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Improving PMO Public Health Control security seal compliance using unique user IDs and passwords

Food and Beverage Knowledge Series

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Executive summary

According to the Grade “A” Pasteurized Milk Ordinance (PMO), Appendix H, VI. Criteria 2, high-temperature-short-time (HTST) and ultra-high-temperature (UHT) pasteurization processes must use security seals to prevent inappropriate tampering with public health control functions.

This document details how Eurotherm standardized safety thermal limit recorder (STLR) and flow recorder/controller (FRC) digital data recording solutions support this requirement with the use of unique user IDs and passwords.

Ref: U.S. Department of Health and Human Services, Public Health Service, and Food and Drug Administration – ‘Grade “A” Pasteurized Milk Ordinance’ 2019 Revision.

Introduction

An FDA PMO compliant pasteurization system must have serialized mechanical security seals applied to STLR recorders, FRC recorders, indicating thermometers, differential pressure controllers and other pasteurizer instrumentation, for protection against intentional or unintentional changes that could compromise the pasteurization process, and therefore, public health. Often these mechanical security seals are also applied to an instrument cover that protects against physical access.

For a pasteurizer using a Eurotherm standardized STLR/FRC solution, a combination of mechanical security seals and electronic security seals (unique user IDs and passwords) can be used to gain traceable compliance to the PMO.

Mechanical sealing

For traditional STLR and FRC instruments, a mechanical security seal is used to prevent access to a configuration switch that is typically found behind a hinged panel. Access to this configuration switch could result in unattributable programming changes that could alter the function of the public health control. Such access could also allow for changes in instrument wiring that could negatively impact public health.

The Eurotherm standardized STLR/FRC solutions are modern electronic instruments that do not have hinged access panels for configuration access. However, the use of mechanical security seals applied to protective covers can still be appropriate for the following reasons.

- For Eurotherm standardized STLR/FRC solutions (based on the nanodac™ recorder/controller and 6100A/6180A paperless graphic recorders) all wiring connections are made at the rear of the instrument. Tampering with the instrument wiring connections could negatively impact the pasteurization process.
- The Eurotherm standardized STLR/FRC solutions (based on nanodac, 6100A and 6180A recorders) can have both Ethernet and USB ports at the rear of the instruments.
  - USB ports can be used for extracting historical data files or transferring configuration files
  - Ethernet ports can be used for transferring historical data files, communication to other devices, or communication to higher level systems

As a Eurotherm standardized STLR/FRC solution will need to transfer contextual metadata over an Ethernet data archiving network, the instrument enclosure can include an Ethernet switch. Typically, all network related devices should be fitted with a cover to help protect the data archiving network from tampering. Covers can be designed for the application of a dairy industry mechanical security seal.

Alternatively, the enclosure housing for Eurotherm standardized STLR/FRC solutions and any network components can be fitted with a padlock hasp. This would allow for a mechanical security seal to be applied to the enclosure door.

User ID and password benefits

Eurotherm digital data recorders help those in the pharmaceutical and biotechnology sectors meet FDA 21 CFR Part 11 and EudraLex Annex 11 compliance. These regulations specifically address digital data archiving and electronic signature requirements. Eurotherm digital data recorders help to improve compliance by featuring an audit trail that can support standard operating procedures (SOP) requiring the use of unique user IDs and passwords.

Operator: An operator's unique user ID and password can be used to input contextual information related to the pasteurization process (Indicating Thermometer reading compared to STLR reading, Indicating Thermometer reading at Cut-Out, Indicating Thermometer reading at Cut-In, and other operator notes). The provision of unique user IDs and passwords for data entry can help to ensure that all contextual metadata is attributable, which is a key tenet of good electronic signature practices.

Supervisor: Access for a supervisory role can be like that of an operator, except that a supervisor can create new operator user logins.

Engineer: Configuration changes can be made at the engineer level. Note, making a configuration change is equivalent to breaking a mechanical security seal, therefore Engineer level access should be carefully managed.

- For the engineer access level, a unique user ID and password can be provided to a person of responsibility (senior plant personnel, pasteurization equipment support personnel, local dairy technical specialist, etc.). However, the use of an engineer level password to make a configuration change should be approved by the person of responsibility at the dairy plant and the regional regulatory authority.
- An audit trail helps to provide attributability for configuration changes made to the Eurotherm standardized STLR/FRC solution, regardless of the access level. An individual must provide a legitimate user ID and password before making configuration changes. For the Eurotherm standardized STLR/FRC solutions the audit trail is a standard feature. The audit trail provides a tamper resistant record of changes, including engineer level access and engineer level configuration modifications, which are appended to the contextual metadata file against a date and time stamp. Furthermore, a configuration change increments a configuration counter that cannot be reset.

Conclusion

Unique user IDs and password access in Eurotherm standardized STLR/FRC solutions offer an acceptable alternative and improved method for limiting access to the control and recording configuration of the public health control device, compared to traditional mechanical security seals used to prevent access to a configuration switch. Configuration access and user-made changes are logged as part of the tamper resistant audit trail for enhanced traceability, helping to improve pasteurization process compliance with the FDA PMO.

For more information on Eurotherm standardized STLR/FRC solutions visit *www.eurotherm.com/pasteurization*

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