ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

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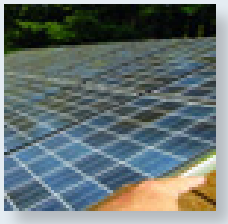
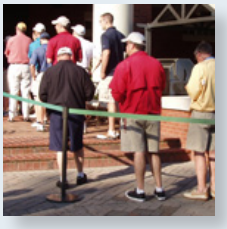
INSIDE THIS ISSUE





Presidents' Messages 2
NEW Board List 2
2012 Energy & Sustainability Forum 4
18th Annual Golf Tournament Draws Record Attendance! 7
Young Professionals Event: Fundamentals of IT Systems Validation 8
Biotechnology Day: Biotechnology in Your Daily Life! 9
EHS Update: New EPA Boiler Rules 12
Upcoming Events and New Members 16

Annual CaSA ISPE Planning Meeting

Prestonwood Country Club in Cary, NC
August 30

Presidents' Messages

David Brande

How quickly a year has gone by! It seems like we were just preparing for our first Board meeting with the newly elected members from the July 2011 election, and now we are again preparing for transition of responsibilities to the new 2012 Board. This transition reminds me of images preceding the London Olympics of the passing of the torch from one athlete to the next. Our new president, Jennifer Lauria Clark, is the next leader of ISPE CaSA. She will lead the way and help to develop new emergent leaders for our organization, some from the Young Professionals of our Chapter.

As I reflect on the year, I realize a satisfaction of accomplishment that is most easily understood by those past presidents that have preceded me. Success in going forward is accomplished by surrounding yourself with quality people and having those people lead the way in your absence. In my tenure, I was able to have with me the best that our Chapter has to offer. Our Board was a group of volunteers who sacrificed their personal time with friends and family and utilized their talents for the realization of our Chapter's goals. I want to personally thank each and every one for their help in accomplishing several milestone successes.

As August 1 approaches, I wish Jennifer and our new Board of Directors congratulations and great luck in the next twelve months. I hope you share my enthusiasm for what the upcoming year brings and I encourage you to offer your time and talent to ensure new successes for our chapter.

Good Luck Jennifer!

David Brande
(Outgoing) Chapter President

Jennifer Lauria Clark

The time has come to celebrate another year of success in the ISPE CaSA Chapter. Under David Brande's leadership, we have maintained 76% of our membership, up 6% over the year before. We have increased participation in our programs and networking events by industry members, students and young professionals. We have increased our communication to our members with e-blasts, publishing six newsletters, and continuous updates to our website. Our Technology Show is a continued success, selling out our vendor tables for a second year in a row and securing 20 reputable speakers from a variety of disciplines. Our volunteers have committed an incredible amount of hours to planning our events and making contributions to our industry. Thank you to everyone for your leadership and continued support of the CaSA Chapter.

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ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

2012-2013 Board of Directors

Officers
- Jennifer Lauria Clark, CPIP, President
- David Brande, Past President
- Matt Gilson, Vice President
- Heather Denny, Treasurer
- Lisa Kerner, Secretary

Directors
- Patrick Buckner
- Andy Ferrell

Committee Chairs
- Wendy Haines, Newsletter
- Amy Lineberry, CPIP, Education
- LeAnna Pearson, Student Affairs
- David Knorr, IT Communications
- John Marr, Networking
- Jerry "Patch" Paciorek, Membership Development
- Jon Doyle, Young Professionals
- David Smith, BioFest
- Bruce Craven, Tech Show Committee Chair

Presidents' Messages

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As the song goes, "There is a time to gain and a time to lose." We have two extraordinary board members departing our Board of Directors this year. It is with sadness that we see Eric Mayer and Blake Derrick complete their terms. Thank you for your service and commitment to the chapter. We truly gained more knowledge and ideas for success under your leadership.

We are grateful for our 2012-2013 elected volunteers. We have been told many times that our organization is only as strong as our volunteers and our success speaks volumes to what ISPE CaSA can accomplish. We have added several new committees to our Board of Directors this year. We will now have a Membership Development Committee that will strictly focus on getting into plants and companies spreading the good news about ISPE CaSA. We have created a Networking Committee that will head up our networking events; an IT Communications Committee that will manage our new Sharepoint site that will house all of our operational chapter documents and our website; a Newsletter Committee that will focus solely on the dissemination of information in a newsletter to our members; and Biotechnology Day Committee that will continue to partner with the North Carolina Museum of Natural Sciences to promote Biotechnology to the state of North Carolina. Our Programs Committee will now be called the Education Committee and focus on the success of the committee and creating new programming that effectively addresses the needs of our members. The Young Professionals, Student, and Technology Show Committees will continue to support the Chapter as they have the past year.

Our new Board will begin work on August 13th with our first meeting of the new year, and high on our list of priorities is the Annual Planning and Membership meeting scheduled for Thursday August 30th. The meeting will be held in the Grand Ballroom at Prestonwood Country Club in Cary, NC. If you do not have this scheduled on your calendar, I highly recommend that you do so today. The Annual CaSA Planning and Membership meeting is very important for two reasons: the opportunity to come and see the inner workings of CaSA and meet the Board members and management company representatives and to determine where you can best engage with the chapter. By attending this meeting you will understand the path to becoming a chapter leader and help guide our Chapter into its next twelve months.

