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ECONOMIC SPOTLIGHT

Did You Know...
You can follow the latest in medical imaging on MITA’s blog, Imaging in Focus.
Visit www.medicalimaging.org/blog.
We at NEMA are proud to bring you this issue of *electroindustry*, focusing on critical issues in medical imaging, radiopharmaceuticals, and radiation therapy.

The Medical Imaging & Technology Alliance (MITA), a division of NEMA, is the leading organization and collective voice of medical imaging and radiation therapy equipment manufacturers, innovators, and product developers, and they have been a busy group over the past year.

On behalf of its member companies, whose sales make up more than 90 percent of the global market for medical imaging technology, MITA has been a leader on major issues ranging from medical radiation safety to ensuring patient access to innovative, lifesaving technologies.

Specifically in this issue, you’ll have the opportunity to learn more about new legislation that has stemmed from MITA’s industrywide initiatives on radiation dose and may very well be a model for other states moving forward. You’ll also see how and why MITA is working closely with the FDA. Its active involvement in numerous regulatory issues affects industry, physicians, and patients alike.

For those who may not be familiar with the world of medical imaging, our medical imaging primer, beginning on page 10, provides a helpful overview of these amazing technologies and how they work. And, last but not least, Suzanne Lindley’s story of surviving metastatic colorectal cancer puts everything into perspective, bringing the invaluable benefits of medical imaging, radiopharmaceuticals, and radiation therapy into crystal clear focus.

Stay well.

Evan R. Gaddis
President and CEO
Regulation and Legislation Matter
Randy Hill, CEO, Customer Solutions Group, Siemens Healthcare

As the 112th Congress begins, healthcare policy will likely maintain its spot at the top of the legislative agenda, but too often we forget that it is regulation—just as much, if not more than legislation—that also affects policy and, ultimately, our industries and our lives.

This issue of electroindustry comes at an exciting but uncertain time.

On the one hand, 2010 left no doubt: study after study continued to reinforce what so many doctors and patients already know firsthand, that medical imaging saves lives.

As just one example, a study unveiled late last year by the National Cancer Institute found that low-dose CT scans reduce lung cancer-related deaths by as much as 20 percent in high-risk populations. And, in September, a New England Journal of Medicine study demonstrated that mammography reduces mortality rates by as much as 10 percent. Additionally, earlier in the year, a study from the National Bureau of Economic Research revealed that cancer imaging innovation accounted for 40 percent of the reduction in U.S. cancer deaths between 1996 and 2006, making it likely the largest single contributor to decreased cancer mortality during this decade.

This is big news, and these studies are just the tip of the iceberg.

On the other hand, there continues to be a gap between the demonstrated value of these technologies and our ability to get them to market, so that patients can access and benefit from them in a timely manner.

As is always the case, the devil is in the details, and indeed, many of the seemingly arcane processes at the U.S. Food and Drug Administration (FDA)—from its 510(k) clearance process to its user fee system—are having a significant, negative impact on innovation and access.

While these processes often do not make the headlines, their ripple effect is immeasurable and it is incumbent upon us to know about them and seek to correct them. That’s what we’ve been doing with MITA, and it is what we will continue to do. Educating not just members of Congress, but also regulators, and advocating common sense policies as well as clear, predictable, transparent, and timely processes that will allow today’s innovations to become tomorrow’s cures.

ABOUT MITA
According to the New England Journal of Medicine, medical imaging is one of the top developments that changed the face of clinical medicine during the last millennium.

The Medical Imaging & Technology Alliance (MITA), a division of NEMA, is the leading organization and collective voice of medical imaging equipment manufacturers, innovators, and product developers. It represents companies whose sales make up more than 90 percent of the global market for medical imaging technology.

These technologies include:
- medical x-ray equipment
- computed tomography (CT) scanners
- ultrasound
- nuclear imaging
- radiation therapy equipment
- magnetic resonance imaging (MRI)
- imaging information systems
- radiopharmaceutical manufacturers

Activities
MITA provides leadership for medical imaging and radiation therapy industries on legislative and regulatory issues at the state, federal, and international levels. It serves as an advocate for fair legislative and regulatory proposals that encourage innovation, investment in research and development, and the continued global competitiveness of the medical imaging and radiation therapy industries.

MITA is also a leading standards-development organization for medical imaging and radiation therapy equipment. These standards are voluntary guidelines that establish commonly accepted methods of design, production, testing, and communication for imaging and cancer treatment products. Sound technical standards of this kind improve safety and foster efficiencies in how care is delivered.

Goals
- increase awareness and understanding of the value of medical imaging
- achieve efficient and reasonable regulation of medical imaging technologies
- interact with appropriate government agencies on reimbursement and technology assessment policies
- expand the global acceptance of the digital communications standard (DICOM) that allows digital imaging technologies to interact seamlessly
- improve regulatory harmonization of the global market for medical imaging products
- develop and represent industry positions in technical, trade, and other issues
- provide market data unique to this industry

Learn more at www.medicalimaging.org.
 › MITA Welcomes FDA Clearance Process Workplan

With the FDA’s publication of the 2011 510(k) reform workplan, the Medical Imaging & Technology Alliance (MITA) now has a better understanding of the Food and Drug Administration’s (FDA) next steps in the process and the opportunities for collaboration.

MITA has been heavily engaged in this reform effort and continues to analyze FDA’s 510(k) and Science Report Recommendations and plan of action for implementation. The proposition of clear timelines, more predicable processes, and a focus on maintaining a high level of expertise among review staff are all welcome moves toward modernization of FDA’s Center for Devices and Radiological Health under the leadership of Jeffrey E. Shuren, director of the center.

Medical imaging manufacturers will now undertake a detailed analysis of all recommendations contained in the work plan and provide feedback in this collaboration.

It is essential for regulators, industry, and other stakeholders to work together to understand all of the implications associated with regulatory and subregulatory efforts in order to ensure that patients have timely access to lifesaving innovations. While we are encouraged that there is a delay and reconsideration of those items determined most controversial, we are continuing to review other items of interest.

“A clear, transparent, and timely 510(k) clearance process is critical to ensuring that Americans have access to the most advanced medical technology in the world,” said Dave Fisher, executive director of MITA and NEMA vice president.

“We endorse President Obama’s call for protecting the public’s health while also promoting innovation and we look forward to continuing to work with the FDA on reform so that medical imaging technologies are available to patients in accordance with the president’s framework.”

Brian Connell, Director of State and Federal Relations | bconnell@medicalimaging.org

 › OSHA Withdraws Controversial Noise Interpretation

The U.S. Occupational Safety and Health Administration (OSHA) announced on January 18 that it was withdrawing a controversial interpretation issued last fall of what constitutes “feasible noise controls” under its workplace hearing protection regulations. OSHA initially published the interpretation in the Federal Register on October 18 and was accepting public comments through March 22, 2011.

Under the proposed interpretation, OSHA stated that personal protection equipment, such as ear plugs or ear muffs, could supplement, but not substitute, administrative or engineering controls. Had such interpretation been implemented, employers may have needed to modify their operations to comply fully with the regulations, resulting in additional costs to business.

In lieu of pursuing the proposed interpretation at this time, OSHA announced that it will continue reviewing comments received on the proposal, hold a stakeholder meeting on preventing occupational hearing loss, and consult with occupational health and safety experts.

OSHA also intends to “initiate a robust outreach and compliance assistance effort to provide enhanced technical information and guidance on the many inexpensive, effective engineering controls for dangerous noise levels.”

NEMA is working with other industry trade associations to evaluate this issue and participate in the stakeholder process. These efforts will persist as OSHA’s initiative continues.

