Compliance to PMO criteria for the evaluation of electronic data recorders

Food and Beverage Knowledge Series

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Executive summary

According to the FDA Grade “A” PMO (Pasteurized Milk Ordinance) 2013, electronic data recorders are now considered suitable replacements for paper chart recorders, particularly in terms of cost savings and reliability. In order for electronic data collection systems to be considered, vendors or manufacturers must describe how the recording products comply with the twelve criteria dictated by the PMO. The purpose of this white paper is to describe how the Eurotherm electronic data recording strategy complies with the requirements of the PMO.

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Introduction

"Electronically collecting data, storing data and reporting information with computers can be a beneficial replacement for circular chart recorders and/or hand-written records." – FDA Pasteurized Milk Ordinance 2013, Appendix H, Section V, page 263.

Historically, process data logging in dairy pasteurization applications has been accomplished through the use of paper chart recorders, typically the circular paper models. There has been little advancement in paper chart recording technology and little emphasis on the transition from paper chart logging to electronic data collection, due to the cost of hardware and the perceived complications of software installation. However, the cost of operation and upkeep of paper chart recorders is increasing every year due to the need for on-site record storage and new requirements for on-demand access to the data. Additionally, the cost of replacement mechanical parts, pens, and charts is growing. During this time, modern electronic data recorders have become more economic, and the network infrastructure required for data storage has become significantly less demanding, depending on the scale of the system. This leads dairy processors to a decision between staying with an existing, ageing paper system or upgrading to a modern, user-friendly electronic data collection system.

According to the PMO, electronic data recording systems may be beneficial replacements for circular paper chart recorders; particularly considering the cost savings and reliability when dealing with electronic data over traditional paper data. However, in order for the electronic data collection systems to be considered, vendors or manufacturers must describe how the recording products comply with the twelve criteria dictated by the PMO.

The purpose of this white paper is to describe how, where appropriate, the Eurotherm electronic data recording strategy complies with the requirements of the PMO found in Appendix H, Section V.

Criteria

PMO Criteria Point 1

"Any computer required making a public health safety report, including data collection computers, data storage computers, or report servers shall be powered with an Uninterruptible Power Supply (UPS) capable of maintaining power to the computerized data collection, storage and reporting system for twenty (20) minutes." [1]

Due to the fact that Eurotherm electronic data recorders would typically be installed in-situ, the provision and installation of a UPS (Uninterruptable Power Supply) would normally reside with the organization building the panel in which the electronic data recorder is installed.

Never lose data

- *In-situ UPS*
- *Data recorded in internal memory*
- *Store-and-forward self-healing data transfer strategy*

The reason for the UPS is to prevent loss of data during a power failure but it is worth mentioning that Eurotherm recording strategies have several other key benefits that prevent data loss. Firstly the data captured by Eurotherm digital recorders is stored at the point of measurement in the memory of the recording product, rather than directly transferred over communication lines to a PC or other storage device. This means the data is securely stored before it is transferred. Secondly, in the event of a communications breakdown, Eurotherm recorders employ a self-healing store-and-forward strategy that backfills any missing data from the on board memory when the communications are restored. The data is typically transferred, either by FTP (File Transfer Protocol) which can push the data to a PC or server, or by Eurotherm Review archiving software installed on a server, which pulls the data straight

[1] "U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p.264

into its secure database. For 'best-practice' these plant network servers would typically have a UPS installed as well, creating a robust data capture system that is resistant not just to power loss but also unexpected interruptions in communications.

Note: APC by Schneider Electric is a global supplier of power protection solutions that provides a range of UPS products to fit all sizes of applications. Find out more at www.APC.com.

PMO Criteria Point 2

"A written user's guide of the computerized data collection, storage and reporting system shall be provided and will explain the system's architecture, the software used and the sensors or instruments monitored. This overview may be presented in text or in a graphical representation. A copy of this overview shall be maintained at the discretion of the Regulatory Agency. This document shall bear the name of the identified representative from the milk plant assigned to administrate this procedure and be available for review at the milk plant by the Regulatory Agency and FDA. This documentation shall explain:
a. System's architecture, the software used and the sensors or instruments monitored;
b. Reporting interface of the computerized data collection, storage and reporting system;
c. Backup procedure for ensuring the safe storage of the public health safety data of all reports;
d. Procedure for any changes or maintenance to the instrumentation, sensors, hardware or computers. This procedure will explain how the plant will ensure that when a physical change occurs the information affected has been checked for accuracy; and
e. Listing and explanation of the reports available on the system, instructions on how to access the reports and examples of each report with a description of their content." [2]

Technical support

Equipment operating procedures and guides are often unique to the processes and plants in which the equipment is installed. Therefore, a user's guide is typically developed by the end-user as part of the operating procedure for the entire system. Documentation on specific products and software is readily available on the Eurotherm website and Eurotherm technical representatives are able to provide any further technical details necessary for the end-user to integrate the new data collection systems into their existing processes.