It is important to know how our membership understands what we are doing. If you have compliments, suggestions for improvement, education ideas, networking event ideas, or complaints, please let me or any other board member know how well we are doing or what we can do to improve.

I cannot end without again thanking our 2011-2012 Board of Directors and Volunteers. Whether you drove a gator at the golf tournament delivering lunches, directed members at the Technology Show, reviewed an article for our newsletter, provided input to our executive leadership, or manned a membership table, our success was not possible without you. Thank you.

And now a To Do List:

- Let us know if you are interested in a volunteering with a committee or in active leadership of ISPE CaSA.
- Send in ideas for 2012-2013 educational programs and networking events.
- Stay cool, enjoy, and relax the last few weeks of summer.

Jennifer Lauria Clark
(Incoming) Chapter President

Chapter Events

2012 Energy & Sustainability Forum

By Martin E. Rock, PE, JD, LEED-AP, Past President & Board Chairman (2005-2006), Volunteer - Chapter Programs Committee

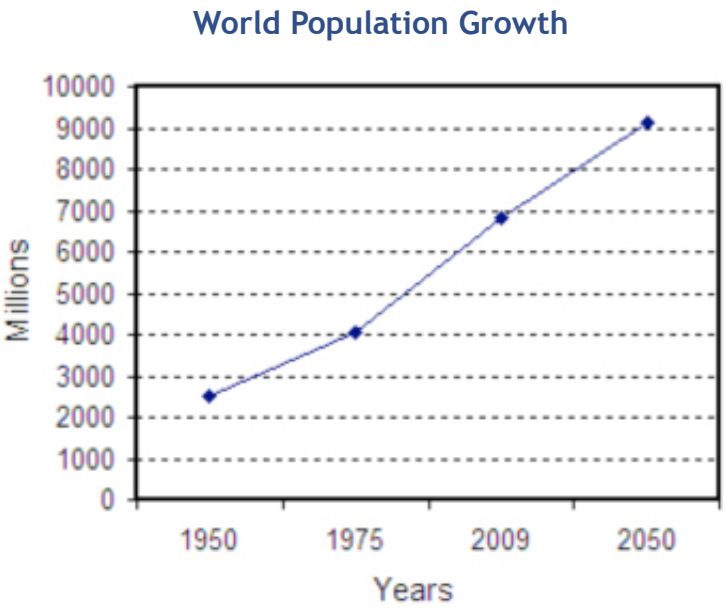
Upon entering the Glaxo Smith Kline (GSK)-RTP Campus, a prominent feature one notices is a small set of photovoltaic solar panels (see photo at right). While these are hardly sufficient to power the entire GSK campus, they do convey the high visibility of GSK's commitment to sustainable practices. Moreover, GSK has other rooftop solar power systems and is certified by the Federal Energy Regulatory Commission (FERC), as a "qualifying facility" which allows renewable energy production of up to 80 megawatts in capacity. As such, this site was an ideal venue and backdrop for the 2012 ISPE CaSA Energy & Sustainability Forum.

One interesting statistic is that during the 30 or so years the GSK-RTP campus has been in existence the global human population on Earth has roughly doubled. Stated another way, during just the last 30-40 years, we have added more people to the planet than were added during all of prior human history. This geometric population growth is one of the key drivers for sustainability initiatives.

Another key driver is regulatory requirements and local, national, and international incentives programs. In the U.S., for example, new rules from the Environmental Protection Agency (EPA) will require energy assessments at most sites that use boilers. (See companion article on these new Boiler MACT requirements.)

We were very pleased to have the following presenters for this year's forum:

- **Biogen Idec**: Mr. Pat Hoy, Global Sustainability Director
- **Novartis**: Mr. Alexander Mitrovic, Mechanical Lead and Energy Manager for Novartis Vaccines & Diagnostics Global Engineering
- **Novo Nordisk**: Mr. David Bright, Site Services Manager



Aside from saving the planet, one clear message from the Forum speakers was that saving energy is simply good business. By saving energy wisely, companies can also improve comfort and safety, reduce operating costs, minimize pollution, improve customer and public relations, and increase employee productivity. Those in attendance learned how these important objectives can be accomplished through practical "real world" projects at pharmaceutical and biotech operating sites.

This simple message was made by all of the speakers (see graphics on the following page from Biogen-Idec and Novo Nordisk).

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Chapter Events

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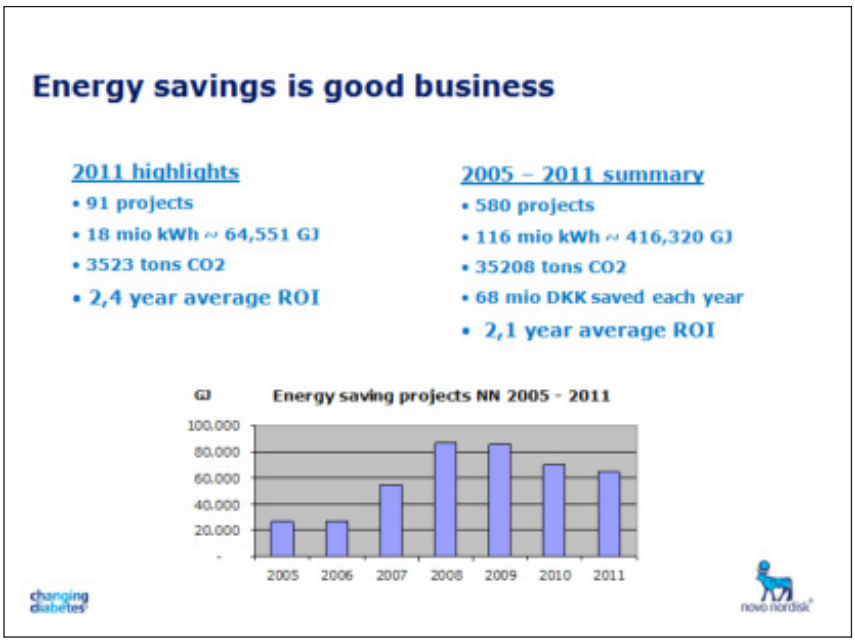

