



Wilmington Section ISA  
Box 9254  
Newark, DE 19714-9254

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

**Ray Mckinney - Applied Control Engineering**  
**"21 CFR PART 11 COMPLIANCE"**  
**5:30 pm - Applied Control Engineering**

**Tuesday, Sep 24, 2002**  
**The Mill At White Clay Creek**  
**700 Creek View Road**  
**Newark, DE 19711**

### ISASENSOR

Published By  
WILMINGTONSECTIONISA

PO Box 9254  
Newark, DE 19714

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E I DuPont (856) 540-3056  
President-Elect: Nick Sands  
E I DuPont (302) 761-2324  
Treasurer (acting): Bill Balascio  
ACE (302) 762-6472  
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Cullen G Lanford Inc. (610) 255-4164  
Arrangement Chair - Joe Baker  
Endress & Hauser (267) 880 1750 (X104)  
Newsletter Editor: Vaidee Sampathkumar  
EDS (302) 456-1305

# The Sensor

September 2002

**ISA - Wilmington  
Section Meeting  
September 24, 2002  
21 CFR PART 11 COMPLIANCE**  
by  
Ray Mckinney  
Applied Control Engineering  
(ACE)

A section of the Food and Drug Administration (FDA) 's rule regulating the use of electronic records and electronic signatures, 21 CFR Part 11, addresses the use of electronic signatures in place of traditional handwritten signatures in GxP regulated arenas. In order for researchers to use e-signatures rather than handwritten signatures on documents that are required to be signed by the 'Predicate Rules', these e-sigs must be in the required format, be accurately date-and-time stamped and contain the required reason for signing. Most significantly, the signatory must show intent to sign the document. Electronic system functionality for the creation of compliant e-signature manifestations are not always available for many existing laboratory or manufacturing systems, and may not be available in new systems, especially in manufacturing. Researchers in regulated environments are heavily challenged in their implementation of complete, compliant electronic signatures.

Ray has a Bachelor of Engineering degree in Mechanical Engineering from the University of Strathclyde, Scotland. He has over 15 years experience in process development, commissioning, and

validation consulting to the pharmaceutical industry. Ray is a consultant to ACE whose expertise lies in validation (computer systems, process, and equipment), and 21 CFR Part 11 compliance. His company, chemera, inc., is involved with software and web development for engineering e-commerce and document management applications. Prior to this, Ray was President of BHS-Filtration, Inc., General Manager of Heinkel Filtration UK, and a Development Engineer with Zeneca, UK.

Ray will be giving a speech to propagate the expertise and knowledge he has on this new regulation that is affecting the pharmaceutical industry

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**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
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**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 will have a sell out of the 70 tables available. 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

