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INProcess

A Newsletter from the
Computer Integrated Food Manufacturing
Center and Pilot Plant
at Purdue University

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Inside this Issue ...

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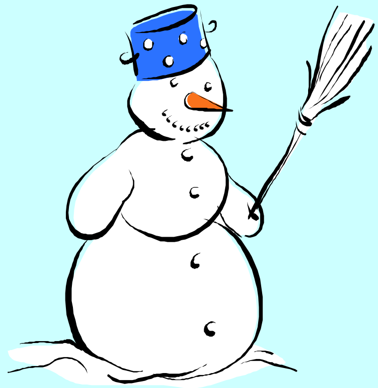

Seasons Greetings

We would like to wish you and your family the best for this Holiday Season. We sincerely hope that the upcoming year will bring you peace, good health and happiness!

Our special Thank You goes to the supporting companies of the CIFM center at Purdue! At this Holiday season, we are reminded of the meaningful relationships we have established over the past several years and we would like to take this opportunity to tell you how much we have enjoyed working with you. Our relationships with the industry and academia strengthens our ability to better educate our students, provide better workshops for the industry and discover better methods of food manufacturing!

Best wishes,

Dr. Timothy A. Haley
CIFMC Director

Sasha V. Ilyukhin
CIFMC Manager

Post PQ Validation

In the recent years, industrial control systems have become more complex and control algorithms have become more sophisticated than ever. With the exponential increase in system complexity, control system validation activities must be performed to ensure the proper equipment operation under normal and abnormal conditions. Control system validation procedure is an integral component of the entire manufacturing process validation.

The importance of system validation is further emphasized in the "Electronic Records; Electronic Signatures" regulation enforced by FDA, which clearly states that the control system validation procedures shall be employed to ensure accuracy, reliability, and consistent intended system performance[1].

According to Good Automated Manufacturing Practices (GAMP), the control system validation process consists of several distinct

[1] FDA (1997) Electronic Records; Electronic Signatures. The Federal Register. Department of Health and Human Services. Food and Drug Administration 21 CFR 11.

steps[2]. The first step is User Requirement Specification (URS), in which a prospective user of the control system outlines the desirable system specifications to the system manufacturer. The last step of the validation procedure is System Performance Qualification (PQ). In this step, final testing of the production system is conducted to ensure its compliance with all applicable regulatory documents and with the user requirement specifications outlined in the URS. After the PQ activities have been conducted successfully, the traditional system validation process is generally considered complete.

It is extremely important to realize that once the traditional validation activities (URS through PQ) have been completed, the system can not be assumed validated till the end of its life cycle (system decommission). System integrity and reliability will decrease overtime due to a number of factors, such as physical wear and tear of control system components, control system defects overlooked in the initial validation process, and unexpected system modification, including the so-called "human factor".

Most of the above-mentioned factors can be minimized by implementing a post PQ validation plan. Such plan could include a well thought-out maintenance program, on-going system verification, and improved system security.

- **Maintenance Programs**

After the process control system has been commissioned a well-planned maintenance program is necessary to ensure continuity of equipment operation, low downtime, and guaranteed equipment and employee safety. A maintenance program can include inspecting, testing, servicing, cleaning, tuning, re-validating and other necessary activities to prolong stable system operation.

It is important to understand that although the probability of system failures can not be completely eliminated, it can be minimized significantly by a well-planned maintenance program. All maintenance programs can be classified into two main types, reactive and proactive.

In case of reactive maintenance, control system equipment repair or tuning is conducted after a system failure has occurred. Reactive maintenance is not a schedule-based activity. The major disadvantage of reactive maintenance is its low cost-efficiency due to high equipment downtime and unpredictable system behavior. Another disadvantage is the necessity to keep spare parts for all components of the system, since no failure intensity analysis for individual system components is conducted.

More progressive maintenance programs employ the techniques of proactive maintenance. In this case, equipment maintenance is conducted before a system failure occurs. There are two main categories of proactive maintenance, preventive and predictive.

Preventive maintenance is a schedule-based activity. Its main purpose is to minimize the number of equipment failures by analyzing various failure-time correlations and incorporating results into a time-based maintenance plan. Mean-Time-to-Failure (MTTF) and Mean-Time-Between-Failure (MTBF) curves can be used to conduct a failure-time relationship analysis.

Predictive maintenance is a condition-based activity. It employs direct monitoring of equipment condition to estimate the MTTF factor. Many intelligent field instruments today have the capability of monitoring their operating condition, analyzing historical patterns, and reporting the probability of failure. To efficiently utilize this data, a real-time maintenance planning software should be collecting the information and automatically planning the maintenance activities. The major advantage of predictive maintenance over preventive maintenance is that predictive maintenance can provide a more precise estimate of elapsed time before system failure.