Sarah Owen, Government Relations Manager | sarah.owen@nema.org
Battery Section to Lead Stakeholders in Product Stewardship for Alkaline Batteries

Consistent with its history of progressive action on health, safety, and environmental matters, the NEMA Dry Battery Section is embarking on a comprehensive effort to identify and implement an end-of-life management system for alkaline batteries.

The vehicle for this initiative will be a national stakeholder process involving broad representation across industry, government, and the NGO (non-governmental organization) community.

This will be a large scale, science-based effort, involving all relevant voices and spearheaded by the people who know most about the issue—the manufacturers. It is also scheduled to proceed on an ambitious timeline, with a stakeholder summit meeting planned for this spring that will set the agenda for possible pilot projects and other actions to begin later this year.

Alkaline batteries are common household, single-use batteries, e.g., AAA, AA, C, D, and 9-volt. Unlike certain rechargeable batteries, alkalines contain no toxic materials and are considered non-hazardous under strict federal waste characterization rules. Moreover, because they contain very little post-consumer value, the economic incentive to collect and recycle alkaline batteries is minimal.

With the growing emphasis on “zero waste” policies, however, regulators and advocacy groups have increasingly focused on alkaline batteries and sought input from industry on legislative approaches.

Meanwhile, NEMA members have devoted substantial resources to lifecycle analyses and other studies. They have found that a limited number of recycling facilities, transportation challenges, regulatory restrictions, and other factors make it extremely difficult to collect and recycle alkaline batteries in the U.S. in a manner that would provide net environmental benefits.

The intent of the stakeholder process is to determine whether and how these obstacles can be overcome and a nationwide system instituted that meets this net benefit threshold.

Another principle that will guide this effort as it unfolds is that the resulting recycling program should demonstrate shared responsibility throughout the value chain, including everything from retail communication to consumer participation.

This is consistent with NEMA’s overall position on product stewardship policies (see NEMA Statement of Principles on End-of-Life Management of Electrical Products at www.nema.org/EOLstatementOfPrinciples). The program should also be consistent nationally; executed in a phased approach to benefit from lessons learned; and be environmentally, economically, and socially sustainable.

Finally, NEMA members believe that once in place, the industry recycling program should proceed independently of legislation. However well intentioned, laws that seek to impose a system on manufacturers could impede the search for a solution that provides optimal environmental and economic benefits.

Mark A. Kohorst, Senior Manager of Environment, Health, and Safety | mar_kohorst@nema.org
NEMA/BIS Survey Finds Varied Levels of Concern over Rare Earth Supply Constraints

As China, the source of approximately 95 percent of the world’s production of rare earth elements, announced that it was reducing its export quotas for these vital materials by 35 percent in the first half of 2011, NEMA sought to understand the effect such restrictions would have on the electroindustry.

NEMA/Business Information Services conducted a survey in January to learn directly from the membership what segments of this industry would be affected and to what extent.

According to the staff member who conducted the survey, Steve Wilcox, director of market research, the responses paint a mixed picture.

“Supply constraints of rare earth elements are being acutely felt in very specific segments of the NEMA membership and only modestly, if at all, throughout the remainder of the electrical industry,” he said.

He noted that the survey responses revealed that lighting appears to be the industry segment most in need of a reliable supply of rare earths. Also affected, though far less frequently mentioned, are motors, meters, imaging systems, batteries, and cables.

One respondent specifically included “products involving high energy magnets…and specific electronic components.”

Even before China reduced its export quotas, increased demand for rare earth materials had begun to strain active sources of these metals. With that in mind, the survey asked members to rate the effect that limited rare earth supply had on their companies.

A plurality of respondents (45 percent) reported little to no effect, but 36 percent had already experienced a significant to major impact. Asking members to evaluate the effect of China’s quota reduction resulted in a slightly smaller proportion of the sample (41 percent) expecting little to no impact, while those who foresaw a significant or major impact increased by nearly 10 points to 45 percent.

“As demonstrated in this survey, rare earth elements are vital to major segments of the electrical manufacturing industry, and finding reliable supplies of those materials, or developing adequate substitutes for them, is a high priority for those affected,” Mr. Wilcox concluded.

When asked to comment about the survey results showing nearly half of members reported little to no effect of tightened rare earth supplies, NEMA President and CEO Evan Gaddis said, “A fair amount of companies appear to be asleep at the wheel. Many are just beginning to find out that while they may not be seeing any direct effects, a wide swath of their products’ supply chain is feeling the impact, which will ultimately hit them with input shortages and escalating costs.”

He added, “In this case, what you don’t know could sink your business.”

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Graphic courtesy of the National Mining Association

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Pat Walsh, Editor in Chief | pat.walsh@nema.org
NEMA Members Work Together on ENERGY STAR®

Several NEMA product sections represent sectors in which the U.S. government is transforming the market through a voluntary ENERGY STAR® labeling and certification program. Member companies frequently work within NEMA to develop and communicate common positions to the U.S. Environmental Protection Agency (EPA), the federal agency responsible for administration of ENERGY STAR requirements.

In general, the purpose of an ENERGY STAR program is to provide recognition and draw consumer attention to the top 25 percent of products in terms of energy efficiency. In 2010, EPA began implementing a transition from a self-certification approach to mandatory certification by an EPA-approved third party.

Most American consumers are familiar with the ENERGY STAR logo and common types of qualified products, such as compact fluorescent lamps (CFLs). But did you know that EPA is developing an ENERGY STAR program for Uninterruptible Power Supply (UPS) units?

Begun in 2010 as the third in a three-program effort focused on improving the energy efficiency of data centers, the UPS specification is expected to become effective in July 2011. Recently, the NEMA Power Electronics Section provided consensus comments to EPA on its proposed energy-efficiency test methods and the required data collection process.

What about those CFLs?

As explained in last month’s electroindustry, EPA is consolidating its three lighting programs into two. This month, members of the NEMA Lighting Systems Division are developing comments in response to proposed requirements aimed at having CFLs and light-emitting diode (LED) lamps compete for ENERGY STAR qualification.

The development of a new lamp program, for which a final specification is expected this summer after several rounds of proposal and comment, follows 10 months of work fine-tuning new requirements for specific types of residential and commercial grade lighting fixtures, or “luminaires.”

NEMA’s Luminaire Section, as well as members of the Lamp, Ballast, and Solid State Lighting sections, have advised EPA on the scope of the new program as well as a host of technical matters, including color, efficacy (lumens per watt), and minimum light output.

For its part, NEMA’s Lighting Controls Section continues to advocate development of an ENERGY STAR program for technologies that could help U.S. homes save even more energy by turning lights down or off when they are not needed. On behalf of the Residential and Commercial Controls Section, NEMA staff is also tracking EPA’s development of a new program for high-end residential climate control units.

Craig Updyke, Manager of Trade and Commercial Affairs

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CPSC Public Database Goes Live

The U.S. Consumer Product Safety Commission’s (CPSC) Publicly Available Consumer Product Safety Information Database goes live at saferproducts.gov this month, allowing consumers to submit reports of harm involving injury, illness, or death (or risk of same) resulting from the use of consumer products.

CPSC is required to submit such reports of harm to the identified manufacturer, private labeler, or importer of the product within five days of receiving the report. Manufacturers can register an individual designated to receive such reports through the Business Portal on SaferProducts.gov.

This portal also will allow manufacturers to provide comments on any reports involving their products and to authorize the publication of those comments in the database, as well as make claims for staff review of “confidential business information” or “materially inaccurate information” suspected to be contained in reports of harm.

Video tutorials on how manufacturers can complete registration and submit comments are available on the website.

