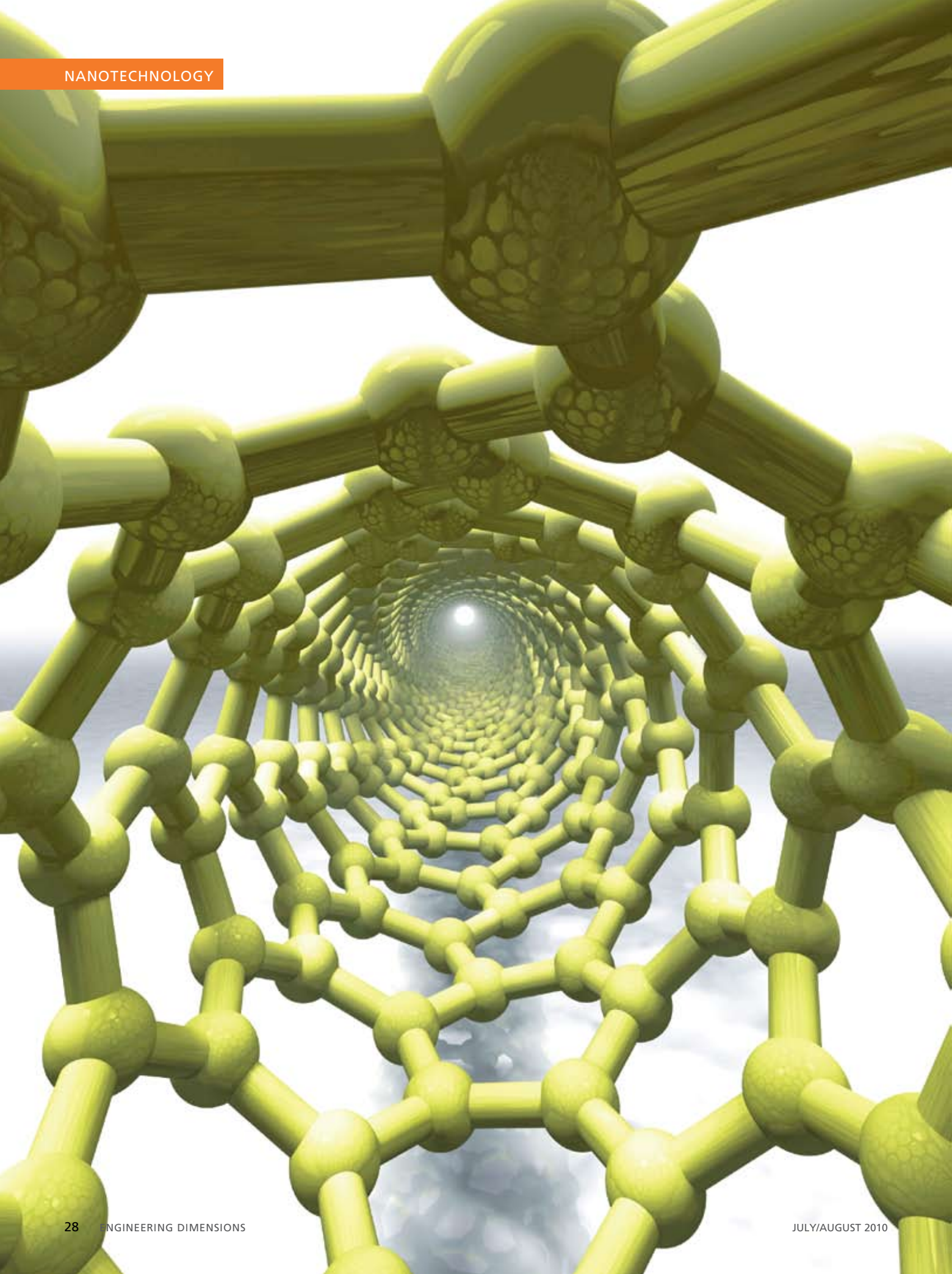


PEO TAKES LEADING *POSITION on* REGULATION *of* NANOTECHNOLOGY

PEO council's recent declaration of nanotechnology as a distinct discipline of professional engineering is the first wave in a commitment to put in place an effective regulatory framework for a technology that is exciting but still poorly understood.