Each presenter told the audience about their corporate and local initiatives to save energy and to adopt sustainable practices. (Some of the presentation slides have been posted to the Chapter website.) Annual savings were shown in the millions of dollars. Among the success stories shared by our distinguished group of speakers were the following:

Biogen Idec

Clean-in-Place (CIP) Acid Elimination and Water Optimization Project in RTP (2010 Sustainability Leadership Award Winner)-Saved more than 5.45MM gals of water and $1.6MM costs from chemical, energy and water reductions from 2009-2010.

- Future Potential Project: Evaluating Savings of Reclaimed Water at RTP (Ph1: Landscaping — Estimated savings of 2.8MM gals of potable water/yr
- Chilled Water Systems Upgrades Supporting RTP Manufacturing Efforts: Rebalancing the existing system, installing a new variable speed chiller. Estimated to reduce energy use by 6.6MM kWh and eliminate 4,7000 metric tons of CO2 annually

Novartis

Mr. Alexander Mitrovic, Mechanical Lead and Energy Manager for Novartis Vaccines and Diagnostics Global Engineering

- Heat Recovery Chiller System: Annual savings of $575K in utility, 109K Dth natural gas, 4600 tons CO2 emissions, 11,115,000 gals water, and chemical treatment; simple payback <20 months
- Active Chilled Beams: Benefits for Lab HVAC Systems:
  - Decouple ventilation/humidity control from sensible cooling, so AHUs are much smaller
  - Provide only 6-8 air changes for ventilation requirements
  - Chilled beams handle remaining sensible load much more efficiently with water coils than with air flow (reduced utilities above ceiling)

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Chapter Events

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Novo Nordisk

Mr. David Bright, Site Services Manager

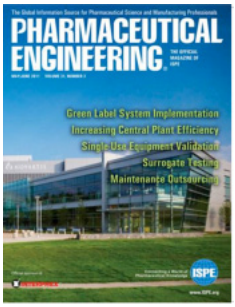
- Benefits of Two Chilled Water Plants Joined into One:
  - **Energy Reduction:** Electric consumption reduced by 2.8 Mkwh or 11% of total usage, cost reduced $190,000/yr
  - **CO_2 Reduction:** CO_2 will be reduced by 1384 tonnes/yr
  - **Accidental Releases:** 1020 kg of R-11 will be replaced by 1800 kg of R-123 reducing cooling agent change by 5026 tons of CO_2 equivalent
  - **Chemical Reduction:** Water treatment chemicals will be reduced by 40%, cost reduced $20,000/yr
  - Water Reduction: Water reduced by 10,000 m^3/yr, cost reduced $25,000
  - **Increased Capability and Redundancy:** 1 central chiller plant for the site, 1 cooling tower 100% site capable, 100% spare pumps and chillers, 100% redundant, dual electrical sources, simple changeover between chillers and pumps
  - **Maintenance Management:** Improved Tridium BMS HMI interface for monitoring chiller KPIs

Key Points

The key take home points from this Forum for pharma and biotech plants are:

1. **Opportunities Abound:** Even sites with aggressive energy and sustainability programs continue to find "low hanging fruit;" that is projects with good pay-back and sizeable benefits are still available at most sites.
2. **Take Advantage of a Win-Win Situation:** Savings in the millions of dollars go right to the bottom line, and the site can tout a "green" reputation to their customers, to their employees, and to the public.
3. **Leadership Recognition is Possible:** ISPE and many other organizations are looking for leadership and success stories to present to their groups. These awards are great morale boosters and they tell the world a great story about your organization.

Recognition & Awards



Novartis: Featured in *Pharmaceutical Engineering* magazine

Biogen Idec: Ranked 32nd out of America's 500 largest companies in environmental performance

Novo Nordisk: Tops list of the World's 100 Most Sustainable Firms

Please plan to attend our next ISPE-CaSA Energy & Sustainability Forum. Share your success stories or offer to present your program results to our audience. Learn from the best practices your colleagues have discovered and experienced.

Remember... saving energy and sound sustainability practices are good for business.

Save Money. Save the Planet.

Chapter Events

18th Annual Golf Tournament Draws Record Attendance!