Sarah Owen, Government Relations Manager sarah.owen@nema.org
**MITA Negotiating with FDA on Clearance Process Seeks Improvement to User Fee Program**

*Dave Fisher, Executive Director of MITA and Vice President of NEMA*

Despite an escalation in manufacturer fees paid to the Food and Drug Administration (FDA), the agency’s performance for imaging products has deteriorated since 2005. As FDA prepares to reauthorize the Medical Device User Fee and Modernization Act (MDUFA III), the Medical Imaging & Technology Alliance (MITA) has been working to ensure that these fees are improving the clearance process and fostering innovation.

Despite an escalation in manufacturer fees paid to the Food and Drug Administration (FDA), the agency’s performance for imaging products has deteriorated since 2005. As FDA prepares to reauthorize the Medical Device User Fee and Modernization Act (MDUFA III), MITA has been working to ensure that these fees are improving the clearance process and fostering innovation.

The fees, originally authorized by MDUFA nearly a decade ago and paid by manufacturers, are intended to make new technologies available to the public more quickly by enhancing FDA and manufacturer communications and bettering FDA performance. Between 2008 and 2012, medical device companies will have provided the agency with nearly $300 million in user fees.

MITA is concerned, however, that the link between industry fees and FDA performance has broken down. For example, as industry fees have continued to go up each year, FDA’s best year for the average number of days required for a 510(k) clearance—one of the two main processes by which the agency reviews and approves medical devices for market—was 2005. The average time required for clearance has increased since then.

FDA convened a public meeting in September 2010 to allow stakeholders the opportunity to voice questions and comments as the agency prepares for MDUFA reauthorization. MITA testified at this meeting and shared our industry’s concern over the medical device user fee program and the FDA’s clearance process.

MITA supports a medical device clearance process to ensure that safe and effective products are cleared for market in a timely manner. Unfortunately, performance has failed to keep pace with funding measures, leaving doctors and patients waiting longer for innovative technologies.

For example, as part of the 2007 MDUFMA negotiations, FDA committed to issuing guidance to manufacturers on devices that involve the use of contrast agents. That guidance had unintended consequences—that impacted manufacturers’ ability to bring products to market, potentially impacting patient access. Fortunately, after much effort, MITA was able to work with FDA on a solution that was put into effect in December.

A Stanford University survey of 200 medical device companies found that many respondents view the current FDA clearance process as unpredictable and plagued by disruptions and delays. This contrasts with the European Union review process, which was rated with strong favorability across the board. The report also found that on average, it costs companies $31 million to bring a product from concept to clearance in the U.S., with $24 million of that total spent on activities related to FDA clearance.

With this in mind, MITA is actively participating in MDUFA negotiations with FDA, alongside other major stakeholder groups, and is calling for the following changes:

- **Reasonable User Fees**
  The medical device industry has absorbed rapidly increasing user fees in recent years, ongoing economic difficulties, and a new $20 billion device tax. These hardships, plus a drastic reduction in reimbursement for imaging procedures and inefficient FDA performance, make higher fees an issue.

- **Measurable FDA Performance**
  Imaging manufacturers have been disappointed in the results of the last reauthorization and are concerned about the value they receive from the program. MITA will be seeking concrete performance goals that are measurable and verifiable moving forward. Improving FDA timeliness and the clarity and stability of the program is essential.
A Primer

The ABCs of Medical Imaging

According to the New England Journal of Medicine, medical imaging is one of the top developments that “changed the face of clinical medicine” during the last millennium. Today, imaging and radiation therapy are cornerstones of quality care, providing earlier, more-accurate diagnoses and highly personalized, more effective treatment.

The following elementary principles are designed to provide the general public a pictorial guide to the use of imaging in modern medicine.

COMPUTED TOMOGRAPHY (CT)

Computed Tomography (CT), also commonly referred to as a CAT scan, combines multiple x-rays taken from different angles to produce detailed cross-sectional pictures of areas inside the body.

The resulting images provide more information than regular x-rays and allow doctors to look at individual slices within the 3-D model.

CT is often used to evaluate:

• organs in the pelvis, chest, and abdomen
• colon health (CT colonography)
• presence of tumors
• pulmonary embolism (CT angiography)
• abdominal aortic aneurysms (CT angiography)
• spinal injuries

Image courtesy of GE Healthcare
**MAGNETIC RESONANCE IMAGING (MRI)**

Magnetic Resonance Imaging (MRI) uses radio waves and a magnetic field to create detailed pictures of organs and tissues. MRI has proven to be highly effective in diagnosing a number of conditions by showing the difference between normal and diseased soft tissues of the body.

MRI is often used to evaluate:
- blood vessels
- breasts
- organs in the pelvis, chest, and abdomen (heart, liver, kidney, spleen)

**POSITRON EMISSION TOMOGRAPHY (PET)**

Positron Emission Tomography (PET) is a type of nuclear medicine that provides physicians with information about how tissues and organs are functioning.

PET, often used in combination with CT, uses a scanner and a small amount of radiopharmaceuticals, which is injected into a patient’s vein to assist in making detailed, computerized pictures of areas inside the body.

PET is often used to evaluate:
- neurological diseases, such as Alzheimer’s and multiple sclerosis
- cancer
- heart disease

**RADIATION THERAPY (RT)**

Radiation Therapy (RT) is used to treat a wide range of cancers by delivering highly targeted radiation to cancerous cells, destroying their ability to grow and divide, while leaving healthy cells intact.

Generally, RT is delivered through beams emitted from a machine outside the body, or through brachytherapy, which involves placing the radiation source directly inside or near the site of the cancerous cells. Cancer patients may be treated with both radiation therapy and chemotherapy to limit the need for more exploratory surgery.
Radiation therapy and medical imaging technologies have revolutionized healthcare delivery in America and around the world.

ULTRASOUND
Diagnostic ultrasound, also known as medical sonography or ultrasonography, uses high frequency sound waves to create pictures of the inside of the body. The ultrasound machine sends sound waves into the patient and converts the returning sound echoes into a picture.

Ultrasound technology can also produce audible sounds of blood flow, allowing medical professionals to use both sounds and visuals to assess a patient’s health.

Ultrasound is often used to evaluate:
- pregnancy
- abnormalities in the heart and blood vessels
- organs in the pelvis and abdomen
- symptoms of pain, swelling, and infection

X-RAY
X-ray technology is the oldest and most commonly used form of medical imaging. X-rays use ionizing radiation to produce images of a person’s internal structure by sending x-ray beams through the body that are absorbed in different amounts depending on the density of the material.

X-rays are typically used to evaluate:
- broken bones
- cavities
- swallowed objects
- lungs
- blood vessels
- breasts (mammography)

RADIOPHARMACEUTICALS
Also known as “contrast agents” or “tracers,” radiopharmaceuticals are used by physicians to enhance images, allowing for improved visualization and characterization of organs and tissues for the diagnosis and treatment of disease.

When used together with medical imaging, radiopharmaceuticals highlight specific parts of the body. Physicians may administer contrast agents in a few different ways, including through a drink or an intravenous line.

Radiation therapy and medical imaging technologies have revolutionized healthcare delivery in America and around the world.

Extending human vision into the very nature of disease, medical imaging is enabling a new and more powerful generation of diagnosis and intervention.

Radiation therapy offers highly personalized and targeted means of killing cancer cells while leaving healthy ones untouched.

Melding these advances with the power of digital and information technology is fostering greater efficiency, quality, and value in healthcare.
Suzanne Lindley knows a thing or two about why innovations in medical imaging—and timely access to those innovations—can be a lifesaver. After all, she has been living with stage IV metastatic colorectal cancer for 12 years (and counting), thanks in part to advancements in radiation therapy and radiopharmaceuticals.