By Michael Mastromatteo

As the buzz surrounding nanotechnology becomes louder, and more and more nanotechnology-based consumer items hit store shelves, engineering organizations are coming to grips with the regulatory aspects of this revolutionary way of manipulating matter at the atomic or molecular level.

Of course, there is excitement around the creation of new materials that on the nano scale exhibit different properties than on the macro scale. After all, this technology promises materials 100 times stronger than steel at a fraction of the weight, pollution-free manufacturing, a transformation of health care, and more efficient renewable energy.

However, there is concern about how this technology might best be regulated in the interests of occupational and public safety. This is not to suggest that nanotechnology poses clearly defined risks, but rather that the impact of certain nano-materials, and new techniques for handling them, has yet to be determined.

Acting on the recommendation of PEO's Emerging Disciplines Task Force (EDTF) in April, PEO council approved recognizing nanotechnology (and molecular engineering) as a new discipline within the wider engineering profession. In its phase one report, the EDTF said the novelty of nanotechnology "results in great potential for adverse health effects to the public and the environment that were not foreseen."

The task force was motivated to make that statement in part by studies that have suggested carbon nano-tubes can be as harmful as asbestos, and the 2009 report of serious respiratory illnesses and two deaths of female workers in China following exposure to nano-particles in a spray paint over several months.

However, in their pursuit of the public interest, engineers must be careful not to overstate the risks of nanotechnology, which could result in a stifling of innumerable economic, health and environmental benefits.

In some ways, the debate about nanotechnology echoes similar concerns about genetically modified organisms (GMO) voiced in the 1990s. The public and consumer groups were uncomfortable with gene-altering technology and called for increased regulation to ensure the safety of genetically modified products. The issue was further complicated by a lack of national and international agreements about GMOs, allowing governments to move ahead under what some believed to be poorly developed, or non-existent, rules.

Regulators, professional associations and governments are loath to see the same situation repeated with nanotechnology and have initiated discussion of harmonizing approaches to identify risk and, among other initiatives, provide product labeling and consumer education.

Professional engineers have an important role to play in establishing a nanotechnology regulatory framework. Part of that role involves ensuring that would-be nanotechnology practitioners are fully prepared with the knowledge to perform the work they're about to take on.

In addition to proclaiming nanotechnology an emerging discipline, PEO council directed PEO's Academic Requirements Committee (ARC) to develop new academic requirements or "board sheets" to set out the essential body of knowledge to identify the field as a distinct area of study and specialization for engineering practitioners.

Council also instructed PEO's CEO/registrar to develop a public awareness campaign affirming that PEO is taking responsibility for regulating this new area of practice.

REGULATORY GAPS

Five years ago, when *Engineering Dimensions* first reported on the emergence of nanotechnology, questions arose as to the regulatory and professional practice implications of this exciting new technology. At the time, policy-makers appeared to be taking their lead from the Canadian Council of Professional Engineers (now Engineers Canada), which, in a 2004 study, called for possible recognition of nanotechnology as a distinct field within the engineering profession.

So it's not surprising that PEO has now deemed nanotechnology a fully emerged discipline worthy of its own academic and practice standards.

"The EDTF Task Force recommends that nanotechnology/molecular engineering does fall under the *Professional Engineers Act* and regulations and should be regulated as other engineering disciplines," the EDTF report says.

PEO's task force has recommended that nanotechnology, as an emerged field within professional engineering, be broken down into four subdisciplines: nano-engineering materials, nano-electronics, nano-instruments and nano-biological systems.

The task force also described nanotechnology as a "horizontal technology" that impacts many fields of practice. By regulating in this new area, nanotechnology would be fully delineated as a restricted form of engineering practice.

PEO appears to be in the lead among Canadian engineering regulators. A random survey of PEO's counterparts in British Columbia, Alberta, Saskatchewan and Nova Scotia reveals that none has nanotechnology on its regulatory agenda, and all await PEO's moves on the issue.