- **On-going verification**

Although on-going system verification can be a part of control system maintenance program, it can also be implemented as a stand-alone activity. The main purpose of on-going system verification is to periodically check the control system reliability after the traditional validation procedure

[2] PDA (1998) Good Automated Manufacturing Practices. Guide for Validation of Automated Systems in Pharmaceutical Manufacture.

has been completed.

Passive on-going verification can be conducted through system performance monitoring and detection of unusual trends in the system behavior. Several leading control system manufacturers today offer software packages that allow user to visualize historical data on manufacturing system performance and to identify the weakest-performing components of the system.

Active on-going system verification can be conducted manually on a scheduled basis or automatically if a self-checking mechanism is built-in the control system or a field device. Scheduled system verification may be implemented as a part of the system maintenance plan and conducted in conjunction with normal system component re-calibration and repair activities. Automated system verification may be implemented as a part of the control system design or software logic. Automated verification, also called "real-time validation", can significantly reduce the operating costs associated with scheduled manual component verification but requires higher initial investments, associated with redundant device installation or system self-checking algorithms development.

Real-time validation can be implemented through hardware redundancy or analytical redundancy.Hardware redundancy requires several identical devices to monitor each parameter of the controlled manufacturing process. The generated signals are than compared using different techniques to provide the system with an accurate and precise input. Hardware redundancy at the supervisory control level offers obvious benefits for high-speed value-added processing by minimizing costs associated with system downtime. Hardware redundancy can also be cost-effective when used for controlling critical factors affecting the safety of the produced product by preventing product recalls.

Analytical redundancy is a process of comparison of the input signal value with an estimated value. An estimated value can be calculated from a pre-determined correlation of a given parameter with the other parameters of the process, which are monitored by other sensors. Another technique to establish an estimated sensor value is to use a mathematical model of the process, and plug the real-time values generated by the other sensors into the model to calculate an estimate for a given sensor input.

Generally, the analytical redundancy is implemented as a part of fault detection and isolation (FDI) process, which consists of residual generation and decision making steps. There are two major approaches to FDI and analytical redundancy: quantitative and knowledge-based. In quantitative approach, a mathematical model of the process is used for fault detection and isolation. If a precise analytical model of the process is unavailable, the manufacturing data (historical log) analysis can be conducted to determine correlations between various process parameters. This approached is called "knowledge-based" analytical redundancy.

- **System Security**

System security program must be in place to ensure successful system maintenance and on-going verification implementation. Continuous improvement and verification of system security is a key factor in providing consistent and safe system operation.

Control system security can be segregated into hardware and software security. Hardware security locks can significantly reduce the probability of intentional or unintentional (accidental) system abuse. All operator interfaces should be key-operated or utilize electronic or biometric signatures, which should be changed on a scheduled basis, to prevent unauthorized access to critical system controls and minimize unexpected system failures.

As modern control systems rely significantly on software components to conduct process control and data recording, software security is becoming more important than ever. As well as system hardware, control system software should be protected from unauthorized access. The system security concepts should be incorporated into software design, such that all incorrect operator inputs or unexpected signals from the field instruments can be properly handled by the control system.

Control system security gains special importance in regulated manufacturing processes. The FDA 21 CFR Part 11 "Electronic Records; Electronic Signatures" regulation specifically states that the record keeping systems must contain an adequate means to protect the records and limit access to authorized individuals. The electronic records must also be available for accurate retrieval, which may necessitate the use of a data back-up system (FDA, 1997).

Such important security issues as the development of a system recovery plan in case of a major failure or a natural disaster, or system safe mode shut-down in case of an emergency should also be given consideration. Good system security in conjunction with proper operator training may significantly reduce the effect of "human factor" on system failure intensity. If properly trained, operator can recognize unexpected system behavior and apply corrective action immediately to avoid costly repairs.

The Computer Integrated Manufacturing Center specialists are currently working on a full-size article on post PQ validation activities. The article will review the above-mentioned topics in more detail as well as provide information on good validation management and minimizing costs associated with system validation. The article will be submitted for publication in a well-reputed journal shortly. 🗎

New Equipment

- **Armfield Thermal Processing Unit**

The Computer Integrated Food Manufacturing Center and the Pilot Plant at Purdue University recently acquired a High Temperature Short Time/Ultra High Temperature (HTST/UHT) thermal processing unit from Armfield, model FT 74. The unit has been purchased using a teaching grant from the department of Agricultural and Biological Engineering. The HTST/UHT will be used for teaching and laboratory demonstrations in the pilot plant as well as research projects conducted by the Food Science Department.

The main component of the Armfield system is a small-size plate heat exchanger designed to thermally process small food product samples in a pilot plant environment. The unit also contains a hot water set, which is used to generate the heating media for the system. The hot water set is designed for efficient heating up to 150° C.