Suzanne was only 31 when she found out she had cancer. Not only did she have cancer, but it was already metastatic and had spread to her liver. She was told she had six months to live. For a short time, she thought that was it. She accepted her prognosis and asked other cancer patients for guidance on how to tell her two young daughters she wouldn’t be around much longer. Thankfully, she soon realized that she was still very much alive.

Suzanne soon started receiving the only therapy for colon cancer available at that time—chemotherapy (Fluorouracil, also called 5FU). She cycled through many different types of chemo, often seeing short term results, only to then see the cancer grow stronger. When she was out of approved chemo options, she turned to clinical trials.

But her liver tumors began to grow and multiply faster than the clinical trials could keep up with and she suddenly found herself back at square one. Like many cancer patients are told every day, she heard, “I’m sorry—there are no more options,” and was given three months to live.

For Suzanne, that just meant she had to find the next stepping stone in her treatment. She went on to try radioembolization (Y90), a combination of radiation therapy and embolization, a minimally invasive treatment in which tiny radioactive beads are implanted in tumors, cutting off the blood vessels that lead to the tumors, ultimately cutting off their lifeline.

It worked! She saw a 65 percent reduction in her liver tumors and some even died completely.

Since then, Suzanne keeps jumping from stepping stone to stepping stone of her cancer journey. She has received additional targeted radiation treatments; external beam radiation for cancer that spread to her spine; gamma knife for cancer that spread to her brain; radiofrequency ablation for a single returning liver tumor; and Cyberknife®, a robotic radiosurgery system, for her lung tumors.

Together, these advanced radiation therapy technologies have given Suzanne a lifetime of experiences. She got to watch her daughters grow up, grow older with her husband, and start her own patient advocacy organization, YES! Beat Liver Tumors.

Through YES!, Suzanne has connected hundreds of patients across the country with doctors and new treatments so successfully that she was called the “medical matchmaker” by TV journalist Katie Couric.

Today, Suzanne continues to receive systemic chemotherapy for her tumors, targeted radiological therapies when needed, and diagnostic imaging to stay on top of any tumor growth.

Access to a steady stream of innovations and clinical trials has enabled Suzanne to turn cancer from a terminal disease to a chronic one. She has spread hope to those who have trouble finding it. She relies on medical imaging innovations to continue bringing her to that next stepping stone, each of which has turned into a lifesaving milestone.
In the Fall of 2010, following a summer of debate, California Governor Arnold Schwarzenegger signed into law SB 1237, The Medical Radiation Safety Act. The legislation echoed many of the core tenets of MITA’s CT (Computed Tomography) Radiation Dose Check Initiative. It is designed to protect patients by facilitating reporting of radiation dose incidents to state authorities and requiring tracking of overall radiation use for all patients.

MITA supported SB 1237, which will require reporting of a medical radiation incident under several different circumstances, such as the x-ray or CT of a pregnant woman, an incorrect site being scanned or treated with radiation, or a scan exceeding 20 percent of its prescribed dose. It also requires that facilities list a scan’s radiation dose on images and record the dose in patients’ records.

The new law will take effect in 2012 and includes many of the same patient safety principles and provisions articulated by MITA and implemented industrywide:

- expanding and integrating appropriateness criteria into physician decision-making
- creating a national dosage registry to ensure longitudinal tracking of dose levels for patients across America
- adopting a standardized method of storing of diagnostic imaging and radiation therapy information within electronic health records
- exploring the expansion of mandatory accreditation for advanced imaging facilities
- establishing minimum standards for training and education for hospital and imaging facility personnel who perform medical imaging exams and deliver radiation therapy treatments
- developing enhanced operational safety procedures and checklists to reduce medical errors
- expanding and standardizing the reporting of medical errors associated with medical radiation across stakeholders in a manner that is transparent for patients, families, and physicians

“Medical imaging is a critical component of modern medicine and the standard of care we have come to expect and MITA has an ongoing commitment to working with the industry to make imaging as safe, effective, and appropriate as possible,” said David Fisher, executive director of MITA.

MITA supports industry safety initiatives such as CT Dose Check, the Radiation Therapy Readiness Check, and national legislation, such as the CARE (Consistency, Accuracy, Responsibility and Excellence) Act, which will begin to standardize training procedures for medical imaging and radiology professionals.

“The industry sees California’s efforts as a step in the right direction,” Mr. Fisher said. “This legislation creates and enhances valuable protections for patients. Reducing patients’ exposure to medical radiation is an industrywide priority; it is one of the reasons we are focused on innovation and it is a positive to see those efforts complimented by California’s legislature. We look forward to a national tracking system for lifetime medical radiation dose in the future.”

Lindsay Morris can be reached at lmorris@medicalimaging.org
In late December, the Food and Drug Administration (FDA) resumed clearing imaging products that include contrast agent functionalities or that are indicated for use with contrast agents in their labeling.

MITA worked closely with FDA to facilitate this much-needed change. It ended what had been effectively an innovation-hindering freeze on the approval of these contrast agent technologies for most of 2010. The recent decision helped to ensure that these critical, lifesaving products could once again start coming to market.

Contrast agents are used by physicians to enhance medical images by highlighting specific parts of the body, allowing for better visualization and characterization of organs and tissues for diagnostic purposes. Physicians may administer contrast agents in a few different ways, including though a drink or an intravenous line.

Prior to the FDA’s announcement, administrative decisions at the FDA prevented imaging products that may be used with contrast agents from being cleared by the agency. This meant that many products and certain functionalities within imaging devices that had been cleared by the FDA in recent years could no longer pass muster with the agency. As a result, companies were “de-featuring,” or removing key functionalities from their devices that had previously been approved by the agency in order to be able to bring products to market.

The FDA’s paradigm shift late last year effectively restarted the clearance process for these innovative imaging products and allowed previously cleared indications with contrast agents to be included in device labeling.

Imaging manufacturers appreciate FDA’s efforts to constructively work with the industry and the medical community to find an interim solution to the challenges brought on by FDA’s interpretation of the contrast agent guidance issued a year ago. We look forward to finding a permanent solution and working with the agency in improving the guidance to fully recognize the central role of imaging in medicine and the broad use of contrast agents with imaging devices.

In addition to MITA, the larger medical imaging community, including patients, patient groups, and medical professionals, are also heartened by this change and hopeful that it is the first of many more steps in the right direction.

“The FDA’s decision on contrast agents is welcome news for patients and their physicians and will ultimately result in improved patient access to lifesaving diagnostic medical technologies,” said Greg Sorensen, MD, professor of radiology and health sciences and technology at Harvard Medical School.

Dave Fisher can be reached at dfisher@medicalimaging.org
**Spotlight on Digital Mammography**

*Lindsay Morris, Director of Federal Relations, MITA*

By detecting breast cancer when it's most treatable, mammography is a proven lifesaver.

The Digital Mammographic Imaging Screening Trial (DMIST) sponsored by the National Cancer Institute and the American College of Radiology found that digital mammography is especially effective in finding cancers in women with dense breasts and those going through menopause, as well as younger women.

According to DMIST data, 65 percent of the women in the trial showed a benefit with digital mammography, proving better diagnosis of the at-risk population. Given this, we can all agree it is essential for women at risk to have access to this demonstrably lifesaving, innovative technology that is a cornerstone of mammography care.

Digital mammography has extremely low radiation levels. Moreover, since the images are digital, they can be manipulated. This leads to a better diagnosis. As we move to a health information technology-centric world, digital mammography makes smart economic sense and is increasingly cost efficient. By producing images that can be stored and shared electronically, digital mammography contributes to better coordinated, more efficient, and less duplicative care—the very goal of the Medicare program's efforts to encourage healthcare providers to adopt electronic health records.