By Jim McGlade, Membership Committee Member

The 18th Annual ISPE Carolina-South Atlantic Golf Tournament returned to Prestonwood Country Club in Cary, NC on Monday, May 7. This year's event broke the attendance record with 172 golfers participating. The beautiful weather and championship courses were to credit for drawing in a record crowd of players ranging from incurable golf addicts to the once-a-year players. The event included a Poker Raffle with players buying poker hands in lieu of tickets. Ten lucky players went home with cash prizes totaling over $1,300 including the $500 grand prize. Regardless of their luck in the raffle, all players went home with an aluminum water bottle courtesy of Mangan Inc. and a FootJoy golf glove courtesy of CRB.

While on the course enjoying the weather, each player had an opportunity to take home a new Harley Davidson motorcycle with a hole-in-one. Unfortunately no one was able to make the right swing. Additional hole-in-one prizes included the chance to win a St. Thomas Vacation courtesy of Hydro Service & Supplies, Inc., a weekend retreat at the Homestead Resort courtesy of RDG Project Management, Inc., and a $500 gift certificate to Ruth's Chris. Once again no golfer was able to make an ace on any of these opportunities.

Additional sponsors included Griffin Engineering and Technical Services Inc. providing the beverage carts, Burkert Fluid Control Systems sponsoring the Scoreboard and Rules Sheet, and the following hole sponsors: Clark Nexsen Architecture and Engineering, Dynamic Systems, Inc., Freelon, Hipp Engineering & Consulting, M.G. Newell

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Chapter Events

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Corporation, O'Brien/Atkins Associates, O'Neal, Inc., and Vaisala Inc.

First and Second place prizes were awarded for each of the two courses played. In addition, the teams with the highest score on each course received a monetary prize for their efforts. Prizes were also given to the Women and Men for longest drive and closest-to-the-pin on both courses. The event concluded with an awards ceremony and a classic BBQ meal including fried chicken, BBQ pork, hushpuppies, and all the "fixin's" sponsored by Mangan Inc.

Proceeds from the raffle and mulligan sales raised over $1,500 which will be donated to charity.

ISPE CaSA sincerely thanks all of this year's players and sponsors. We hope to see you all back to play again plus 68 more players so we can fill all three courses! See you next year!

Adam Barlow, Paul Snyder, Roy Snipes (presenting award), Mark Holland, and Kris Kelly

Scott Billman, Jim McGlade, Roy Snipes (presenting award), Kevin Pait, and BJ Hull

Young Professionals Event:

Fundamentals of IT Systems Validation

By Remil Aguda, Young Professionals Committee Member

Speaker: Dr. Ray Miller, Eisai
Date: April 25, 2012

As part of the educational seminar series of the ISPE CaSA Chapter, Dr. Ray Miller, Senior Manager of the Manufacturing Applications at Eisai, was invited to share his knowledge and experience on information technology (IT) system validation. His presentation walked the audience through the validation process for computer systems. This started with how computer software gets tested. He gave examples of how these systems are used in raw materials testing in manufacturing, chromatography data in the laboratory, and balancing checks and tracking payments on your personal smart phones. Ray presented the relationships of user requirements with performance qualification, functional requirements with operational qualification, detailed design with construction of the system and finally its installation qualification. These elements are part of a System Development Life Cycle validation model created by ISPE called the GAMP 5 V-Model.

This presentation was followed by a Q and A session from an audience of ISPE young professionals and members of the on-going CPIP study group. The attendees discussed the challenges in meeting FDA regulations with the rapid changes in IT hardware and software such as cloud computing.

Chapter Events

Biotechnology Day: Biotechnology in Your Daily Life!

By David Smith, CaSA Board Member

Back in February of this year, we began embarking on a partnership with ISPE and the NC Museum of Natural Sciences to put together an inaugural event, "Biotechnology Day: Biotechnology in Your Daily Life!" Little did we know that what began as a neat little idea in conversation would develop into a success story that is too good not to share. Our goal for the event was bring together a unique cross-section of local biotechnology organizations for one day to educate the public (scientists and non-scientists) about the effects biotechnology has on our everyday lives. We had the privilege to engage over 150 companies, educational institutions, and non-profits from around the state to participate with hands-on demonstrations, experiments and crafts, as well as to secure speakers to present on key topics. Through the planning phase of this event alone, we were able to garner responses and begin conversations with prospects that had previously ignored our communications entirely.

As a sitting board member of ISPE, I was given the opportunity to lead the creation of this event. I had a tremendous amount of help from Angela Stewart, NC Science DM and her staff. Despite having only ninety days to plan and the complications of a holiday weekend, the event turned out to be a tremendous success.

Here is a short summary of the huge impact of this event:

- Attendance was estimated at 6,700 people
- We had 25 organizations exhibiting and close to 200 individuals participating in the exhibits ranging from finance and accounting professionals, scientists, engineers, senior executives (including CEOs and EVPs), IT professionals, healthcare providers and others. This was clearly not a science only event!
- Several organizations posted the event on internal messaging boards, intranet feeds and email list serves.
- We were able to secure well over 100 face-to-face appointments as well as hundreds of phone appointments with both current customers and prospects. Our Kelly Team connected with over 150 organizations, and we secured executive and C-level meetings with over 40 of them.
- We estimate that we reached 50,000 industry professionals prior to the event through direct email campaigns and social media pushes.
- Press releases were sent out through 14 news organizations — both in print and TV. We posted to over 100 LinkedIn groups, which led to the event being shared to numerous other groups. We also developed a Twitter following, as well as a live Twitter feed throughout the event.
- Kelly sponsored cost of the event.