"In Canada, no other provincial or territorial engineering association/ordre regulates the design of nanotechnology or molecular engineering as a unique engineering discipline," the task force report says. "While PEO has legal jurisdiction only with respect to the design of nano-engineered products and their processes in Ontario, PEO's designation of nanotechnology and molecular engineering as a unique engineering discipline could serve as a model of regulation for other engineering associations across the country and perhaps internationally."

It's hoped that PEO's efforts to recognize nanotechnology as belonging to the realm of engineering will kick-start progress towards a regulatory framework involving all relevant stakeholders. It's an issue gaining prominence in professional associations in Canada and internationally.

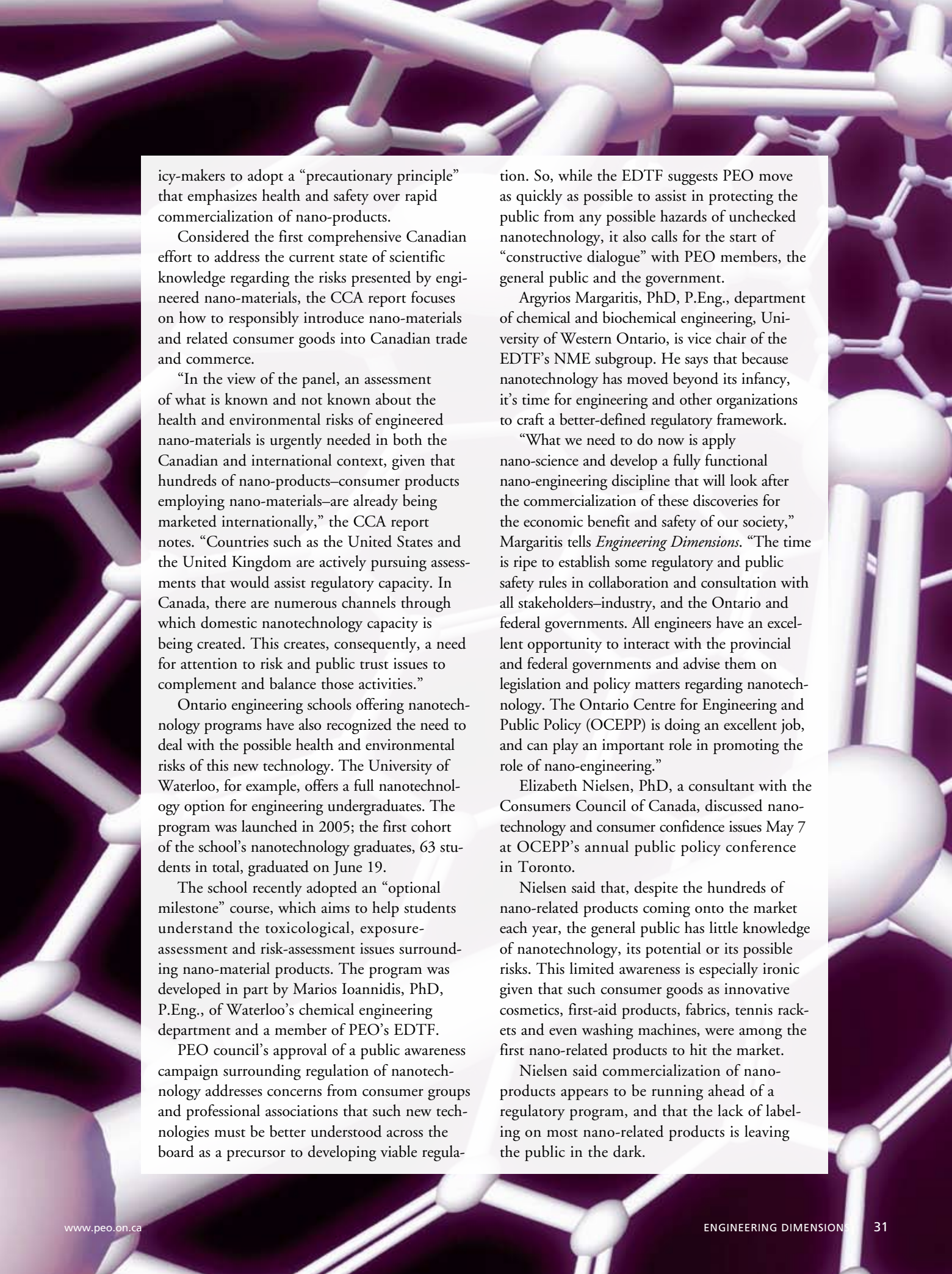
UNIQUE STRUCTURES

Canada's *Environmental Protection Act* (1999) is one of the only pieces of legislation with even a passing reference to nano-materials. The act governs "new" material and its regulation in Canada. In 2007, Environment Canada issued an advisory stating that it considered a material "new" if it possesses "unique structures or molecular arrangements." It's possible that PEO's efforts to bring nanotechnology and molecular engineering under its domain could bring some clarity in this area.

And there is no doubt that regulatory gaps exist. In April 2009, Carleton University's School of Public Policy and Administration released its *International Approaches to the Regulatory Governance of Nanotechnology*. The study addresses the response of Canada and international jurisdictions to the emergence of nano-materials in the marketplace, and noted a clear need for greater coordination at all levels in the regulatory governance of this new technology.

"The many potential applications of nanotechnology are extremely varied," the study reads, "encompassing food, chemical, and electronics products, medicines and medical devices, environmental technologies, and multiple other applications. This poses a unique regulatory governance challenge on a scale never before witnessed in the regulation of emerging technologies. At present, no single regulatory structure spanning such a wide range of consumer products exists in any jurisdiction in the world. Coordinating the regulation of nanotechnology between departments and agencies at the jurisdictional level, not to mention between regulatory streams within individual departments, will be key to ensuring that we identify and fill any potential regulatory gaps which might exist. This coordination will also be essential to create a consistent and common language among regulators from different industrial sectors. Finally, the coordination will improve the consistency of decision making and be less confusing to the regulated, who may have to deal with multiple regulatory agencies."