<p>chance on door prizes to be given away.</p> <p>If any members have suggestion of interesting topics for the seminars please forward your ideas to <i>Mwegter@rodel.com</i>. 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.</p>	<p>softball game,with the ominous implications for next year's sales. It has been replaced by a families of members enjoying themselves on the softball field, in a non-competitive, relaxed way. Relaxed play was a good idea, because it was hot. Ray Kreuger and Nick Sands made the sacrifice of grilling the hotdogs, hamburgers, and chicken that we all enjoyed, though they probably lost 5 pounds each from the heat. The picnic committee of (John Wood,.....) provided everything we could have wanted, and in the shade and away from the heat of the grill, a good time was had by all who attended. As usual one of those attending was this years scholarship winner .....</p>	<p>meeting will feature a talk on 21CFR, Electronic Signatures and Tracking. This is a hot topic in the pharmaceutical industry and should be of interest to everyone in industry, as more of our systems are becoming electronic instead of paper.</p> <p>Our Wilmington Instrument Exhibit and Training Seminar is scheduled for November 14<sup>th</sup> at the Wilmington Select on Naamans Rd. Topics to be presented include Process Control Network Security and IEC 61511as well as many others. Please come out to hear these talks as well as to see the latest technology from our local vendors.</p>
<p><b>ISA Blue Rocks Outing Notes Thursday, August 22nd 2002</b></p> <p>The Wilmington ISA section visited the Blue Rocks for a picnic and to watch a ball game. The weather was perfect and we had a sellout of the 75 tickets the ISA section had purchased.</p> <p>We would like to thank Rodel Inc. and Applied Controls Engineering for their support, both companies sent a large group of employees and family members. The new picnic area was nice and there was ample room in the bleachers that offered a good view of the game after you were done eating. The Blue Rocks put up a good fight but lost control in the later part of the game and the Myrtle Beach Pelicans were the winners.</p> <p>Next time the ISA group needs to cheer a little more and maybe the Blue Rocks can win.</p>	<p><b>President's Message</b></p> <p>September 2002 Newsletter</p> <p>Fellow Wilmington ISA members,</p> <p>My name is Lori Diamond and I am the new section President and I would like to welcome you to a new ISA year for the Wilmington Section. Your support has enabled our section to many outstanding years and we would like to share the benefits of this success w1th you in the upcoming year! Many of our upcoming events are in the final planning stages and I am excited about the variety of programs we have scheduled for the year.</p>	<p>Your section has made great strides in keeping pace with the progress of communications. All of the local events are listed on our web page <a href="http://www.isa.org/~wilmdel/">http://www.isa.org/~wilmdel/</a> as well as published in the sensor. All of the section officers are available by email and we would like to hear from you!</p> <p>The greatest benefit our section can offer you learning. Whether it is a technical presentation at one of our meetings or shows or networking at fun event like the Shrimp Boil, Picnic or Blue Rocks game, we want to help you increase your skills and help your with your job. Please join us this year for both learning and fun!</p> <p><b>Lori Diamond Wilmington Section President</b></p>
<p><b>WISA Picnic Notes Tuesday, June 25th 2002:</b></p> <p>On June 25th, Wllmington ISA held its yearly family picnic at Our Lady of Grace grounds in Newark, Delaware. I use the word family, because it has become more of a family event in the time that I have been a member of this section.</p> <p>Gone are the days of the fiercely competed Users vs. Vendors</p>	<p>I would also like to welcome our new Program Chair, Joe Baker from Endress &amp; Hauser and thank Joe for his involvement in the Wilmington Section. I look forward to all of the programs he has scheduled. Please show your support and appreciation of Joe's time and effort by attending as many section meetings and activities as possible. Our Sept. Section</p>	<p><b>MEMBER BENEFIT WEB SEMINARS \$25.00 EACH FOR MEMBERS</b></p> <p>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-</p>

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 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**

ISA 2002 returns to Chicago, from 21-24 October 2002. ISA values your presence at this important industry event and would like to offer you these VIP Alumni (any person who has attended the ISA expo in the past) benefits when you register by 1 September 2002:

- \* Free ISA 2002 exhibition registration

**September Event**

**Section Meeting  
5:30 pm**

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"21 CFR PART 11 COMPLIANCE"  
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Control Engineering**

**Applied Control Engineering  
The Mill At White Clay Creek  
700 Creek View Road  
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**Mark Your Calendar!!**

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

- \* Free ISA 2002 or Emerging Technologies Conference Session of your choice
- \* Alumni only discount coupon for the ISA Bookstore at ISA 2002
- \* Exclusive Alumni restaurant at ISA 2002
- \* Alumni ribbon for easy identification at ISA 2002
- \* Exclusive Alumni Only registration Web site
- \* Double the chance to win a new PT Cruiser at ISA 2002's Short Track to Big Rewards

New! ISA 2002 features:

- \* Daily Key note Presentations
- \* ARC Forum-"Driving Operational Excellence in Plant Asset Management.": Join this discussion to learn how you can drive improvements in operational performance.
- \* 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.

To activate your VIP Alumnus status at ISA 2002, by phone, call (919) 549-8411 and identify yourself as an ISA VIP Alumnus.

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

**Calendar of Events - 2002**

*Tuesday September 24 2002:* Section Meeting - Applied Control Engineering Inc.

*Tuesday September 24 2002:* Exec. Committee/ Show Meeting - Applied Control Engineering Inc.

*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