Here are some of the comments we received during the day:

- "Awesome event! I've had a lot of fun. Thank you to all the staff!" — *Huanyao Gao, Univ. GA Researcher*
- "I'd have to say that the inaugural #biotech day @natural sciences was a smashing success - thanks to @DavidGSmithNC and his awesome staff!" — *David Kroll, Dir Sci Comm - NC Museum of Natural Sciences*
- "Thanks David for organizing this. It was a brilliant idea and a successful realization. I really enjoyed it!!" — *Gabriel Weinreb, Computational Biologist*
- "Awesome! Was a great event! Thanks again for setting it all up!" —*Dale Karlson, Monsanto*
- "This was a totally awesome event!!! Can't wait until next year! We have to be out here to exhibit!" —*Leanna Pearson, Catalent*
- "This was so much more fun and exciting than I thought it could be. Thank you so much for letting us be a part of it" — *Liquidia*
- "This event was simply awesome! We definitely want to be a part of this again next year!" — *Senior Scientist, BASF*
- "What a great opportunity for us to promote STEM education. Thank you so much for inviting me to be a part of this!" — *CEO, Lonerider Brewery*
- "This is big. Great event! So many opportunities for families and industry people to connect" — *Director of Manufacturing, Biogen Idec*
- "This is a really great idea and I'm so glad that you put a creative game like this together to engage the kids to have fun but also understand some basic concepts. This is so cool." — *Protein Scientist*

Our next steps include:

- We were requested to hold this event annually, and next year it will be held on April 6, 2013
- We will be creating a "teach the teachers" component for next year which will require outreach to school boards and educational organizations

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Chapter Events

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- Post-event marketing via social media and press releases about the success of the event
- Survey to exhibitors and presenters on lessons learned and ideas for next year's event
- Creation of a steering committee of executives for next year's event
- Goal for next year is to increase to 100 exhibitors, 24 speakers, and attendance of 20,000

Event Summary:

25 exhibitors and 9 presentations during the day including:

Speakers

- ***How A Drug Comes to Market***. Pam Paulsen, Senior Learning Technologist, PPD
- ***Are You Taking Biotech Medicines?*** Tim Bloom, PhD, Vice Chair and Associate Professor, Department of Pharmaceutical Sciences, Campbell University
- ***The Primate Armpit Microbiome Project***. Julie Urban, Ph.D., Assistant Director, Genomics and Microbiology Laboratory
- ***A Day in the Life of Beer***. Sumit Vohra, CEO and Chief Drinking Officer Lonerider Brewing Company
- ***Why Drugs Are So Expensive***. Clare A. Matti, MA, RAC (US, EU), Assistant Director, Regulatory Services, Duke Clinical Research Institute
- ***Better Crops for a Better Future***. Joerg Bauer, PhD, BASF Corp
- ***Development of Vaccines Against Insect-Borne Viral Diseases***. Malcolm Thomas, CEO Arbovax Inc
- ***Taking the Good from the Bad: Protein Purification Techniques Used in the Biotechnology Industry***. Nii Odoi Oddoye, Senior Technology Engineer, Pfizer
- ***What Can Growing Plants in Space Teach Us about Growing Plants on Earth?*** Dr. John D. Mayfield, Postdoctoral Research Fellow, Duke University Institute of Genome Science and Policy

Exhibits

- **BASF:** "Plant Science Innovation Yields Results" – Take a Look at DNA Extraction Techniques!
- **Bayer Crop Science:** "Bayer CropScience – Science for a Better Life"
- **Biogen Idec:** Partnering with BTEC (see below)
- **North Carolina State University BTEC:** "Biotechnology and Biomanufacturing in your Life - Some Fun Experiments" - Grape Soda Column Chromatography and Starch Iodide Experiment
- **BioNetwork Capstone Center:** "DNA Code Bracelet" – DNA Origami! Crack the DNA Vocabulary Code! Take a look at a Portable Hood with Particle Counter!
- **BRITE:** "BRITE IS BIOTECHNOLOGY" – Gel Loading Stations – Learn how to Use a Micropipette!
- **Campbell University:** "Biotech RX – Biomanufacturing Medications" – Coloring and Cutting out Nucleotides, Learning how to Pipette, Yeast Respiration Demonstration
- **Duke Clinical Research Institute:** Learn CPR. Save a Life.
- **East Carolina University**
- **Environmental Protection Agency:** "Going Green: New Technologies for Environmental Studies" – Learn about tracking pollutants at a personal level and how they affect health!
- **FujiFilm Diosynth Biotechnologies:** "Biotechnology in Your Daily Life" - Fun Experiment Dealing with Ink and Filter Paper!
- **GrassRoots Biotechnology:** "Tapping Into a Greener Future" – Take a look at a glow in the dark plant!!
- **Intrexon:** "Biotechnology in Agriculture" - Examples of Plant Regeneration, Plant Tissue Culture, and Plants Used for Biofeuls. Also DNA Extraction from Plants!
- **ISPE, Carolina-South Atlantic Chapter:** "There's More to Biotechnology than Meets the Eye"
- **Johnston County Community College:** "Biotech Basics for Everyone to Know" – Make Slime!!
- **Kelly Scientific Resources:** "Understanding the Immune Response" – Come play a fun game while learning how our bodies fight infections!
- **Liquidia Technologies**
- **Medicago:** "Plant-Based Vaccines" - Learn the Planting Process!
- **Monsanto:** "Applications of Biotechnology to Enhance Crop Productivity"
- **North Carolina Biotechnology Center:** VIDEO: "Heal, Feed, Sustain: How Biotechnology Can Help Save the World."
- **North Carolina FFA:** "North Carolina FFA"
- **North Carolina State University Plant Pathology:** "Advancing Agriculture"
- **Novozymes:** "Rethinking Every Day Products with Biotechnology" - Everyday Products that Utilize Enzymes!
- **Pfizer:** "Pfizer" - Take a look at the Filters, Clamps, Pipes, etc. that are used in Biotechnology Every day! Also, come get the chance to see some bacteria plated!
- UNC: "How Muscles Do Work: The Sarcomere"
- http://naturalsciences.org/programs-events/biotechnology-day

