



Wilmington Section ISA
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Wilmington Section ISA

ISA—The Instrumentation, Systems, and Automation Society 

Check out our web page at <http://www.isa.org/~wilmdel/>

Wilmington ISA Section Event

Section Meeting

Jim Harten - Applied Control Engineering
"S88 BATCH CONTROL"
5:30 pm - Applied Control Engineering

Tuesday, Oct 22, 2002
The Mill At White Clay Creek
700 Creek View Road
Newark, DE 19711

ISASENSOR

Published By
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The Sensor

October 2002

**ISA - Wilmington
Section Meeting
October 22, 2002
S88 BATCH CONTROL**
by
Jim Harten
Applied Control Engineering
(ACE)

This topic is aimed at providing guidelines for operation and design of batch manufacturing plants. This is "**NOT TO MISS**" meeting for professionals who are in charge of or work in such environments.

In today's batch process manufacturing environment, enterprises face growing pressures with conflicting requirements to reduce time to market for new products, increased regulatory reporting, improved asset utilization and increased demand for customization, quality and value by customers. To meet these requirements, an agile batch recipe management and execution control system is necessary.

It has always been a challenge to build an agile batch recipe management environment that integrates the business level recipe requirements for collaboration among Research & Development, Process Engineering, Sales, Marketing, and Manufacturing with the real-time operations management requirements of recipe execution in manufacturing processes. Cross-functional professionals assigned the responsibility for defining an agile batch recipe management and execution system require a

common language and model to communicate their business requirements.

The U.S. standard **ISA S88.01** for Batch Control Systems, and its IEC equivalent IEC 61512-01, have become two of the most widely adapted standards for manufacturing control systems in the U.S. and Europe. These standards define a common set of models and terminology that can be used to describe and define batch manufacturing systems. The models emphasize good practices in the design and operations of these systems, and a methodology called "Modular Batch Automation" has been developed to codify the good practices.

The standard has been applied to the typical batch industries, such as specialty chemicals, pharmaceuticals, food and beverage, and consumer product industries, where the physical and chemical processes require the production of material in batches. The standard has also been effectively applied in flexible manufacturing facilities, where companies want to use the same production equipment to make many different products, even if the manufacturing processes could be run continuously.

A non-profit organization called the World Batch Forum holds annual meetings in the United States where batch manufacturing companies can share their experiences applying the S88.01 standard. Companies have generally found that they can **reduce** their first time project **expense** and time up to

30% over their previous methods by applying Modular Batch Automation, and they have been able to **increase** their plant **throughput** up to 10%. These dramatic advantages have meant that the ISA S88.01 and IEC 61512-01 standards are being aggressively applied by the leading edge manufacturing companies. Dramatic improvements have come in a wide range of industries, such as milk production, pharmaceutical manufacturing, consumer products, and specialty chemicals.

The methodology and standard can also be applied regardless of the level of automation in a factory. It can be used for entirely manual plants, fully automated plants, or the more common semi-automated plants. Most analyst studies have found that only 30%-40% of manufacturing facilities in the United States is fully automated, even in the most heavily automated industries. There have been many successful applications of the standard in fully manual operations, such as pilot plant facilities, as well as partially automated operations in pharmaceutical and consumer product industries.

The S88 standards are a philosophy to be applied in design and operation of batch manufacturing plants. Implementing and using these standards require a clear understanding of the beliefs prescribed. **Jim Harten** of Applied Control Engineering will share his experience in using these standards.

Directions to ACE:

From I-95:

- Take I-95 to Route 273 (Exit 3)
- Go West on 273 until you reach Library Road (4.5 miles)
- Make a right onto Library Road (Sign reads 72 North, 2 East)
- Move to the left going under the train overpass
- Turn left at the next light onto Cleveland Avenue
- Go straight on Cleveland Avenue until you reach the Chapel St/ Paper Mill Road intersection (2nd Traffic Light)
- Make a right onto Paper Mill Road
- Just before the bridge on Paper Mill Road, turn right onto Creek View Road
- Go straight on Creek View Road to Applied Control Engineering, the last building on your left

From Route 1 in Pennsylvania:

- Take PA US Route 1 to Route 796
- Go South on Route 796 and merge with Route 896 (New London Road)
- Follow Route 896 South into Newark DE, you will pass University of Delaware's Clayton Hall on your left (13.5 miles)
- Turn left at the next light onto Cleveland Avenue
- Go straight on Cleveland Avenue until you reach the Chapel St/ Paper Mill Road intersection (2nd Traffic Light)
- Turn a hard left onto Paper Mill Road
- Just before the bridge on Paper Mill Road turn right onto Creek View Road
- Go straight on Creek View Road to Applied Control Engineering, the last building on your left

Instrumentation Exhibit

2002 ISA Industrial Measurement and Control Exhibit and Technical Seminars

It is time to start making plans to attend the ISA exhibit that will be held on **November 14, 2002** at the **Holiday Inn Select** off I-95. We are having a good response from vendors and so far we have 58 booths reserved. We will have a number of Technical training session going on during the day. The training is free so come out and see what's new in instrumentation and learn something. Training topics currently scheduled are Mass Flow Measurement, LOPA, IEC 61511, Electronic Security. All attendees will be entered in a drawing for chance on door prizes to be given away.

