inlet	ABC Co. #11115	Yes	
Temperature Indicating Device	TI-2	Product Temperature RTD – Hold Tube Outlet	ABC Co. #11118	Yes	
Pressure Transmitter	PT-3	System Pressure PTD – Hold Tube Outlet	ABC Co. #11119	Yes	

12.5 Deviation Handling A Deviation handling section should be created for the Installation Qualification protocol if a deviation or abnormality is experienced during IQ. Proper documentation will ensure that the deviation is handled correctly and followed up. The validation team should evaluate if the deviation in the IQ protocol is significant enough to consider revalidating all items related to the failure. See Table 9 below for example.

Table 9: Deviation Handling During Installation Qualification			
Deviation Description	**Recommended Corrective Actions**	**Results Verification**	**Signature and Date**

13.0 OPERATIONAL QUALIFICATION (OQ)

After Installation Qualification has been completed, the Operational Qualification phase can begin. The purpose of the OQ is to confirm that the electronic chart recording system operates as intended during normal and abnormal operating conditions. This is accomplished through completion of functionality challenge tests which will verify the operation of each item listed in the Functional Specification. In addition, several Standard Operating Procedures (SOPs) must be created and implemented prior to closure of Operational Qualification.

13.1 Standard Operating Procedures (SOPs) – The OQ protocol developed will verify implementation of several critical Standard Operating Procedures for the electronic chart recording system. The SOPs should include a System Operation SOP and a Logical Security SOP detailing the requirements and handling of user IDs and passwords. The Logical Security SOP should be completed prior to performing the OQ functionality tests as the operation of the procedure will be tested during the challenge tests.

Table 10: Required Standard Operating Procedures		
Standard Operating Procedure (SOP)	**Verification/ Comments**	**Signature and Date**
Electronic Chart Recorder User Procedure	SOP # dated 01/01/01	
Logical Security Procedure (User ID and Password Handling Program)	Document # dated 01/01/01	
E-Recordkeeping & Record Review Procedure	Document # dated 01/01/01	

13.2 Functionality Challenge Tests – OQ Functionality Challenge Tests should clearly demonstrate that the electronic chart recording system will function as expected, and that data can be collected, stored, retrieved and secured as per 21 CFR Part 11, local/predicate rule and corporate requirements. In

order to ensure that all local/predicate rule requirements have been met, functionality tests must be performed during each mode of operation of the processing equipment as applicable (i.e., Cleaning in Place, Equipment Pre-sterilization, and Production modes for an aseptic system). As with IQ, testing results must be documented with applicable sign-offs. Below is a list of functionality test cases that must be conducted during OQ phase.

Functionality Challenge Test Cases:

Data Collection

- Set up and verify organization of processing charts on e-recorder display screen for each mode of operation and on data management software (including chart format, chart display of date & time, graduation/scale, etc.).
- Verify proper date and time are recorded by recording system; verify Daylight Savings Time adjustment control is enabled.
- Verify that the data captured by the e-recorder is stored in the internal memory of the recorder prior to being transferred to the memory card and server.
- If memory card is used, determine the capacity and amount of data it will hold before it is transferred to a secondary storage system (i.e., server), or begins to overwrite.
- Set up and verify data transfer from e-recorder to the data management software and to the network server (test on both administrator and user computer).
- Set up and verify processing data collection and transfer rate for e-recorder internal memory and memory card.
- Verify data for each critical sensor is properly recorded and not transposed from another sensor.
- Verify data transfer to the server at the designated rate (whether transferred via FTP or done by archiving software installed on the server).
- Verify server data scheduled backup (i.e. once every 12 or 24 hours).
- Set up and verify accuracy of product, equipment and processing information on electronic records to ensure traceability.
- Set up alarms and challenge alarm to initiate for out of spec readings, if applicable.
- Verify alarms are functioning to alert reaching a critical limit (i.e., minimum or maximum).