PMO Criteria Point 3

"A written record shall be maintained by the milk plant identifying any changes or updates to the computerized data collection, storage and reporting system, software, drivers, networking or servers in order to assure the collection, storage or reporting of any data needed for compliance has not been compromised. This document shall bear the name of the representative from the milk plant assigned to administer this procedure and be available for review at the milk plant by the Regulatory Agency and FDA." [3]

Change note and version control responsibility typically falls into the purview of the end-user/plant management team. However, Eurotherm manufacturing processes are designed in such a way that changes to firmware, software, or hardware for the electronic data recording devices are communicated to the end-user and then, in regulated or validated processes, not changed or modified until there is buy-in or agreement from all stakeholders. Configuration

[2, 3] "U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p.264-265

changes are also audit trailed and securely stored giving full visibility of the recorder build level at any time.

PMO Criteria Point 4

"In the case of CIP and raw and heat-treated storage tank records, data shall be stored at a rate to provide a reasonable account of the process being recorded. This shall never exceed a maximum of fifteen (15) minutes between data records. The data for the reporting system shall be backed up at least once every twenty-four (24) hours. Alternatively, the final reports may be stored and backed up at least once every twenty-four (24) hours." [4]

Sample rates and data backups

- *Data sampled once every 125ms*
- *Up to 125ms recording rate easily meets 5s requirement*
- *Backup by USB, FTP or Eurotherm Review archiving software*

The speed at which data points are electronically sampled varies with the capabilities of the data recording hardware. However, all Eurotherm electronic data recorders can sample data points at a frequency of 8Hz (8 times per second). The data recording speed is fully selectable from a maximum of once every 125ms to once a day, and the recording sample speed can either be fixed at a constant rate, or configured to log at an idle speed that can be increased in the instance of a process event.

This electronically recorded data is stored locally in the recording unit's internal storage memory. The internal data storage space is non-volatile memory, which is persistent even in a power off condition. The recorded data may be transferred from the electronic recording device by a number of methods. First, an operator with a USB stick may walk from recorder to recorder pulling data on demand. This is especially beneficial to smaller plants which do not have networking capabilities. Secondly, if Ethernet ports are available, the electronic data recorder may be configured to initiate an FTP transfer of the data to a location on a PC workstation or server. Finally, and most often, the Eurotherm Review Full software version can be used to schedule data pulls at regular intervals from any number of Eurotherm electronic data recorders on a plant network. This method allows operators who would normally be tasked with replacing paper charts and ink pens to be assigned to other tasks.

The data transferred into the Eurotherm Review software database can be reviewed, annotated, and signed electronically, and charts can be created and printed on demand. Provided a typical server back-up routine is established by the local IT representative, the data will be available for access indefinitely.

PMO Criteria Point 5

"In the case of pasteurization records, data shall be stored no less than every five (5) seconds for each required variable. Any event required to be recorded in manual reporting, such as a divert condition; shall be recorded no matter how short the duration. Provisions shall be made to allow operators to report additional events electronically, such as a record of unusual occurrences. The data for the reporting system shall be backed up at least once every twenty-four (24) hours. Alternatively, the final reports may be stored and backed up at least once every twenty-four (24) hours." [5]

Similar to criteria point number 4, the speed at which data points are electronically sampled in the data recording hardware can be set to the speed required by the process. All Eurotherm electronic data recorders are fully capable of recording data points at the required five second

[4, 5] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p.265

interval and are in fact capable of recording speeds up to once every 125ms (8 times per second).

Capture unusual occurrences

- *125ms sample rate to capture events*
- *Operator messages*
- *Scheduled backups*

In the case of pasteurization records, while the data points only need to be recorded at a rate of once every five seconds, the process input is actually being electronically sampled at a rate of 125ms. This means that, even if a data point is sampled and stored every five seconds, process events, such as divert conditions, are still sampled, alarmed, and logged at a permanent rate of 125ms. The result of such an electronic sampling design is that *all* process events, regardless of duration, will be logged.

In addition to automatic logging of process deviations or diversions, the Eurotherm electronic data recording devices allow operators to enter full annotations using either a selection from a list of preset event or alarm messages or the operator may utilize the inbuilt keypad to enter a free form event message. Whether a pre-generated message is chosen or a free-form message is entered, the end result is that the text is time and date stamped and appended permanently to the process data.