The second research study, *Nanotechnology: Is it Safe?* (February 2010), conducted by the Council of Canadian Academies (CCA), suggested that more research is needed to determine the long-term impact of nano-materials, especially those now in the market. This study, conducted in conjunction with the Canadian Institute for Advanced Research, called for pol-



icy-makers to adopt a "precautionary principle" that emphasizes health and safety over rapid commercialization of nano-products.

Considered the first comprehensive Canadian effort to address the current state of scientific knowledge regarding the risks presented by engineered nano-materials, the CCA report focuses on how to responsibly introduce nano-materials and related consumer goods into Canadian trade and commerce.

"In the view of the panel, an assessment of what is known and not known about the health and environmental risks of engineered nano-materials is urgently needed in both the Canadian and international context, given that hundreds of nano-products–consumer products employing nano-materials–are already being marketed internationally," the CCA report notes. "Countries such as the United States and the United Kingdom are actively pursuing assessments that would assist regulatory capacity. In Canada, there are numerous channels through which domestic nanotechnology capacity is being created. This creates, consequently, a need for attention to risk and public trust issues to complement and balance those activities."

Ontario engineering schools offering nanotechnology programs have also recognized the need to deal with the possible health and environmental risks of this new technology. The University of Waterloo, for example, offers a full nanotechnology option for engineering undergraduates. The program was launched in 2005; the first cohort of the school's nanotechnology graduates, 63 students in total, graduated on June 19.

The school recently adopted an "optional milestone" course, which aims to help students understand the toxicological, exposure-assessment and risk-assessment issues surrounding nano-material products. The program was developed in part by Marios Ioannidis, PhD, P.Eng., of Waterloo's chemical engineering department and a member of PEO's EDTF.

PEO council's approval of a public awareness campaign surrounding regulation of nanotechnology addresses concerns from consumer groups and professional associations that such new technologies must be better understood across the board as a precursor to developing viable regulation. So, while the EDTF suggests PEO move as quickly as possible to assist in protecting the public from any possible hazards of unchecked nanotechnology, it also calls for the start of "constructive dialogue" with PEO members, the general public and the government.