Data Security

- Verify that Electromagnetic Interference (EMI) from mobile phones, walkie talkies and other sources (e.g., electronic drills) does not affect reading and/or recording of critical instrument data.
- Verify that the system is setup such that it will automatically logout inactive users after a defined time period (e.g., automatic logout after 10 minutes).
- Verify that system will not lose data for specified time after power outage.
- Verify system reaction for power loss or communication failure (e.g., will there be an alarm?); verify how the archiving function will resume under such situations (i.e., manually or automatic?).
- If UPS in place, how long is the backup power supply available for and verify that UPS covers both server and recorder.
- Verify that data is stored locally without interruption, when the communication to the server is disrupted.
- Verify that the data is transferred to the server without missing records when the communication with the server is restored.

Data Access

Test e-recorder/server/software accessibility by unauthorized and authorized users at the plant, corporate and supplier access (if applicable).

Audit Trail and Record Traceability

- Verify comments made by the operator and/reviewer have an audit trail (i.e., who, when and what).
- Verify that electronic signatures/initials have a date and time stamp.

- Verify that event log (i.e., who, when & what) can be properly displayed on the electronic chart recorder.

Copies of Records & Record Retention

- Set up and verify creation of process records/charts on data management software.
- Verify that data can be extracted by users with authorized credentials only (e.g., record reviewer).
- Verify that the data transferred to data management software can be retrieved and signed; charts can be created and printed as required.
- Verify process records archiving and record retention duration as per regulatory and corporate standards (e.g., check archived data every month).
- Set up and test printer functions correctly and is capable of printing records with correct scale graduation and/or resolution. If the data are printed in a graphical format for the record reviewer, the printed copy must meet the corresponding predicate regulations.
- Verify that record retention timeframe meets regulatory and corporate requirements.
- Verify that printed records from e-chart recorders meet the requirements of applicable regulations (i.e., predicate rules requirements).

Electronic Signatures

- Verify the requirements/procedures listed in the Logical Security SOP, including:
    - Verify that record reviewer can successfully apply electronic signature with timestamp to electronic record using secured software program.
    - Verify that "reviewed" electronic records are "saved" to the data storage device and preferably segregated from "un-reviewed" records.
    - Verify that passwords expire every X months, after which time user will be asked to reset their password.
    - Verify that after X unsuccessful user ID and password login attempts, login credentials are locked and user must be reinstated by a system administrator.

Additional functionality tests may be required based on the Risk Assessment. The list above should be reviewed to ensure all functions are covered. Table 11 below shows an example format for documenting the Functionality Challenge Tests. This will be the proof and verification that each of the functionality tests was completed and satisfactory results were achieved.

Table 11: OQ Functionality Challenge Tests

Test	Anticipated Result	Actual Result	Signature and Date
Verify how system will react to power outage/communication failure	System reacts appropriately for specified time following simulated power outage/communication failure		
Verify Electromagnetic Interference (EMI) on e-recording system	EMI from mobile phone, 2-way walkie, and other sources does not affect recording of critical instrument data		

Table 11: OQ Functionality Challenge Tests			
Test	**Anticipated Result**	**Actual Result**	**Signature and Date**
Verify proper date and time are recorded by e-recording system	Correct date and time are recorded by recording system; Daylight Savings time enabled		
Verify that users can properly apply electronic signature with timestamp after review	Users can properly apply electronic signature and timestamp to records after review		
Verify SOPs are appropriately implemented	All necessary requirements as outlined in the procedure are implemented as defined		
Verify data collection and transfer rate	Data collection and transfer rate (e.g., 3 data points per second) is enabled		

13.3 Deviation Handling – A complete and comprehensive Operational Qualification, including all SOPs and tests, is required prior to moving forward with the validation. A Deviation Handling section should be created for this document in case a deviation or abnormality is experienced during OQ. The validation team should evaluate if the deviation in OQ protocol is significant enough to consider revalidating all items related to the failure. See Table 12 for example.

Table 12: Deviation Handling During Operational Qualification			
Deviation Description	**Recommended Corrective Actions**	**Results Verification**	**Signature and Date**

14.0 PERFORMANCE QUALIFICATION (PQ)

The Performance Qualification verifies that the chart recording system performs as intended throughout all anticipated operating ranges. In practice, this is to ensure that the system in its normal operating

environment produces acceptable records that meet predicate rules and 21 CFR Part 11 requirements and that sufficient documentary evidence exists to demonstrate that these requirements were met.