The feed pump is a small Seepex progressive cavity pump. The typical feed rate through the pump is 10 liters per hour. The Armfield system is designed to conduct testing of small quantities of food products. The unit also allows for short start up time, rapid response to temperature control and short product changeover time.

The Armfield system includes a preheat/regeneration section, which allows for more efficient heat exchange. The system also has a holding tube to ensure a proper time/temperature process. The hold time can be adjusted by changing the flow rate of the Seepex pump. The thermally-processed product is cooled in a plate heat exchanger section using tap water.

Several temperature and pressure sensors are located throughout the system. These sensors monitor the product and media parameters and ensure proper system operation.

The CIFMC has also acquired an additional interface device (Armfield model IFD3-FT), which converts the sensor signals into a standard RS-232 serial signal that can be used with any modern control system. The interface device allows for remote data recording and system monitoring. 🗎

For more information about the Armfield HTST/UHT systems, please visit their website at: http://www.armfield.co.uk

- **Allen-Bradley PowerFlex Frequency Drive**

The Computer Integrated Food Manufacturing Center has recently acquired a brand-new Allen-Bradley PowerFlex 70 frequency drive. The new AC drive provides a wide-range of output power (0.5-20 hp) in a small package. The drive also has a large backlit LED display with extended keyboard (model 20-HIM-A3) for easy operation.

The drive is now installed on a 10-hp Seepex progressive cavity pump in a Hoffman NEMA-4 enclosure. The new PowerFlex drive offers simplicity and reliability, while providing a broad spectrum of features for easy configuration, operation and maintenance.

The Seepex pump with the new PowerFlex drive will be used for the annual Aseptic Processing and Packaging Workshop, as well as for research activities conducted in the pilot plant. 🗎

For more information on PowerFlex family of drives, go to the Allen-Bradley website at: http://www.ab.com/drives/

Advanced Manufacturing Summit

Purdue University will host an Advanced Manufacturing Summit on March 19-20, 2002. This event will bring together professionals from a wide variety of manufacturing sectors to discuss common problems and issues in manufacturing. At this time, it is anticipated that speakers will include representatives from the Indiana State Government, Purdue University administration and executives from large and small manufacturing industries.

The CIFMC is actively participating in the Summit and will co-chair the Food Processing sessions. More information will be available in the coming months. If you are interested in attending this Summit, please contact the CIFMC at CIFMC@Purdue.edu. You will be placed on a mailing list to receive an invitation and other materials as they become available. 🗎

FoodSim 2002

Applications for presentations are currently being accepted for The 2nd International Conference on Simulation in Food & Bio Industries will be held on June 17-18, 2002 in Cork, Ireland at the Blarney Park Hotel. Themes for the conference will include:

- Simulation in Food Sciences and Biotechnology
- Simulation in Food Economics, Traceability and Supply Chain management
- Methods & Tools applied to Food and Bio-Industries
- Simulation & Training
- Environmental modeling

Contact CIFMC director, Tim Haley (TimHaley@purdue.edu) if you are interested in giving a presentation at this conference.

Upcoming Aseptic Workshop

We are gearing up for our 19th annual aseptic processing workshop to be held in the new Food Science building and pilot plant on May 13-16, 2002. The workshop will consist of lecture and hands-on laboratory session. Some of the topics will include:

- Microbiological Principles in Aseptic Processing
- Chemical Considerations of Aseptic Processing
- Aseptic Packaging Technology
- Principles of Thermal Processing as Related to Aseptic Processing
- Thermal Process Calculations
- Quality Assurance and FDA Regulations for Aseptic Processing and Packaging

The hands-on laboratory sessions will include quality evaluation, packaging, engineering concepts and equipment features. A Social Mixer and Dinner are included. For more information, contact **Steve Smith** at (765) 494-8256 or smithrs@foodsci.purdue.edu.

First Annual ESL Processing and Packaging Workshop

Purdue University will hold its First Annual Extended Shelf Life (ESL) Processing and Packaging Workshop in August, 2002. This workshop is intended for food processors that currently produce or are thinking of producing food products for extended shelf life. The program is designed to give individuals the basic knowledge involved in the development and operation of an ESL system. The course is appropriate for food scientists, food and packaging engineers, microbiologists, chemists, and anyone wanting an in-depth knowledge of ESL food processing and packaging.

The program will include lectures and hands-on laboratory sessions held in the Food Science Pilot Plant. A notebook with summaries of all lectures and references on each subject will be provided to each participant. A social mixer, dinner and refreshment breaks are also included in registration.

Enrollment will be limited to 40 participants. Therefore, advance registration is requested. Spaces will be allocated according to date of receipt of registration, so prompt enrollment is strongly advised. For more information, contact **Steve Smith** at (765) 494-8256 or smithrs@foodsci.purdue.edu.