Similar to criteria point number 4, this electronically recorded data is stored locally in the internal storage memory of the unit and can be scheduled to regularly back up automatically to the Eurotherm Review database for historical review, annotation, electronic signing, and report chart creation. Provided a typical server back-up routine is established by the local IT representative, the data will be available for access indefinitely.

PMO Criteria Point 6

"Upon the initial installation, computer generated reports shall be verified visually for accuracy for seven (7) consecutive days and be found to be accurate and error free in actual service in the milk plant where installed. These seven (7) days of reports shall be printed out and shall bear the signature of both the vendor of the system and the identified representative from the milk plant, or they shall be accompanied by a cover letter signed by the vendor and the identified representative from the milk plant. If the milk plant develops the computerized data collection, storage and reporting system, the programmer and the identified representative from the milk plant shall be two (2) different individuals. This seven (7) day report verification period shall only be required at initial installation and one (1) time only whenever a chart recorder and/or hand-written record is being replaced by electronic data collection, storage and reporting. These seven (7) days of reports shall be kept on file at the milk plant and a copy shall be provided to the Regulatory Agency when requested." [6]

The Eurotherm electronic data recorders may be run in parallel with the existing paper chart recorders for a validation period. Typically, upon completion of the validation period, Eurotherm personnel work closely with end-user/plant personnel to review and compare the chart data. The data records, housed in the Review archival software database, may be electronically annotated and signed to provide a permanent and retrievable copy of the validation data. Additionally, any anomalies or discrepancies are fully investigated and explanations are provided in conjunction with plant personnel.

Eurotherm also provide GAMP validation template documentation and engineering services to aid Good Automated Manufacturing Practises.

[6] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p. 265

PMO Criteria Point 7

"Whenever changes, updates or observed anomalies that affect the reliability or accuracy of the reporting system occur following the initial installation of the system, these changes, updates or observed anomalies shall be evaluated and investigated and if corrections are warranted shall be addressed. The records of each evaluation and corrections made shall bear the signature of the vendor or the identified representative from the milk plant. The records shall be maintained and be available for Regulatory Agency when requested." [7]

Technical support

Eurotherm technical representatives are available for consultation and investigation when such an anomaly occurs.

PMO Criteria Point 8

"The electronic computerized data collection, storage, and reporting system shall provide for any signatures or initials required by this Ordinance. Acceptable operator signatures or initials, captured electronically, may be any combination of alpha and/or numeric characters that identify the individual performing the test or operation. Input of this signature or initials may be done by any means, including, but not limited to, a biometric reader, a card or radio frequency device, or by simple direct entry that provides a unique identifier directly associated with a specific person. Input of this signature or initials shall occur each time it is required by this Ordinance. Except, that in the case of pasteurization records, the operator's signature or initials shall occur whenever an operator changes and at a minimum frequency of once every twenty-four (24) hours." [8]

Digital signatures and initials

- *Review, annotate and sign digitally in Review software*
- *Audit trail option for password, access and permission management*
- *USB ports for barcode /biometric data entry*

With regard to any data collected and stored for validation or review, the primary data collection and archival point is the Eurotherm Review Full software. This software is intended to be installed on a server and configured to extract the electronically recorded data from any Eurotherm electronic data recorders on the plant floor. Once the data is extracted, it is available permanently and may be reviewed, annotated, and signed. This review and signing automatically appends the individual's name when logged in to the PC or server; this name is as defined by Microsoft Active Directory. Any and all annotations, notices, or signatures are time and date stamped and the Active Directory user name is introduced to the text as it is inserted into the permanent data.

An added benefit of using Eurotherm products is the security management option that provide a tamper resistant audit trail for recording User Names, Passwords and Access Permissions, where all operator activity is logged and recorded in the secure database. The permission to change configuration parameters can be by electronic signatures designed to assist with regulations like FDA 21 CFR Part 11 and 21 CFR Part 113. For example, an operator could be given permission to change configuration by digital signature or they may need to get a second level of authorisation from a quality engineer. The important thing is that the changes will be logged for quality personnel and auditors to review should they need to. Features like these that bring traceability of 'who did what' in a process are useful to help maintain Good Automated Manufacturing Practices (GAMP) and Hazard Analysis and Critical Control Points (HACCP) guidelines.

Eurotherm recording products typically feature USB ports that allow entry of operator signatures and information via barcode/biometric readers etc. Timers and batch features can

[7, 8] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p. 265

be used to trigger alarm messages in order to remind operators to enter signatures or initials at changeover periods or specified times.