Prior to performing PQ, training should be completed to encompass all SOPs generated from Operational Qualification. Plant personnel (e.g., Operators, Supervisors and Record Reviewers) who will use electronic signatures must certify prior to use that their electronic signatures are intended to be the legally binding equivalent of their handwritten signature. Training must be documented and must cover procedures specific to operator, record reviewer and maintenance duties.

Following training, verification tests should be completed as defined in the PQ test protocol. PQ test results must be documented with applicable sign offs and should be performed during normal operating conditions.

The success criteria for PQ should include at minimum, but not limited to, the following:

14.1 All requirements (e.g., user needs and regulatory musts) as outlined in the URS are met and demonstrated through three independent, successful, normal production runs. This includes meeting 21 CFR Part 11 and applicable predicate rule requirements (e.g., 21 CFR Part 113).

14.2 All tests as outlined in PQ test protocol produce anticipated results and are appropriately documented. See table 13 below for example.

- For systems under 21 CFR Part 113, monitor the display of the unit over several cycles and compare readings with calibrated RTD and/or reference TID.
- Compare records from the electronic chart recorder with readings from either calibrated or reference instruments to verify their accuracy. The display of the current data, the display of the historical data, and the printed records should be verified for accuracy.
- The response time in the changes of values throughout the process must be within the limits specified in the user manual or Design Specifications for the unit.
- Intentionally generate failures to verify the proficiency of the operators in identifying the failure and following SOP. For example, generate low temperature deviation, and/or deviations in other critical variables monitored by the electronic chart recorder, challenge communication failure, ensure clarity of the data display, check that the information on the chart display is legible and does not create confusion for the end user, challenge the proficiency of the operators/supervisors in entering data, reviewing and signing records.
- Challenge record retrieval from storage device, drive, and/or server by responsible parties (e.g., personnel from IT, QA, PA).
- Verify the accuracy and accessibility of historical (back up) records: Historical records are verified against process logs, comments, audit trails etc.
- Verify that the staff knows how to associate a time/temperature history with the corresponding process cycle under review: When charts are pulled and records are reviewed, the transferred files have a time bar across the bottom that is the correct time, which allows cross-referencing a particular process time and cycle from the operator logs. Therefore, the reviewer can check that he/she is reviewing the correct record.
- Verify that when records are reviewed, the data are stored in such a manner that they are clearly accessible via the user interface. This prevents the accidental misreading of data and eliminates the possible confusion. Data are pulled from the Chart by group and stored in the same structure.
- Verify that the electronic chart records are reviewed within one working day by the staff for accuracy and completeness of notes.

- Verify that when the reviewer adds comments to the record, the detailed audit trail (i.e., who, when, what) are appended to the record. Verify that the audit trail information can be displayed with the record.
- Verify charts can be printed out to meet predicate rule requirements (e.g., chart scale graduations).
- Some companies and consulting groups conduct most of the challenge testing of the system under normal and abnormal operating conditions during the OQ phase of qualification.

Table 13: Performance Qualification Tests

		RUN 1		RUN 2		RUN 3	
Test	**Anticipated Result**	**Actual Result**	**Sign and Date**	**Actual Result**	**Sign and Date**	**Actual Result**	**Sign and Date**
Operator Log On	Input of correct User ID and Password will allow access to the recorder.						
Operator/Supervisor Data Entry and Record Review	Users can make comments, add e-signature to the chart and follow applicable SOP's.						
E-Recorder Display Set Up	E-recorder graduation scale cannot be amended by unauthorized user, Display clarity is acceptable and E-recorder is set up such that it is easy to use by the end user.						
Critical Factor Trends Printing Capability	Printed chart working scale does not exceed 55 F° per inch and graduation not exceeding 2 F° to meet predicate rule requirements.						
Quality Manager/ record reviewer log on to review data	Quality Manager/ record reviewer can log on and review data using software.						
Quality Manager/ Record Reviewer signature	Quality Manager/ Record Reviewer can input signature, add comments with date & timestamp within required time frame.						

