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PPR Application guide for PMO Appendix H Section V

Anderson-Negele Paperless Process Recorder (PPR) with Legendary™ software is intended to be used in PMO applications. The blue text of this document explains how the recording system and review software meet the 2019 PMO requirements for non-control applications (requirements shown in black text). The blue bullet points indicate where additional information on this topic can be found.
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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.*

- All digital records/charts created by PPR are securely synchronized with Legendary™ cloud-based approval workflow software. Authorized employees can access those records using their Legendary™ credentials.
- If Legendary™ is not accessible, local removable SD-media storage device can be accessed for the latest revision of all records created in last 100 days.

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.*

- All users of PPR will have to self-identify with PIN code before adding any annotation, approving a record, or making calibration or configuration changes.
- Anderson-Negele (A-N) assumes responsibility for the integrity of the stored data records in the Legendary™ cloud for the life of the Legendary™ subscription. If the subscription is discontinued the plant is responsible for maintaining the records beyond the subscription period.

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.*

- The milk plant would be responsible for documenting system changes, upgrades and normal operating procedures.
- PPR allows only authorized plant users to change configuration or calibration through the PPR user interface. The milk plant will/must assign a plant administrator who is responsible for user management.
- Software updates; cannot change or jeopardize the integrity of the previously recorded information.

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CRITERIA

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 shall have an assigned and identified representative from the milk plant that is responsible for the system. This person's name shall be available to the Regulatory Agency and FDA.

PPR users can enter all PMO required chart information either through the "system information" workflow which is accessible from the home screen of the recorder or through the "Add Notes" annotation workflow. Each annotation method requires valid user credentials before adding information to the record.
- PPR Operating Manual Section 4.4.3: Adding Annotations to PPR Records

Once configured the recorder will automatically place plant information on each record generated e.g. plant name, address, IMS ID number, etc.
- PPR Operating Manual Section 5.4: Recorder Configuration

Each Grade "A" plant is responsible for identifying an individual to be responsible for their and Legendary™ software.

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.*

   Paperless Process Recorders hardware consumes a maximum of 48 watts, to ensure uninterrupted data recording for 20 minutes a 0.66 Amp hour UPS is required. The plant is responsible for the installation and maintenance of UPS. Additionally, PPR includes a field replaceable cr2032 battery that ensures the system time clock will remain accurate for a minimum period of 1 month in an unpowered recorder.
   - PPR Operating Manual Section 5.2: Date and Time

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;*
   - PPR Operating Manual Section 2.1: System Overview

   b. *Reporting interface of the computerized data collection, storage and reporting system;*
   - PPR Operating Manual Section 2: PPR Record Creation and Data Storage
   - Legendary™ Operating Manual Section 6: Legal Record

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c. *Backup procedure for ensuring the safe storage of the public health safety data of all reports;*
Data in the PPR is recorded at a customer defined frequency, as often as every 3 seconds. Under normal operating conditions all completed records are backed up to the cloud within 15 minutes of the creation of the record. To adhere to this requirement in applications where the chart period may exceed 24 hours, a daily chart is created and backed up on a local removable SD-Media storage device every 24 hours.
- PPR Operating Manual Section 2.1.2 PPR Record Creation and Data Storage

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*
Covered in PPR Operating Manual Section 5: Configuration & Section 6: Calibration

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.*
The PPR keeps a log of system actives including calibration changes, configuration updates, and software updates. The typical report generated by PPR is a Chart Record.
- PPR Operating Manual Section 4.3.6: Common Interactions System Activity log
- PPR Operating Manual Section 2.1.3: PPR Record Layout

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 plant is responsible for maintaining a log of any external changes to the device. PPR will also automatically capture changes to the software, configuration, and calibration updates in its system log.

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.*
Data in the PPR is recorded at a customer defined frequency, as often as every 3 seconds. Under normal operating conditions all records are backed up to the cloud within 15 minutes of the creation of the record. To adhere to this requirement in applications where the chart period may exceed 24 hours, a daily chart is created and saved to a local removable SD-Media storage device every 24 hours.
- PPR Operating Manual Section 2.1.2: PPR Record creation and Data Storage

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.*

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The PPR allows the user to configure the frequency of data being recorded through the Human Machine Interface (HMI) while J9 jumper is in Program mode. In menu "Recorder Configuration", tab "Recorder Setup" shown in image below. For pasteurization applications the rate of data being recorded should not exceed 5 seconds.