Argyrios Margaritis, PhD, P.Eng., department of chemical and biochemical engineering, University of Western Ontario, is vice chair of the EDTF's NME subgroup. He says that because nanotechnology has moved beyond its infancy, it's time for engineering and other organizations to craft a better-defined regulatory framework.

"What we need to do now is apply nano-science and develop a fully functional nano-engineering discipline that will look after the commercialization of these discoveries for the economic benefit and safety of our society," Margaritis tells *Engineering Dimensions*. "The time is ripe to establish some regulatory and public safety rules in collaboration and consultation with all stakeholders–industry, and the Ontario and federal governments. All engineers have an excellent opportunity to interact with the provincial and federal governments and advise them on legislation and policy matters regarding nanotechnology. The Ontario Centre for Engineering and Public Policy (OCEPP) is doing an excellent job, and can play an important role in promoting the role of nano-engineering."

Elizabeth Nielsen, PhD, a consultant with the Consumers Council of Canada, discussed nanotechnology and consumer confidence issues May 7 at OCEPP's annual public policy conference in Toronto.

Nielsen said that, despite the hundreds of nano-related products coming onto the market each year, the general public has little knowledge of nanotechnology, its potential or its possible risks. This limited awareness is especially ironic given that such consumer goods as innovative cosmetics, first-aid products, fabrics, tennis rackets and even washing machines, were among the first nano-related products to hit the market.

Nielsen said commercialization of nano-products appears to be running ahead of a regulatory program, and that the lack of labeling on most nano-related products is leaving the public in the dark.

LACK OF RESEARCH

"It is mainly the lack of research into the health and safety impact of the technology and the lack of test procedures to identify and characterize the materials that prevents governments from regulating," Nielsen tells *Engineering Dimensions*. "They are not able to enforce regulations for materials that they cannot identify or measure. The commercialization has far outpaced the research into these areas, leaving a vacuum."

Nielsen suggests the lack of labeling on most nano-related consumer goods may be related to the past GMO controversy. Owing to a lack of awareness about the full impact of new products and new technologies, the public quickly backed away from anything bearing a label announcing it had been genetically modified.

She believes, however, PEO's effort to identify nanotechnology as an engineering discipline is a step in the right direction as far as public acceptance of the technology is concerned.

"I was quite pleased to see PEO becoming involved in this area and having it recognized as a separate discipline," she says. "Nanotechnology will affect just about all products and materials used in all aspects of our lives–energy, construction, transportation, products in the workplace and in the home, and in other areas. Engineers will be faced with understanding the effect of nano-materials on the products and materials they use and for ensuring that the engineering work they carry out using these products and materials is as safe as possible, and does not pose a risk to the public."

In addition to the Canadian consumer group, other government agencies and professional organizations outside Canada are studying what to do about nanotechnology.

The Canadian Standards Association (CSA) is working with international standards-setting bodies to consider bringing some uniformity to nanotechnology regulation.

Brian Haydon, P.Eng., CSA's project manager, nanotechnologies, told *Engineering Dimensions* June 14 that standards development, including the work done by regulators, should help integrate nanotechnology safely in society, without stifling its commercial potential.

Haydon says the CSA has been working with its volunteer committees since 2005 to input and review globally based solutions in International Standards Organisation (ISO) and International Electrotechnical Commission (IEC) standards for nanotechnology. The first round of this international work was completed in 2008, with about 40 additional standards projects still underway.

"It's CSA's understanding that the federal government is involved in local and international initiatives in the field of nanotechnologies," Haydon says. "An international example is its participation in the OECD [Organisation for Economic Co-operation and Development] Working Party on Manufactured Nanomaterials [WPMN]. Collaboration among WPMN members can assist towards common regulation among countries."

Haydon says it's important for PEO to develop its own regulations about nanotechnology as a guide to engineering practitioners, which could, in turn, lend support to an evolving regulatory framework.