Table 13: Performance Qualification Tests							
		RUN 1		RUN 2		RUN 3	
Test	Anticipated Result	Actual Result	Sign and Date	Actual Result	Sign and Date	Actual Result	Sign and Date
Data Backup to Server	Data is appropriately backing-up to the designated server and data is stored at a pre-defined frequency.						
Data Storage and Retrieval	Data can be stored and retrieved from E-recorder internal memory, external memory card and server by responsible parties (e.g., IT, QA, Process Authority etc.)						
Audit Trail	Audit trail (i.e., who, when & what) is appended to the record. Audit trail information is displayed with the record.						
Critical Factor Data Records	Processing data for all critical factors are recorded and trended as per corporate and applicable regulatory requirements.						
E-Recorder Critical Factor Readings	Process critical factor readings on E-Recorder matches with calibrated sensor and/or TID. Append operator log sheets, PLC printouts, e-chart images/trends etc.						
User Proficiency to Identify Failures	Operator and Record Reviewers identified failures/deviations and Communication failure via E-recorder monitoring or during record review.						

Table 13: Performance Qualification Tests							
		RUN 1		RUN 2		RUN 3	
Test	Anticipated Result	Actual Result	Sign and Date	Actual Result	Sign and Date	Actual Result	Sign and Date
E- Record Identification	Records/trends accurately correspond to process cycle under review. The record ID is based on batch code and/or day code which allows cross-referencing particular process time and cycle from the operator logs to ensure correct record is reviewed.						
Remote Data Access via user interface	Software is configured such that data is pulled from the chart by group name and stored in the same manner to prevent misreading and to eliminate confusion.						

14.3 Any deviations from PQ tests are documented. The cross functional team should review the impact that the deviation may have on validation and evaluate if changes must be made to the URS, FS, DS, IQ, OQ, and PQ. Corrective actions are verified and approved by the responsible party.

Table 14: Deviation Handling During Performance Qualification			
Deviation Description	Recommended Corrective Actions	Results Verification	Signature and Date

15.0 VALIDATION REPORT

The qualification activities should conclude with the creation of a final validation report. This final report will act as documented evidence that the validation was completed with successful results. The validation report may be a summary of all the documentation generated from the validation plan, URS, FS, DS, IQ,

OQ, and PQ. The validation records should include applicable team sign-offs for each activity as well as documented sign-off on the overall outcome of the validation.

The validation documents and final validation report must be considered as permanent records and kept on file at the plant and/or at the corporate level. If any regulatory question should arise, these validation records should be made readily available to an auditor or FDA investigator.

16.0 CONTINUED VERIFICATION, ONGOING TRAINING, AND CHANGE CONTROL

The documentation of the validation for the electronic chart recorder is a live document. Continued verification is an integral part of any well qualified and validated system. The functioning and operation of the electronic chart recording system should be verified and documented on a periodic basis throughout its lifetime to ensure integrity and reliability. The hardware should also comply with suitable standards for protection in a factory environment (e.g., electrical shielding, dust and water etc.).

Training and awareness sessions around the functioning of electronic chart recording system should be conducted to educate the end users, and to ensure continued compliance with 21 CFR Part 11 and related SOPs. Depending on access level, different types of training sessions may be required for the end users. Such training sessions should be documented for all users and conducted on a regular basis for new and experienced personnel. The validation documents are a useful source of training information for new trainees or staff turn-over.

Once qualified, an electronic chart recording system must be maintained in its validated state through the site's effective change control program. Changes to hardware, software and/or procedures might be necessary to upgrade the system, to replace obsolete components, and/or to enhance its functionality. The impact of these changes must be reviewed, approved and documented by the validation team. Any changes to the system may have an impact that may require reviewing and/or editing part or the entire validation documentation such as URS, FS, DS, IQ, OQ, and PQ.

17.0 REFERENCES

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The Institute for Thermal Processing Specialists is a non-profit organisation established exclusively for the purpose of fostering education and training for those persons interested in procedures, techniques and regulatory requirements for thermal processing of all types of food or other materials, and for the communication of information among its members and other organisations.

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