- PPR Operating Manual Section 5.4: PPR Record Configuration

Figure 1: Rate of Data Being Recorded

The status of the Flow Diversion valve is measured and recorded on the PPR through microswitch position detection on the STLR Relay Board. Diversion events that last 100 milliseconds or longer automatically recorded as a change in status of the STLR event pen on PPR records. This recording takes place independent of the Rate of Data Being Recorded described above.

- PPR Operating Manual Section 2.1.7: STLR Recording and Control
- PPR Operating Manual Section 3.7: STLR Relay board Wiring
- PPR Operating Manual Section 5.4.4: STLR Record Configuration

Unusual occurrences and annotations that are required to be on STLR records can be added by authenticated users through the "Add Notes" annotation workflow on PPR or through Legendary™.

- Legendary™ Operating Manual Section 6: Legal Record

Note: For pasteurization applications the PPR must be ordered with the proper input and output hardware. The 4th character in the PPR order matrix must be specified as "T" for STLR applications.

- PPR Product Brochure: Product Code

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.*

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The Milk plant is responsible for printing, verifying accuracy, and storing versions of their existing records and new electronic records created by the PPR.

A-N can provide a cover letter to state our systems intended use within the dairy industry for PMO applications.

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.*

The PPR system log will automatically note recorder anomalies such as changes to the run/program jumper position, software updates and system configuration changes in the System Activity Log.

- PPR Operating Manual Section 4.3.6: Common Interactions System Activity log

When an approval or annotations are added either through PPR or Legendary™, PPR will create a new revision of chart. Once PPR creates a chart it cannot be overwritten.

- PPR Operating Manual Section 2.1.2 PPR Record Creation and Data Storage

Legendary™ allows the plant to attach additional evaluation, correction, or other documents to each PPR record, if needed through the "Other Attachments" workflow.

- Legendary™ Operating Manual Section 6.3: Add Other Attachments

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.*

The PPR allows users to add annotations to records through the "Add Notes" workflow and the "System Information" workflow, both workflows require a valid user ID and authentication via PIN.

- PPR Operating Manual Section 4.3.4: User Authentication

Records created by PPR can be reviewed and approved either locally at the PPR HMI or in the Legendary™ software, each require valid user credentials.

- PPR Operating Manual Section 4.4.6: Record Approval
- Legendary™ Operating Manual Section 6.4: Record Approval

User administration is handled by a Legendary™ plant administrator through Legendary™ cloud software, this administrator is responsible for verifying the identity and assigning a unique identifier (Initials and Name) for each user they configure. User management done through Legendary™ cloud software is automatically synced to each PPR associated with that end user Legendary™ instance.

- PPR Operating Manual Section 2.1.4: PPR Record Approval Workflow
- Legendary™ Operating Manual Section 7: Administration

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

PPR's data storage scheme securely stores the database used to generate chart images within PPR's internal memory. The Internal memory is not directly accessible to customers and thus may not be overwritten or modified. The PPR's data storage architecture is time-based to ensures that the PPR will never overwrite data into its own database.

- PPR Operating Manual Section 2: PPR Record Creation and Data Storage

The PPR's internal database is password protected, requiring Anderson-Negele software developer credentials to view or edit the database. These credentials and the source code within the system are considered Intellectual Property and will not be shared with customers.

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.*

PPR system anomalies are defined as power interruptions and input sensor errors, each of which are automatically recorded as annotations in the current record Period.

- PPR Operating Manual Section 4.4.3.3: System Generated Annotations

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.*

The typical review process allows users to view the PPR records through Legendary™ software, or on the PPRs local Human Machine Interface, each of these review methods are exempt from the chart spacing requirements.

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

If paper copies of the PPR records are desired, they can be printed through the Legendary™ software platform by viewing the All Charts List, downloading and printing the image file. The chart scales and divisions shown on each Record are defined by the major divisions, minor divisions, Recording Lower Range and Recording Upper Range Values in the Recorder Configuration. If the plant plans to print paper records these parameters should be configured by the plant to adhere to PMO requirements for their application.

- PPR Operating Manual Section 5.1.4: Recorder Setup Parameters