Thanks Interphex 2012!

Patrick Buckner accepted a check of $1000 that was generously donated from Interphex 2012 to support CaSA ISPE's Young Professional Initiative.

Got News or Story Suggestions for Upcoming Newsletters?

Send it to:
omni_tox@yahoo.com

Entries should be brief and be of general interest to the readership. Entries must include a name and telephone number for verification purposes. We reserve the right to edit and select entries.

Technical Section

EHS Update: New EPA rules will require an energy assessment for most facilities with boilers

By Martin E. Rock, PE, JD, LEED-AP, Past President & Board Chairman (2005-2006)

On December 23, 2011, the U.S. Environmental Protection Agency (EPA) published revised Boiler Maximum Achievable Control Technology (MACT) standards, 76 FR 80,532 and 76 FR 80,598. The Clean Air Act (CAA) requires the EPA to set technology-based standards for hazardous air pollutants that are based on emission levels achieved by the best performing existing sources. The EPA said it expects to finalize the regulations in 2012. After 22 years and an EPA-estimated price tag for North Carolina of over $1 billion, this may be the final version of the Boiler MACT and Commercial and Industrial Solid Waste Incineration rules.

New proposed regulations retain strict emissions limits for mercury, hydrogen chloride, particulate matter, and carbon monoxide (the last two of which serve as surrogates for metallic and organic pollutants) but, nonetheless, impose new limits. These proposed regulations, however, eliminate the numeric emission limit for dioxins/furans, noting in the preamble that the level previously proposed could not be accurately measured with existing technology. Instead, the new regulations tackle dioxin/furan emissions by imposing work-practice standards that include periodic tune-ups to ensure good combustion.

Because some energy recovery units, such as boilers, burn secondary materials, the definition of solid waste is integral to determining how a unit will ultimately be regulated under the Section 112 MACT requirements. Some units that burn secondary material and are otherwise considered boilers or process heaters and regulated under CAA Section 112, may be considered incinerator units and regulated under CAA Section 129. The EPA sent the major and area source boiler rules for Office of Management and Budget (OMB) review May 17, and the incinerator and waste definition rule May 18. Although some uncertainty remains, the provisions affecting energy assessments are unlikely to change significantly from existing law.

What is the Compliance Schedule?

Under the final Area Source Rule, existing sources subject to tune-up requirements must comply by March 21, 2012 (the proposed Rule would extend this to March 2013); and existing sources subject to emission limits and energy assessments must comply by March 21, 2014. New sources must comply upon start-up.

For large boilers, existing sources subject to the Boiler MACT rule must comply with required energy assessments by March 21, 2014. Under the proposed rule, existing boilers would have three years from the effective date of the new rules to comply — plus the ability to apply for an additional year, if circumstances warrant.

The Current Rule Applicability is given in the following table:

Boiler Size and Construction Date	Fuel type [2]	Summary of Requirements
All Gas-fired boilers [1]	Gas (all types)	• None (not covered by the rule)
Other New and Existing Small boilers (<10 MMBtu/hr)	Coal, Biomass and Oil	• Tune-up every other year
Existing boilers: Commenced construction or reconstruction of the boiler on or before June 4, 2010		
Existing Large boilers (≥10 MMBtu/hr)	Coal	• Emission limits for Hg and CO • One-time energy assessment
	Biomass and Oil	• Tune-up every other year • One-time energy assessment
New boilers: Commenced construction/ reconstruction or switched from natural gas fuel to solid fossil fuel, biomass or liquid fuel after June 4, 2010		
New large boilers (≥10 MMBtu/hr)	Coal	• Emission limits for Hg, CO, and PM
	Biomass and Oil	• Emission limit for PM • Tune-up every other year

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Technical Section

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The key questions to determine the applicability at your site are:

1. Do I have a boiler or boilers?
2. Is my boiler subject to the rule?
3. Am I a major source for hazardous air pollutants (HAPs)?
4. What size are my boilers?
5. What type of boiler do I have?
6. What fuel or fuels do I combust?
7. What are my installation dates on my boilers?