MITA applauds cost-effective and efficient patient access to digital technologies that dedicate our nation's best science and clinical expertise to continuously improving care and replicating the successes achieved in breast cancer for the benefit of other life-threatening illnesses and conditions.

**DICOM Sets Standard for Health Information Technology**

Central to medicine is the ability of health information technology to connect healthcare systems together using appropriate standards so that data can flow and be understood between different systems.

More than 30 years ago, imaging equipment manufacturers and users of digital imaging equipment recognized the need for digital data exchange between providers using equipment from different manufacturers. Through the cooperative efforts of the American College of Radiology (ACR) and the medical division of NEMA—now the Medical Imaging and Technology Alliance (MITA)—the Digital Imaging and Communications in Medicine (DICOM) standard emerged.

DICOM, which is now managed by MITA, is a living and constantly evolving document that addresses the information transmission needs of new and existing modalities in a structured format.

With the near universal use of the DICOM 3.0 standard today, all DICOM-compliant systems can communicate with one another reliably, securely and efficiently to exchange patient data such as demographics, exam properties, images, numerical data, text and curves. DICOM has evolved to support new imaging technologies and new storage paradigms, playing a key role in creating a fully digitized record that fits in the new virtual environment in medicine.

Through the widespread availability, adoption, and use of DICOM, providers have the ability right now to transmit, store, retrieve, and archive medical images and imaging information. Use of DICOM for communication of imaging information is fundamental to achieving the goal of development and implementation of a nationwide health information technology infrastructure.
You can’t simply waddle into the market. You have to get there fast and make them melt. That’s why Intertek’s Energy Efficiency solutions address your success. For starters, we have the size and speed to save you both time and money. Our 18 Energy Efficiency testing laboratories across the globe have the capacity to slide you into market, faster. What’s more, with our unflappable core of energy expert reviewers ready, you’ll get ENERGY STAR certification in 24 hours after testing is complete.

Now is not the time to wing it. Built with 50 years of Energy Efficiency testing experience, from the innovators who brought you 15-day ETL testing, we help products prepare for today’s harsh climate. So, see the big picture. Get Intertek and get to market first. We’ll help you move up the pecking order, faster.
Vids for Grids Brings Smart Grid to the Classroom

The challenge—Encourage tomorrow’s workforce to get energized about the electric grid

The solution—Vids for Grids: New Media for the New Energy Workforce (V4G)

Last year, NEMA responded to a call from the Department of Energy (DOE) to develop a well-trained, highly skilled electric power workforce that can implement a national Smart Grid, as well as promote economic recovery, by connecting students who need employment to power sector employers who need employees.

The resulting V4G video series demonstrates a best practice in integrating new media into engineering core curricula.

The first four episodes of the 12-video series have been released on YouTube (www.youtube.com/vids4grids). When completed, the set of 10-minute videos and three 30-minute podcasts, which will incorporate open-ended questions with student-selected subject-matter experts, will be posted on YouTube. Curriculum materials will also be available.

The first four videos were filmed at NEMA member companies: “Surge Arresters,” at Hubbell Power Systems; “Switchgear,” at Eaton Electrical; “Smart Meters,” at Itron; and “Conductors,” at Southwire.

Future videos will address capacitors, conductors, connectors, dynamic line ratings, energy storage, flywheels, industrial automation, lighting management systems, and meters. NEMA expects to release one new video per month.

Drawing on the manufacturing expertise of its members and working in close collaboration with Northern Virginia Community College and George Mason University, NEMA developed V4G as a means to feature Smart Grid equipment, explain electrical engineering concepts, and portray careers with good employment opportunities in power engineering in a way that appeals to today’s YouTube Generation.

Each 10-minute video targets high school seniors and first-year college students, and covers a fundamental electromagnetic concept integral to the deployment of Smart Grid or a particular piece of grid equipment by incorporating brief interviews; equipment demonstration; and scenes from assembly, installation, and use.

In addition to the videos, the project will include a curriculum that can be adapted by any secondary or postsecondary school.

This program addresses the dual crisis of the outdated power grid infrastructure and the dearth of potential workers by

• attracting new students to entry-level engineering technician positions in Smart Grid and power equipment manufacturing companies, as well as similar positions throughout the energy sector

• encouraging students to acquire math and science skills

• facilitating institutional knowledge transfers across the generation gap between new energy sector workers and those nearing retirement

• improving the image of electroindustry careers

According to NEMA President and CEO Evan R. Gaddis, there is a dire need for workforce training in the electric power sector.

“Smart Grid is our future,” he said. “An aging workforce has created a brain drain in the electric power sector. This series will introduce Smart Grid concepts to tomorrow’s engineers.”

Of the approximately three million American students who complete high school annually, many lack the science, technology, engineering, and math skills necessary to pursue a technical career. This is partly due to a declining emphasis on career and technical education at the high school level, which has similarly affected the supply of skilled electric workers. The American Public Power Association reported in 2003 that the number of high school students taking trade- or industry-related vocational and technical courses had declined 35 percent in the prior 10 years.

Companies participating in V4G include A123, Beacon Power, Cooper Power Systems, Eaton Corporation, Hubbell Incorporated, Itron, Leviton, Rockwell Automation, Southwire Company, Thomas & Betts, and The Valley Group (a Nexans Company). Video services are provided by Metro Productions.

V4G is one of 54 Smart Grid workforce training programs funded by DOE through the American Recovery and Reinvestment Act of 2009, commonly referred to as ARRA or the Stimulus Bill. It is the only one funded in Virginia and the only one awarded to a non-profit association.

Pat Walsh, Editor in Chief and V4G Education Consultant | pat.walsh@nema.org
› ESFI Expands Efforts in Canada with Launch of ESFI Canada

On January 28, Electrical Safety Foundation International (ESFI) President Brett Brenner announced the establishment of ESFI Canada, a designated ESFI affiliate organization. ESFI Canada will champion ESFI’s mission to reduce electrically-related deaths, injuries, and property loss in that country.

“ESFI has always had a great working relationship with electrical safety stakeholders in Canada, but the establishment of ESFI Canada takes our work in that country to the next level,” Mr. Brenner said after the announcement, which was made during a presentation at the 18th Annual IEEE IAS Electrical Safety Workshop, held in Toronto, Ontario.

Much like the establishment of ESFI, formerly the National Electrical Safety Foundation (NESF), in 1994, ESFI Canada was formed by a committee of industry stakeholders that recognized the need for a national organization to serve as the resource and leading authority for electrical safety. ESFI Canada will leverage the visibility, history, and success of ESFI in its efforts to promote electrical safety awareness in Canada.

“ESFI Canada will use approaches and resources that are unique to Canada in order to extend the international reach of ESFI’s important safety messages,” Mr. Brenner said. “ESFI Mexico, which was established in 2009, has utilized a similar strategy with great success.”

ESFI Canada’s founding organizations are the Canadian Standards Association, Electrical Safety Authority, Electro-Federation Canada, Howe Brand Communications, Ontario Electrical League, Sonepar Canada, Thomas & Betts Limited, and Underwriters Laboratories of Canada.

ESFI Canada has applied for non-profit status in Canada and will elect a Board of Directors to lead the foundation’s activities. Peter Marcucci, vice president and chief public safety officer for the Electrical Safety Authority, has agreed to serve as interim chairman during this start-up period.

“We are pleased that leading Canadian electricity and safety organizations have come together to support the creation of ESFI Canada,” said Mr. Marcucci. “We look forward to welcoming many others to be part of our efforts.”

Kate Janczyk, Program Manager, ESFI | kate.janczyk@esfi.org

› NEMA’s Illuminations Weekend Returns to D.C.

