White paper about PMO

(Pasteurized Milk Ordinance)

JUMO LOGOSCREEN 601/700

White paper

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1 Criteria

With this White Paper JUMO GmbH & Co. KG provides an official position about the conforming use of the paperless recorder LOGOSCREEN 601/700 (type 706521 and 706530) with extra code “888” in accordance with the defined requirement criteria in APPENDIX H SECTION V. "CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING" of the Pasteurized Milk Ordinance (2017 Revision).

... for the evaluation of electronic data collection, storage and reporting background

Electronically collecting data, storing data and reporting information with computers can be a beneficial replacement for circular chart recorders and/or hand-written records. This method of presenting Grade “A” PMO required information should essentially replace and duplicate the purpose and functionality of their manual or chart recorder counterparts. These would include CIP records, pasteurization records, raw and heat-treated product storage tank's temperature and cleaning requirements and temperature monitors for membrane filtration. This criteria for the evaluation addresses the difference between manual records or chart recorders and electronic or computer record keeping. These differences are identified in the criteria below that address the verification of system reliability, security and dependability and what information is available and accurate for assuring public health safety and inspection.

Following are some of the differences between manual records and chart recorders as compared to electronically collecting data, storing data and reporting information using computers:

Demands/criteria of PMO	Implementation on the LOGOSCREEN 601/700
1. Manual Records and Chart Recorders are Visual in Nature: Milk plant employees and regulatory personnel can see and physically hold the records and place them in files for safe keeping. Whereas, computerized data collection systems are not so, they need to have methods in place to assure that the information is reliably placed and safe.	✓ The data acquisition system, which consists of the paperless recorder LOGOSCREEN 601/700 (hereinafter referred to as recorder) and the associated PC programs, has functions that guarantee safe and reliable storage of process data. ✓ It is ensured that invalid or modified documents (or manipulation attempts) are identified and not available for evaluation. ✓ The option to print out and to sign process data when required is available.
2. Manual Records and Chart Recorders are Physical in Nature: Milk plant employees and regulatory personnel can physically record on and actually sign the records and; therefore, become responsible for the required public health activity. Also, the quality assurance manager is typically responsible for the integrity of the stored records. Whereas, computerized data collection and reporting systems need to collect the identity of the person performing the function and they also need to have someone at each milk plant responsible for the integrity of the stored records.	✓ The recorder supports a user administration with which the identity of the person is ensured. ✓ Each person/user can be assigned different usage rights. ✓ Each user has to log on to the recorder with user ID and password. Only then does he/she have access to the functions that are enabled for him/her. ✓ User-related rights for the retrieval and saving of process data can be assigned.

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3. **Manual Records and Chart Recorders are Typically Hard Wired Directly to Dedicated Instrumentation:** Very little complexity exists between the sensor, such as a temperature or flow sensor, and the final recording device. This allows routine maintenance and compliance monitoring and inspection of manual records and chart recorders to be relatively simple. Whereas, the computerized data collection, storage, and reporting systems need to have documented procedures in place to assure that system changes, upgrades, and normal operating procedures do not compromise the integrity of the public health safety information and reports.	➢ *This is the responsibility of the operator and must be regulated through Standard Operation Procedure (SOP).*

The following criteria are to be used for the evaluation of electronic collection, storage and recording or reporting of any information required within Items 12p and 16p(D) of this Ordinance.

NOTE!

These criteria do not address computer instrumentation or the electronic control of pasteurization for public health safety.

All computer-generated records and reports shall contain the information required in this Ordinance that is applicable. The computerized data collection, storage, and reporting system must have an assigned and identified representative from the milk plant that is responsible for the system. This person's name must be available to the Regulatory Agency and FDA.

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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.	➢ *This is the responsibility of the operator, meaning that he/she must operate the recorder over a UPS-system*.
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:	➢ This is the responsibility of the operator or the system manufacturer, meaning that he/she must prepare the respective plant documentation in the required form. ✓ JUMO offers a template for an IQ/OQ documentation that can be adjusted by the plant operator for his/her plant.
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.	

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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.	✓ The recorder and associated PC programs possess a clear version administration. ✓ The recorder version is described using a distinct order code. ✓ The recorder is labeled with its own fabrication number so that it is traceable.
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.	✓ The recorder supports the required saving intervals. ✓ The data backup demands are ensured through the PCC communication software which supports an automatic retrieval and archiving of the process data including the reports. That means that the recorder and communication software must be configured according to the required saving and backup intervals.
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 will 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.	✓ The recorder supports the required recording interval. The alarm function of the recorder allows the specification of process values to be monitored – these are then saved in an event/alarm list with date and time stamp if overrange or underrange occurs. If an exceptional incident occurs then the user can save a manual comment as a note in the event list with date and time stamp. If required, an electronic signature with a comment can be saved. ✓ The data backup demands are ensured through the PCC communication software which supports an automatic retrieval and archiving of the process data including the reports. That means that the recorder and communication software must be configured according to the required saving and backup intervals.

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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 will 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 will 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.	➢	*This is the responsibility of the operator.* *The system supplier (JUMO) assures the confirmed characteristics (continuous data recording, compliance with the configured measurement cycles, security against manipulation, monitoring of limit values).*
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.	➢	*This is the responsibility of the operator.* *Note:* *This requirement corresponds to a revalidation of the plant.* *For this purpose an IQ/OQ specification document can also be used.*

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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 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.	✓	The recorder has the function that a user can provide an electronic signature. ✓ The electronic signature can only be provided by an authorized user. The recorder checks on the basis of the entered user ID/name and the secret password if he/she has the authorization for an electronic signature. ✓ The recorder can manage the authorization of up to 50 users. The administration of the user list takes place through an administrator at the PC with the so-called PC security manager software. Note: The demand for signature after a change in operators or after 24 h must be regulated through a Standard Operation Procedure (SOP).
9.	The data supporting electronic reports shall be stored in a database or data archival system in a Write Once, Read Many (WORM).	✓	The PCA3000 evaluation software supports the process data evaluation directly from a storage media such as a CD-ROM/DVD-ROM.
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.	✓	The recorder has a monitoring function that recognizes such problems as a probe break, probe short circuit, or internal system errors. Equivalent occurrences are saved in the event or audit trail list.

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.

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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.	➢	*Not applicable*
12.	Printed reports shall present data in a form that is compatible with the applicable requirements of this Ordinance.	✓	The PCA3000 evaluation software supports the print output of all stored process data in a form that is analyzable for the user.

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