PMO Criteria Point 9

"The data supporting electronic reports shall be stored in a database or data archival system in a Write Once, Read Many (WORM)." [9]

Secure Data

The ideal architecture for the permanent storage of the data logged by the Eurotherm electronic data recorder is the use of the Eurotherm Review Full software. This software is a database archival program which allows the user to schedule a transfer for each Eurotherm electronic data recorder installed. The scheduled transfer times may be set to a frequency determined by the process stakeholders. This frequency may be once a day, as referenced by the prior PMO criteria points, or even as often as once every 5 minutes. Once the data is collected by the Review Full software, it is available as a permanent record. It may be accessed, reviewed, and printed as often as required but cannot be edited or altered in anyway. This is accomplished with the secure encryption of the database file into which the recorded data is copied.

Another benefit of using Eurotherm recording strategies is that unlike PC data collection systems that typically record data in a .csv file format, Eurotherm data is stored in a secure tamper resistant file format called .uhh files. These binary checksummed files are not readable without Eurotherm Review Software, in contrast to .csv files which are openly editable in software packages like Excel. Csv files themselves are therefore not suitable for pasteurization applications as they are not resistant to tampering by over-writing before the archiving process.

PMO Criteria Point 10

"The system shall provide an anomalies report indicating any system or communication failure that could have affected the validity of the required reports. This anomalies report shall be automatically attached to any report that may have been affected by the system anomaly. A separate error log or system log shall not suffice for meeting this requirement, since any anomaly requires an evaluation and investigation to correlate the anomaly.

NOTE: While electronic and computerized systems can furnish a wide range of process validation and anomaly reporting, these criteria only require appended reporting of data loss that affects the reports that are required to comply with this Appendix and Items 12p and 16p(D) or other required reporting contained in this Ordinance. " [10]

Record Anomalies

- *Alarms logged in memory*
- *Time and date stamped messages*
- *Permanently recorded with the data*

All anomalies detected by the electronic data recording system can be alarmed and logged to the internal memory. This log may be a simple event notification or a full text description of the problem detected. The error or anomaly is time and date stamped and added to the permanent memory. In addition to these automated messages, errors or anomalies detected by external operators or plant personnel may be entered manually into the data recorder's permanent electronic memory. These messages, whether automatic or manual, are fixed permanently and can be part of an event and alarm report printed from the Review data archiving software.

[9, 10] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p.266

PMO Criteria Point 11

"When a report is viewed on a computer screen, this format is exempt from the graduated temperature divisions, temperature-scale divisions and line spacing requirements of this Appendix." [11]

While the electronically recorded data viewed from a computer screen is exempt from the viewing criteria levied upon paper charts, such scaling and divisions can easily still be applied either in the display configuration of the digital recorder or afterwards by formatting charts in the Review data archiving software. The software user may also simply 'point and click' a time location on the x-axis of a review chart to see the exact recorded process value at that data point.

PMO Criteria Point 12

"Printed reports shall present data in a form that is compatible with the applicable requirements of this Ordinance." [12]

The Review program offers the user the ability to print data with a scaling format suitable to their individual process requirements. While the user may alter the scaling and time formatting to change the amount of data viewed, he or she may never delete or alter the source data itself.

It is also worth noting here that Eurotherm are able to provide a smart reporting package designed specifically for use in industrial processes that can automatically generate reports on demand. Reports can be configured to automatically pull in charts and other relevant data, saving time for the quality engineer who often has to do this task manually.

Conclusion

"The FDA has thoroughly discussed this issue and determined that the criteria for an electronic data collection, storage and reporting system are clearly outlined in the PMO (Appendix H, Section V).

As such, the FDA no longer feels there is a need to evaluate electronic data collection, storage and reporting systems.

The vender simply has to demonstrate to the end user and the regulatory agency that their system complies with the criteria noted in Appendix H, Section V."

– Randy Elsberry, FDA Regional Milk Specialist

With the recent advancements in food safety requirements, there is more pressure than ever on producers to provide immediate, on-demand access to process data records. The long term use and storage of paper charts on-site can create numerous problems both when trying to locate data amongst reams of paper and on-going costs of maintaining the paper systems. Modern electronic data recorders with secure untamperable file formats, are a perfectly acceptable replacement for paper systems, when demonstrating compliance with the criteria of the PMO.

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[11, 12] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration", *Grade "A" Pasteurized Milk Ordinance*, 2013 Appendix H, Section V p.266