Join us October 28–29, 2011, at the Mayflower Renaissance Hotel for a mix of seminars, general sessions, strategic outlooks, and networking opportunities. Take advantage of the spectacular proximity to policymakers and join your fellow NEMA members to discuss the most important issues facing the electroindustry.

Stay tuned for details about this year’s programs and speakers in upcoming issues of electroindustry.

Francine Meyer, Meeting Manager | fran_meyer@nema.org
Leviton Cord and Plug Connected EVSE Complies with NEC®

Kenneth Brown, Director of Engineering for C&E San Diego, Leviton Manufacturing Co., Inc.

Leviton’s EVSE meets the terms of applicable requirements of the NEC, Underwriters Laboratories (UL), and SAE J1772 Surface Vehicle Recommended Practice. As noted in NEC Article 625.13, if the EVSE is “…part of a system identified and listed as suitable for the purpose, achieving the requirements of NEC 625.18, 625.19, 625.29 shall be permitted to be cord-and-plug connected.”

The Leviton cord-and-plug-connected EVSE are part of a system identified and listed as suitable for the purpose, and meet the terms of NEC Articles 625.18, 625.19, 625.29.

Another example of compliance is noted in a proposal that was submitted to the NEC (NEC-P12) related to Article 625.13 to clarify that voltages up to 250 VAC can be cord-and-plug connected. The NEC rejected the proposal because the existing code allows the use of cord-and-plug-connected product at voltages higher than 120 VAC.

The actual verbiage from the code making panel is: The panel reaffirms its action on this proposal. An EVSE meeting the requirements of 625.18, 625.19, and 625.29 can be cord-and-plug connected even when the voltage is greater than 120 VAC. •

Kenneth Brown, who is leading efforts to develop electric vehicle supply equipment, is a voting member of the new NEMA EVSE Section, chair of the IEEE Surge Protective Devices Committee, and member of the UL Standards Technical Panel.

IEC Approves Standard for Ground-Fault Circuit Interrupters (GFCIs)

At last, the International Electrotechnical Commission (IEC) Subcommittee 23E: Circuit-breakers and similar equipment for household use has granted approval for a standard that addresses ground-fault circuit interrupters (GFCIs) that are associated with receptacles. It was first considered by the group in 1993.

The publication of IEC 62640: Residual current devices with or without overcurrent protection for socket-outlets for household and similar uses is particularly significant because it will provide greatly expanded market access for U.S. manufacturers of these devices, which have been installed by the millions in the U.S. and many other countries.

In the U.S., GFCIs have been certified to Underwriters Laboratories (UL) 943, which was first published in 1972. A number of previous attempts to develop an IEC standard, by the U.S. and several ally countries, were thwarted for a variety of alleged technical reasons, without bringing to light suspected commercial concerns.

IEC standards for circuit breaker style GFCIs, called residual current devices in much of the rest of the world, received better acceptance and have been published for a number of years. These include: IEC 60755 (first published 1983), IEC 61008 (first published 1990), and IEC 61009 (first published 1990).

NEMA has been trying to get the receptacle-style GFCIs covered in IEC for more than 18 years.

All countries that adopt IEC standards for their regulations to determine what products are available to their population will now have a standard that specifically addresses these products. Without this standard, competitors of U.S. manufacturers, whose products operate using a different technology, could argue that the U.S.–style products are not specifically permitted and thus the non-U.S. products would be the only ones allowed.

NEMA and representative experts from U.S. manufacturers of GFCIs have been actively pursuing acceptance of products under the scope of this new standard and should be congratulated on the achievement. Work is still needed to include additional requirements. One example would be “second-grounded neutral protection,” which refer to new specifications that include those for self-testing and power-denial that will increase the protective capabilities of devices certified to IEC 62640.

The standard’s publication is a result to be cherished. •

Ken Gettman, Director of International Standards | ken_gettman@nema.org
NEMA High Performance Buildings Council (HPBC)

New building construction and retrofit projects impact virtually every product in the electroindustry. In response to government and industry trends toward energy efficiency, increased occupant productivity, safety, and cost-effectiveness, NEMA has established the HPBC, with an emphasis on expanding the market for existing electroindustry technologies.

Why is the HPBC Important?
HPBC members represent a cross section of products. It is the one place in the electroindustry that brings together a program in government relations, codes and standards, and industry marketing focused on the built environment.

Examples of Key HPBC Initiatives

**Government Relations**
- Leading monthly educational briefings to the U.S. Congress and staff via the High Performance Building Congressional Caucus Coalition (www.HPBCCC.org)
- Directing the U.S. General Services Administration in the implementation of the Federal Buildings Personnel Training Act
- Working with the Zero Energy Commercial Buildings Consortium to provide input to the U.S. Department of Energy on lighting, daylighting, and lighting controls technologies
- Coordinating and directing major events on Capitol Hill during High Performance Buildings Week

**Codes & Standards**
- Promoting NEMA members’ technologies to improve existing codes, standards, and rating systems with groups such as ASHRAE, the International Code Council, and the U.S. Green Building Council, in turn filling electroindustry gaps
- Co-sponsoring development of a standard with ASHRAE for interoperability between high performance buildings and the Smart Grid in conjunction with the National Institute of Standards and Technology

**Industry Marketing**
- Becoming a recognized leader in development of next-generation building information modeling (BIM) solutions through a partnership with the National Institute of Building Sciences
- Creating a website to drive potential distributors, architects, engineers, building owners, facility managers, etc., to HPBC members

NEMA HPBC can help expand the market for your company. Contact Jim Lewis, Manager of High Performance Buildings and Industrial Energy Efficiency, at 703-841-3244 or jim.lewis@nema.org.
NEMA’s LVDE Section Publishes Switch Inspection and Maintenance Guide

NEMA’s Low Voltage Distribution Equipment (LVDE) Section recently published KS 3-2010 Guidelines for Inspection and Preventive Maintenance of Switches Used in Commercial and Industrial Applications.

This document takes the user through the maintenance and inspection procedures that will ensure the safe operation of a switch over its lifetime. It covers switches that are qualified under UL Standards: UL 98 Enclosed and Dead-Front Switches, UL 977 Fused Power-Circuit Devices, and UL 1429 Pullout Switches.

KS 3 explains how the temperature of a switch’s external cover can be an initial indication of a problem. Visual inspection is a key factor in determining the condition of a switch. The guide contains color photos providing examples of such frequently occurring problems as pitting and heat damage.

A section on non-destructive testing provides procedures to verify that the switch mechanism is operating freely; that insulation is adequate between line and load terminals, between poles, and between poles and ground; and that internal connections and contacts in the switch demonstrate electrical integrity.

Test procedures for verifying the operation of commonly used accessory devices are also provided. These include shunt trip releases, electrical operators, and auxiliary switches.

Under normal operations, switches should only require maintenance for verification of environmental conditions and to ensure that the correct enclosure type is being used. The operating life of the switch may be affected by the frequency of short-circuit-current faults and the environmental condition in which it operates. Preventive maintenance may be needed when an abnormal condition occurs or to confirm that the switch life is not compromised by its environment.

Guidelines for cleaning, lubricating, and reassembling switches are provided. Any additional preventive maintenance should only be performed as authorized by the manufacturer.

The document provides safety procedures to avoid injuries when inspecting or maintaining switches. Safe working practices described in NFPA 70 (National Electrical Code®) must be followed and only procedures authorized by the manufacturer should be undertaken.

The guide will be of great benefit to maintenance departments responsible for industrial and commercial facilities. It gives them information to guarantee reliable protection of the electrical system and how to determine whether a switch should be returned to service or be replaced.