If any members have suggestion of interesting topics for the seminars please forward your ideas to *Mwegter@rodel.com*. Any new vendor wishing to reserve a table can contact the above e-mail address or Call Janet Cunningham at Barr Enterprise 301-668-6001.

**Section Notes
Sep 24, 2002
21 CFR PART 11**

by
Ray Mckinney
Applied Control Engineering
(ACE)

Ray started: "Tonight we will introduce the terribly dry and boring subject of electronic data security and electronic signature...". It turned out to be an ironical statement. The audience was paying full attention to the speaker despite the dim lights in the conference room.

The presentation provided the non-

pharmaceutical professionals an introduction to the subject of "21 CFR Part 11", which is a regulation imposed by the Food and Drug Administration (FDA) department on the pharmaceutical companies. This rule is effective from 20th August 1997.

This regulation insures electronic tracking of manufacturing data. It ties into the quality of food and drug we consume on a day to day basis. The fuzziness comes into play when one tries to define the scope of this regulation. Other industries are taking a closer look at this to analyze and understand this regulation as it might spread to theirs also. The crux of this regulation is to "Log Everything Electronically". The whole gamut of operations starting from changes in set points to tracking changes in design document have to be documented electronically. The timestamp of the change (with the time zone), who made the change etc have to be logged.

Other than following the regulation, the industries also see savings in logging and maintaining these records electronically than to store them in paper format. This "Change Control" is required to maintain quality of products, to do analyses, to track down batches that may have a quality problem etc. This could be better achieved through electronic logging of data.

The regulation has three sections: 1) General Provisions; 2) Electronic Records; and 3) Electronic Signatures. As the name suggests, General Provisions section lays out the scope, implementation techniques, and defines terms. The Electronic Records section talks about authentication, data integrity, Non-repudiation of related signatures, and confidentiality. Finally, the third section talks about

the acceptable electronic signatures.

This kind of change control process is part of the Good Manufacturing Practice (GMP) and is applicable to all industries. The "21 CFR Part 11" is a regulation, which means the a particular facility could be audited based on this process. It is also extensive and hence understanding this regulation is important.

ISA, Wilmington Section would like to thanks **Ray Mckinney** for having shared this invaluable knowledge with us.

**MEMBER BENEFIT
WEB SEMINARS
\$25.00 EACH FOR MEMBERS**

In an effort to provide our Members convenient and inexpensive access to technical information, Members can now logon to the ISA website and register for any ISA pre-recorded web seminar for only \$25 per seminar. The seminars are recent recordings of live broadcast that are presented by an ISA expert instructor covering topics like ethernet, safety instrumented systems, OPC, fieldbus, and more. Each seminar is 90 minutes in length. This new, low cost quality training on topics is sure to be of professional interest to ISA members.

(Non-members pay \$225.00 for each seminar.) Read all about it: <<http://www.isa.org/isastore/isastore.cfm?>>

Bring a Friend Drive

Do you know someone who might be interested in ISA? Is there anyone you work with who might join if they knew what we were about?. Now is

September Event

**Section Meeting
5:30 pm
Tuesday, October 22, 2002
"S88 Batch Control"
Jim Harten - Applied Control
Engineering**

**Applied Control Engineering
The Mill At White Clay Creek
700 Creek View Road
Newark, DE 19711**

Mark Your Calendar!!

**Thursday, November 14, 2002
Instrumentation Exhibit
2002 ISA Industrial
Measurement and Control
Exhibit and Technical
Seminars
Holiday Inn Select**

your opportunity to encourage them to attend one of our programs. The Wilmington Section is starting a "bring a friend" drive to help attract new members. At each meeting there will be a sign in sheet where members can sign in and list the "friends" (non-ISA) members that they have brought to the program. At the end of the year (June 2003), the person who has brought the most guests to the section meetings (not including the family picnic) will win a prize. Please stay tuned for more details.

**ISA 2002
21-24 October 2002
McCormick Place,
South Chicago**

ISA 2002 features:
* Daily Key note Presentations

* The 8th International Temperature Symposium-Co-sponsored by NIST. This year's symposium theme, "Its Measurement and Control in Science and Industry," includes topics ranging from fundamental temperature scale research to practical measurement/control solutions.

* Dick's Last Retort-hosted by Dick Morley, R. Morley, Inc., with special guests: Ken Krader, Control.com, Dave Smith, formerly of Wonderware and Object Automation, and more industry experts to be announced. This lively panel discussion will evaluate recent mergers and acquisitions; the corporate direction of instrumentation, systems, and automation; and the outlook for a truly open systems future.

* The ISA President's Fall Meeting takes place in conjunction with ISA 2002 Saturday, 19 October, through Sunday, 20 October. For more information about the President's Fall Meeting contact ISA at (919)549-8411.

For more information on ISA 2002, go to <http://www.isa.org/isa2002>

Calendar of Events - 2002

Tuesday October 22 2002: Section Meeting - Applied Control Engineering Inc.

Tuesday October 29 2002: Exec. Committee Meeting - Applied Control Engineering Inc.

Thursday November 14 2002: Exhibit & Training Seminars - Wilmington Holiday Inn Select