Based on this review, the facility can determine the status and requirements for boilers at the site. The overall scope of the Boiler MACT/GACT Energy Assessment under current law is given in the following table:

SCOPE OF ENERGY ASSESSMENT	
< 0.3 TBtu/yr	1. Energy assessment for facilities with affected boilers using less than 0.3 trillion Btu (TBtu) per year heat input will be ***one day in length maximum***. The boiler system and energy use system accounting for at least 50 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities, within the limit of performing a one-day energy assessment.
0.3 to 1 TBtu/yr	2. Energy assessment for facilities with affected boilers and process heaters using 0.3 to 1 TBtu/year will be ***three days in length maximum***. The boiler system(s) and any energy use system(s) accounting for at least 33 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities, within the limit of performing a three-day energy assessment.
> 1 TBtu/yr	3. Energy assessment for facilities with affected boilers and process heaters using greater than 1.0 TBtu/year, the boiler system(s) and any energy use system(s) accounting for at least 20 percent of the affected boiler(s) energy output will be evaluated to identify energy savings opportunities.

Existing boilers with heat input capacity greater than 10 million Btu per hour that are biomass-fired or oil-fired must have a one-time energy assessment performed by a qualified energy assessor.

In the new, proposed rule, the EPA clarified three items regarding the energy assessment.

1. **Scope:** Limited to only those energy use systems, located on-site, associated with the affected boilers and process heaters. The final definition for "Energy use system" was intended only to list examples of potential systems that may use the energy generated by affected boilers and process heaters.
   - The EPA did not intend that the energy assessment would include energy use systems using electricity purchased from an off-site source.
   - The EPA also did not intend that the energy assessment include energy use systems located off-site.
2. **Compliance Date:** Energy assessments must be completed by the compliance date (currently March 21, 2014) for existing sources.
3. **Maximum Duration Requirements:** Change the maximum time from one day to eight technical hours and from three-day to 24 technical hours and to allow sources to perform longer assessments at their discretion.

A boiler is defined in the rules as an "enclosed device using controlled-flame combustion and having the primary purpose of recovering thermal energy in the form of steam or hot water." EPA estimates that there are more than 1.5 million boilers in the country.

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Technical Section

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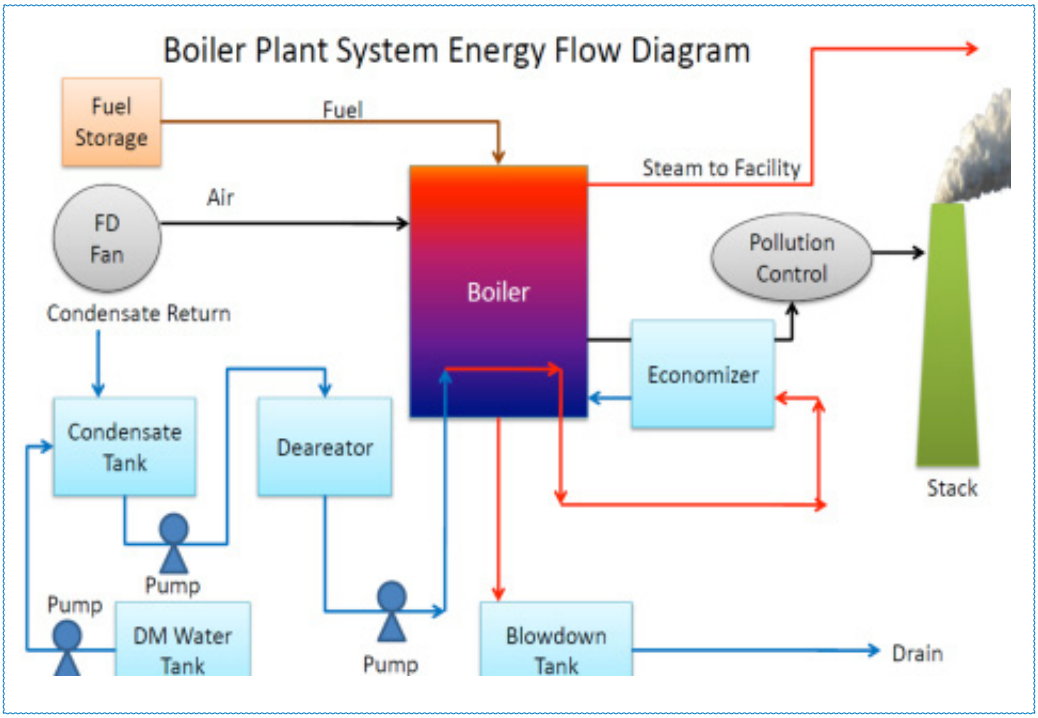
For purposes of an energy assessment, the boiler plant systems are included, and a typical boiler plant system diagram is given below:



Based on the EPA Current and Proposed Rules, Energy assessments must include the following:

- A visual inspection of the boiler system
- Establish unit characteristics – energy system specifications, operating/maintenance procedures, unusual operating constraints
- An inventory of major energy-consuming systems
- A review of available architectural and engineering plans
- A review of the facility's energy management practices
- A list of major energy conservation measures
- A list of energy savings

- A comprehensive report detailing the ways to improve efficiency and detailing how efficiency can be improved, what it will cost, what the benefits are for the improvements, and the timeframe for return on investment.

A boiler tune-up refers to the act of reestablishing the air-fuel mixture for the operating range of the boiler. Oxygen and unburned fuel (carbon monoxide is generally the indicative measurement) are balanced to provide safe and efficient combustion. Carbon monoxide (CO) concentrations are also measured to ensure proper burner operation.

A primary goal of a boiler tune-up is to improve boiler efficiency with respect to combustion operations.