KS 3 may be downloaded at no charge, or a hardcopy purchased for $58, by visiting www.nema.org/standards/ks3.cfm.

Gerard Winstanley, Program Manager | ger_winstanley@nema.org

Example of heat damage

Examples of pitting
Economy Blamed for Delaying Code Adoption in Washington

Washington State was scheduled to begin review of the 2011 National Electrical Code® (NEC) in November 2010, with adoption slated for July 2011. The one event that was unanticipated in this plan was the extent of the economic downturn around the country and in the state.

In mid-November, Governor Christine Gregoire signed Executive Order 10-06 that suspended all rule development and adoption until at least January 1, 2012. The governor cited the economy as the reason for the order, saying that a stable regulatory environment is an important element for an economic recovery. (www.governor.wa.gov/execorders/eo_10-06.pdf)

Prior to the executive order, the state had opened the electrical code revision process, receiving proposals from the public to be considered as amendments to the 2011 NEC or to the state’s rules. The order came just a week prior to the scheduled meeting of the Technical Advisory Committee, which was canceled. There is a provision in the executive order to allow new rulemaking if it is of an emergency or critical nature or would help stimulate the economy or create jobs. It was determined in January that neither the adoption of the 2011 NEC nor any of the proposed amendments could be considered under the criteria for an exception.

While the obvious impact is a delay in adoption of the newest electrical code, with its many safety enhancements, it also means that any amendments to the 2008 NEC will remain for another year, notably that arc-fault circuit interruption (AFCI) protection will remain for bedroom circuits only. That amendment was targeted to be removed in favor of the requirements in the 2011 NEC.

Chief Electrical Inspector Ron Fuller had indicated that he and the state Department of Labor and Industries were in favor of the expansion of the AFCI protection to most 120-volt residential circuits. Now it appears that the expansion will not go into effect until July 2012.

Additional information about the Washington electrical rule development status may be found and tracked at www.in.wa.gov/TradesLicensing/Electrical/LawRulePol/RuleDev/Default.asp.

Joe Andre, Field Representative | joe.andre@nema.org
NEMA Program Featured in Smart Grid Conference in Canada

NEMA’s North America Smart Grid program, Development of a Secure, Robust, and Reliable North American Smart Electrical Grid, was featured as the only example of a viable program currently underway in the U.S. that directly addresses standards, investment climate, and favorable policy development in a presentation made by the U.S. Department of Commerce as a representative of the Obama administration in a key event organized to support the efforts of the U.S.–Canada Clean Energy Dialogue to promote a more efficient electricity grid.

Smart Grids in the North American Context: A Policy Leadership Conference was held at the Centre for International Governance Innovation in Waterloo, Ontario. The venue offered an excellent environment for leaders from both sides of the border to share, discuss, and debate the evolution of the Smart Grid and its implications on broader societal objectives. The workshop brought together leaders in government, business, academia, and non-governmental organizations to engage in a discussion about the relationship between smart grids, climate change, and the emerging governance issues.

The program featured a variety of tracks that covered a broad range of impacts of the emerging Smart Grid, including such topics as Smart Grids and the Clean Energy Dialogue covered by the Canadian Minister of Natural Resources; Smart Grids and Climate Change—Possibilities; Democratizing the Grid—Why Should Governments Care, by U.S. Assistant Secretary of Energy for the Office of Electricity Delivery and Energy Reliability; U.S. Smart Grid Developments and Their Impact on Canada; Key Issues for the Policy Agenda; and the current status of the Ontario Smart Grid Forum.

NEMA’s North American Smart Grid program has three foci of activities:

- educational outreach on investment and tax policies to favor utility companies’ adoption of Smart Grid products
- development of interoperability standards to expand the market
- support of utility investment in Smart Grid products and systems

From the outset of this program, operating plans called for cooperation between Smart Grid teams in all three areas of focus. NEMA’s role in the program is to facilitate the communication between the standards development bodies in each country to achieve a common set of North American standards for Smart Grid that can ensure interoperability.

Because both Canada and the U.S. have ongoing Smart Grid programs, each country in the past would have produced its own independent sets of standards that would later become candidates for a harmonization process.

The objective of the NEMA program is to identify the similarities and differences of the Smart Grid programs in each country and identify how both countries can share information so that common North American standards can be developed and promoted to the IEC and other standardization bodies.

In Canada, electricity is provided by a network of provincial electric utilities, which are crown corporations who own generation, transmission, and some distribution systems. They are managed under the guidance of the National Energy Board of Canada.

This is in sharp contrast to the U.S. system, which is made up of numerous companies (some in the public sector, many in the private sector). Most of them are quite independent of each other from an ownership and governance standpoint, but must cooperate closely from an operational standpoint to ensure seamless operations across state and local boundaries.

Because of these structural differences between the electrical supply systems in the U.S. and Canada, the tactical approaches to develop a Smart Grid in both countries will naturally be different. This is a major target of the new program, which is slated to continue over the next two years.

Gene Eckhart, Director of International Trade | gen_eckhart@nema.org
OSHA Regulatory Update Regarding IECEx Scheme

The U.S. National Committee (USNC) serves as the U.S. representative of the IEC System for Certification to Standards Relating to Equipment for use in Explosive Atmospheres (IECEx). The objective of the IECEx system is to facilitate international trade in equipment and services for use in explosive atmospheres, while maintaining the required level of safety.

On October 8, 2010, a meeting was held between NEMA and OSHA (Occupational Safety and Health Administration) to discuss acceptance of the IECEx Scheme under OSHA’s Nationally Recognized Testing Laboratory (NRTL) program.

OSHA was represented by Assistant Secretary of Labor and OSHA Director David Michaels, PhD, Kevin Robinson, electrical engineer/NRTL program auditor, and MaryAnn Garrahan, director of technical programs for OSHA’s Office of Technical Programs and Coordination Activities (OTPCA). NEMA was represented by President and CEO Evan Gaddis, Vice President of Government Relations Kyle Pitsor, Vice President of Technical Services Al Scolnik, and Government Relations Manager Sarah Owen.

OSHA’s NRTL program recognizes private sector organizations as meeting the qualifications specified in the regulations. IECEx Certification Bodies include UL (Underwriters Laboratories), FM Approvals, and ITS (Intertek). Such identification allows an NRTL to determine that specific equipment meets consensus-based standards of safety to provide the assurance, required by OSHA, that these products are safe for use in the U.S. workplace.

During the October 2010 meeting between Dr. Michaels and NEMA, NEMA argued that an update to OSHA’s March 1995 interpretation, Nationally Recognized Testing Laboratories; Clarification of the Types of Programs and Procedures, is needed to allow NRTLs to accept product evaluations from the IECEx Scheme for national certification for “zone” applications.

OTPCA is slowly beginning to move forward with an update to its 1995 interpretation, which was already out of date when it was published. The update was expected in November 2010 and has now been pushed to the fall of 2011.

It is likely OSHA will acknowledge the IECEx Scheme, similar to what it has done with the IECEE CB (Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components) Scheme.

OTPCA is considering either modifying Program 9 of the NRTL program to include the IECEx Scheme or creating a separate program, with a preference being for the latter.

Regarding the U.S. national standards for hazardous equipment based on IEC standards, OSHA will likely recognize both UL and ISA (International Society of Automation), the only two accredited American National Standards developers in the hazardous locations arena.

This would be a change from previous positions when OSHA stated that it would review the U.S. consensus standards to determine equivalence between existing U.S. standards for division application and that of the IECEx, which is the IEC 60079 series of standards based on the zone classification scheme.

The extent to which OSHA will recognize manufacturer testing laboratories remains a question. It also still needs to be determined if OSHA would audit the laboratories.