"If a role for PEO in helping establish a regulatory framework can gain support in other provincial jurisdictions towards national acceptance, this opportunity could be explored," he adds. "The important role that consensus-based standards can play for reference in regulations should also be explored."

In any case, it appears other bodies are also looking to international co-operation for the sake of nanotechnology.

In its 2004 report *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, for example, Britain's Royal Society found some good things to say about an emerging regulatory regime for nanotechnology.

"The evidence suggests that at present regulatory frameworks in the European Union and United Kingdom are sufficiently broad and flex-

ible to handle nanotechnologies at their current stage of development," the UK report says. "However it is important that regulatory bodies include future applications of nanotechnologies in their horizon scanning programs to ensure that any regulatory gaps are identified at an appropriate stage."

Peter DeVita, P.Eng., chair of the EDTF, outlined some priority areas for coming to terms with nanotechnology and its regulatory framework at the May 7 Engineering and Public Policy Conference. DeVita said regulators must recognize that nanotechnology spreads across a number of disciplines and areas of professional competence. He said that while many engineers will likely be using nanotechnology and molecular-engineered products, there is a strong possibility there will also be an increase in the number of non-engineers performing nanotechnology-related work.

In fact, as was noted in the EDTF report, many engineers might be using nanotechnology-enhanced materials and products and not even be aware of it. Furthermore, the rapid growth of research and development in this area means many people might be practising nanotechnology and molecular engineering without being engineers. The task force authors suggest that establishing nanotechnology as a new discipline–and licensing its practitioners–could be the best way to control this "grey area" and protect public safety.

Although PEO's efforts to declare nanotechnology as a branch of professional engineering is at the early stages, the regulator is clearly being driven by the long-standing imperative that members of the profession should be stewards of new, evolving technologies. As is stated in the emerging disciplines' far-sighted report: "PEO has a mandate to protect the public safety and the complexity of nanomaterials' potential ecotoxicity, the difficulty in detecting them and the almost certainty that they will enter the environment. [That] means that the best chance to avoid problems is by putting the burden of safety and hazard avoidance on those who are developing the technology. With the rapid growth rate of products that contain nanomaterials entering the market, prudence would imply action from PEO with regards to implementing regulation on the practice of nanotechnology and molecular engineering."

However, DeVita is also quick to point out nanotechnology is not something to be feared despite the current lack of a clear regulatory regime.

"We want nanotechnology and molecular engineering because they will do very many good things for humanity" he says. "But there are risks associated with those good things if not handled properly." He says that like the discovery of fire, the benefits and risks must be fully appreciated. "It is a matter of skill by the practitioner. We can have the good things and avoid the bad ones with nanotechnology as well, as long as we know what we are doing and do not 'burn the house down.' This is what the licensing of nanotechnology engineers is about." Σ

WHERE *to* READ *the* REPORT

PEO has devoted considerable resources to its review of nanotechnology and molecular engineering, with a view to possible regulatory considerations. The Emerging Disciplines Task Force phase one report, which was submitted to PEO council in April, is the work of: Yuri Kuzyk, PhD, P.Eng., Sentinelle Medical Inc.; Peter DeVita, P.Eng., DeVita Associates (EDTF chair); Marios Ioannidis, PhD, P.Eng., department of chemical engineering, University of Waterloo; Argyrios Margaritis, PhD, P.Eng., department of chemical and biochemical engineering, University of Western Ontario (vice chair, EDTF NME subgroup); Harry Ruda, PhD, P.Eng., department of materials science (and electrical and computer engineering), University of Toronto; and John Yeow, PhD, P.Eng., department of system design engineering, University of Waterloo. The report is available at www.peo.on.ca/publications/Reports/NME_Phase_I_Report_Mar24_2010.pdf.

The University of Waterloo graduated its first cohort of undergraduate nanotechnology students in June 2010. Fred McCourt, PhD, acting director of the nanotechnology program (far left) and Marios Ioannidis, PhD, P.Eng., director of the program (on sabbatical) pose with some of the program's first graduates (left to right), Thomas Lever, Teddy Mamo, Mike Murkovic and Anne Gaspar.