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Technical Tip from IPS

When designing the automation of a positive displacement pump during CIP ensure the pump speed matches or slightly exceeds the required CIP flow for that CIP cycle. Alternatively have the pump controlled to maintain a constant differential pressure for flexibility with CIP cycles of differing flow rates.

Erich Bozenhardt, P.E.
BioProcess Engineer
Integrated Project Services - IPS

Technical Section

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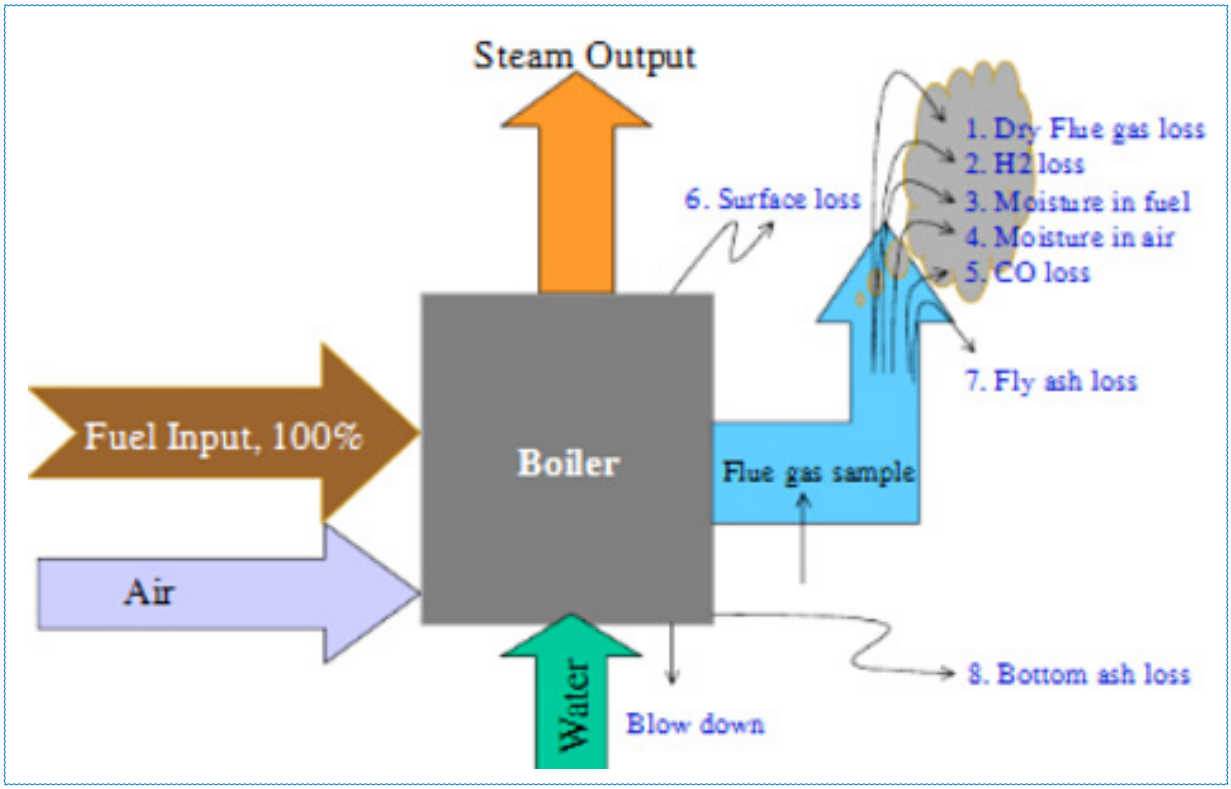
Various heat losses in a typical boiler system are shown in the diagram below:



For liquid, gas, and solid fuel fired boilers, the following losses are typical:

1. Losses due to dry flue gas (called sensible heat)
2. Loss due to hydrogen in the fuel (H_2)
3. Loss due to moisture in the fuel (H_2O)
4. Loss due to moisture in air (H_2O)
5. Loss due to carbon monoxide (CO)
6. Loss due to surface radiation, convection, and other

For a solid fuel fired boiler, the following losses are typical in addition to the above:

7. Unburned losses in fly ash (Carbon)
8. Unburned losses in bottom ash (Carbon)

Minimum Tune-Up Procedures:

- Inspect the flame pattern and burner. Adjust, clean, and replace as necessary.
- Inspect the system controlling the air-to-fuel ratio.
- Optimize CO emissions.
- Measure CO concentrations in the flue gas stream, both before and after the adjustments are made.

Caveat: Doing a more thorough review may not be required, but may provide more cost savings opportunities.

Part 2 of this article will be published in the next Chapter Newsletter. Part 2 will delve into the technical aspects of Energy Assessments and Boiler-Tune-ups including the following: steam trap audits; feedwater systems, condensate lines and deaerators; piping conditions and operating pressures; insulation and gaskets; and calculating return on investment.

Martin E. Rock is a registered professional engineer (5 states) and a licensed attorney (2 states). He serves as President and Senior Principal with OMNI Professional Environmental in Research Triangle Park, North Carolina. He has been a member of ISPE for over 10 years, including a previous tenure as Chapter President of the ISPE-CaSA Chapter.

Questions or comments on this article can be submitted to the author at omni.professional@gmail.com

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