Joel Solis, NEMA Conformity Assessment Manager and USNC/IECEx Secretary | joel_solis@nema.org

Members of the USNC/IECEx visited ATEC Training and Certification Services during the January meeting.
› 2011 CANENA Annual Meeting to Focus on Future

Register now to attend the 2011 CANENA (Council for Harmonization of Electrotechnical Standards of the Nations of the Americas) annual meeting, Focusing on the Future, March 2–3, in historic San Antonio, Texas.

Founded in 1992, CANENA’s goal is to foster the harmonization of electrotechnical product standards, conformity assessment test requirements, and electrical codes among all democracies of the Western Hemisphere.

After a very successful 2010 conference in San José, Costa Rica, this year’s annual meeting will return to its traditional format, starting with the Members Forum on Wednesday, March 2, followed by the Council plenary session and business meeting on Thursday, March 3, 2011.

Special program features have been added to help make this year’s meeting especially valuable to you and your business. You won’t want to miss this opportunity to help regroup and refocus CANENA as we look forward to unprecedented opportunities for broader cooperation in electrotechnical standardization.

Be sure to invite other members of your organization to join us. They will find out, first-hand, why CANENA and standardization plays an important role in market development, and they will get information on issues of strategic importance, from renowned experts, that they can’t get anywhere else.

Preliminary programs along with hotel reservation and meeting registration materials are available online at www.CANENA.org.

Register now. We look forward to seeing you in San Antonio. ●

Joel Solis, CANENA Secretary General | joel_solis@nema.org

› IECEX Certificate of Personnel Competencies Scheme Affects Well Operations

A disparity regarding certification of personnel competencies (CoPCs) has been identified between national programs in the United Kingdom and Norway (both considered to be world class) and the IEC System for Certification to Standards Relating to Equipment for use in Explosive Atmospheres (IECEX) CoPC.

As a result of the sinking of the Deepwater Horizon in the Gulf of Mexico following the April 2010 explosion, there are now additional regulatory requirements regarding drilling in the outer continental shelf. They specifically state that each drill operator must “[e]nsure that all personnel involved in well operations are properly trained and capable of performing their tasks under both normal drilling and emergency well control operations.”

The CoPC focus, however, is only on competency. Lacking is any assessment of the credentials of those providing explosive (Ex) training. This includes assurance that the trainers knows what they are doing and that the training program is adequate, up-to-date, and covers the necessary materials.

CompEx, which is used by the oil industry in the North Sea, has undergone major changes since 2007 because of changes to the IEC hazardous location standards, specifically the IEC 60079 series of standards. It is believed that having both—certification of personnel competencies and an assessment of training centers/program—could be used by oil service providers to satisfy national regulatory requirements.

The USNC/IECEX will be developing a proposal for a new service—or at least a standard that clarifies what training should occur, in line with the IECEX standards and the CoPC scheme. This new service would be called: “ExTrng” or “ExTrL.” It would provide training guidelines to an Ex Certification Body (ExCB) when it is assessing an individual for a CoPC.

In order to get an IECEX training accreditation, the training center should have to demonstrate that it is capable of teaching up-to-date IECEX standards in the module arrangement that the CoPC scheme calls for.

Part of the problem, though, is the competency assessment which the ExCB must do to issue a CoPC. Ex training centers do both the training and a competency assessment via lab work. ISO 17024 doesn’t allow this, which puts training centers at a disadvantage and creates problems for both the ExCB and the candidate. ●

Joel Solis, CANENA Secretary General | joel_solis@nema.org
Economic Spotlight

› Improving Economic Fundamentals Increase Prospects for Sustained Manufacturing Sector Recovery

Though it has slowed from the rapid pace set in the immediate aftermath of the recession, manufacturing production has continued to post healthy increases.

Indeed, output advanced at a four percent annualized rate in the second half of 2010. Preliminary data, including positive signals from a number of forward-looking indicators, suggests a similar pace of growth is attainable in the first quarter of 2011—and beyond—as the broader economy increasingly gains its footing.

Among the reasons for optimism:
• New orders for core durable goods averaged double-digit percentage gains in the second half of 2010.
• The bellwether Institute for Supply Management (ISM) index of manufacturing activity climbed to its highest level since 2004 in January.
• The new orders component of the ISM index climbed to its highest level since 2004, while the new exports orders component reached its highest mark since the late 1980s.

Tim Gill, Director of Economics | tim_gill@nema.org

› Available from NEMA/BIS—The Electroindustry Economic Outlook

Based on popular demand for up-to-date data and forward-looking analysis of the electroindustry and the economic fundamentals that drive it, NEMA/BIS offers a subscription-based, regularly updated compendium of the information that industry professionals and executives most often request. The Electroindustry Economic Outlook is the preferred source for timely, comprehensive coverage of the economic trends and events shaping the U.S. electroindustry.

• Extensive Coverage
• Frequently Updated
• Affordably Priced

To find out how NEMA/BIS’s Electroindustry Economic Outlook can help your business, contact Tim Gill at 703-841-3298, or tim_gill@nema.org.
NEMA Executives’ Assessment of Business Conditions Improved in February

The Electroindustry Business Confidence Index (EBCI) for current North American conditions, which is derived from a survey of senior industry executives, climbed to 69.6 in February, up 6 points from January’s reading of 63.6.

The index has topped 60 points in each of the last four months, indicating a sustained improvement in the economic environment facing a broad cross section of electrical equipment manufacturers. A reading above 50 indicates more panelists reported better conditions compared to the previous month than reported worse conditions.

A plurality of panelists—48 percent—reported improved conditions in February, up from January’s figure of 36 percent. Only 9 percent reported deteriorating conditions, the same proportion as in the previous month. The balance of panelists reported conditions were unchanged.

The survey’s measure of the intensity of change in current North American conditions also shows the electroindustry business environment on a steady climb of late. It rose to +0.6 in February from +0.5 in January, and from +0.4, and +0.3 in December and November, respectively. Panelists are asked to report intensity of change on a scale ranging from −5 (deteriorated significantly) through 0 (unchanged) to +5 (improved significantly).

Though the EBCI for future North American conditions slipped modestly in February from the previous month’s near seven year high, it remained at an elevated level by historical standards at 84.8. A majority of survey panelists (70 percent) expect to see conditions improve during the next six months, while none of the 23 respondents anticipate deterioration.

Tim Gill, Director of Economics | tim_gill@nema.org

**SURVEY RESULTS:**

<table>
<thead>
<tr>
<th>Region</th>
<th>Current Conditions (Compared to Previous Month)</th>
<th>Conditions Six Months from Now (Compared to Current Conditions)</th>
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Number of Respondents =23

Values reflect the percentage of respondents expecting “Better” conditions, plus one-half of the percentage of respondents expecting “Unchanged” conditions.

A score of 50 or higher suggests conditions appropriate to expansion of the electroindustry sector.
Economic Spotlight

Why spec LEDs with 40 – 50,000 hour life if your LED driver doesn’t make it past 5K?

Built on a tradition of high quality, high efficiency power products, Phihong’s high quality LED drivers support multiple strings with independent current control, a wide range of applications (3-200W) and feature dimming, IP67 rating for outdoor environments and UL and FCC certification.

Phihong ships millions of OEM products every month with millions of hours DMTBF. Make sure your next LED product design keeps operating. Phihong LED drivers won’t leave you standing in the dark.

For complete technical information visit www.phihong.com/LED or call 1.888.PHIHONG (744.4664)

Think Phihong energy efficient LED drivers

Shouldn’t your LED driver last as long as your LEDs?

Why spec LEDs with 40 – 50,000 hour life if your LED driver doesn’t make it past 5K?

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