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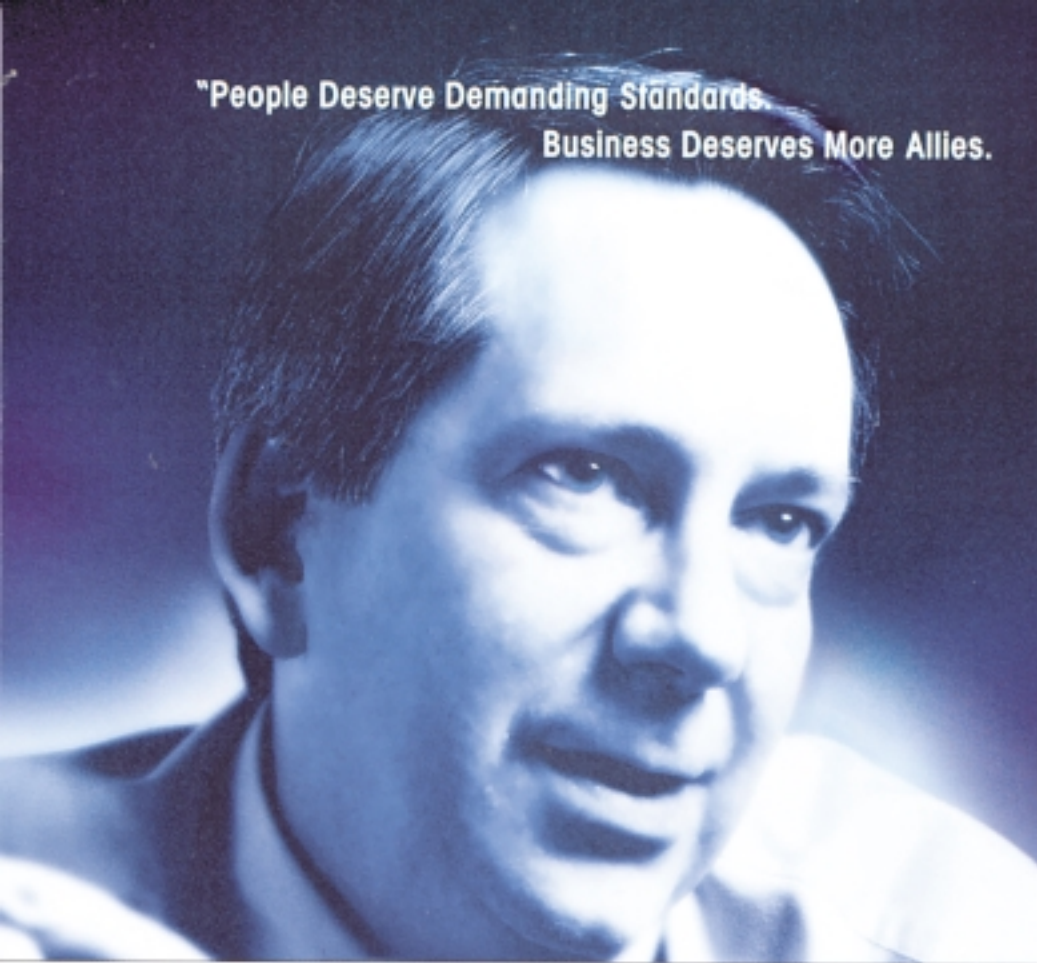
# CONSENSUS

*Canada's Newsmagazine of Standardization*

**World Standards Day**  
*Building on standards*

"People Deserve Demanding Standards.  
Business Deserves More Allies."

"We Answer With Solutions."



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President & CEO - CSA International

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**CONSENSUS**

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**Search back issues of *CONSENSUS* on the Web!**  
Go to <http://www.scc.ca> and click on "search centre".



## First two facilities receive GLP recognition

The Standards Council of Canada and Health Canada's Pest Management Regulatory Agency (PMRA) recently announced the first two facilities confirmed to be operating in compliance with the requirements of the Good Laboratory Practices (GLP) initiative for pesticides – an initiative that increases global harmonization of standards and facilitates international cooperation in regulating pesticides.

Vaughn Agricultural Research Services Ltd., of Branchton, Ontario, and Uniroyal Chemical Co. Research Laboratories, of Guelph, Ontario, are now recognized under the GLP initiative for conducting non-clinical studies of the effects of pest control products on human health and the environment. Vaughn Agricultural Research Services is now a recognized field site, while Uniroyal Chemical Co. Research Laboratories is a recognized test facility.

Before a pesticide is considered for registration in Canada, it must undergo extensive testing to determine potential risks to human health and the environment as well as the pesticide's effectiveness. The manufacturer conducts these detailed scientific tests and studies and submits the data and results to the PMRA, the government agency that determines whether the

product is acceptable for use in Canada.

Compliance with GLP principles helps ensure that studies of pesticides are carried out to the highest quality standards. The Standards Council's Program for the Accreditation of Laboratories – Canada (PALCAN) administers the Canadian GLP compliance-monitoring program for pesticides.

The Organisation for Economic Co-operation and Development (OECD) developed the GLP guidelines used in this initiative to ensure that evaluations of chemicals – in this case pest control products – are based on data that are of high quality, rigour and reproducibility. The GLP principles address all aspects of conducting studies, from the planning stage to data archiving. They ensure that appropriate staff, facilities and

equipment are in place and that documented standard procedures are followed through the studies. Recognition under the initiative also facilitates acceptance of studies in other OECD member countries. ■

## From guide to standard

ISO members are deciding this fall whether a new standard should take the place of ISO/IEC Guide 25, the basic requirements document for laboratory accreditation.

Guide 25 lays out the basic requirements for laboratory accreditation in generic terms, and is used by testing and calibration laboratory accreditation bodies around the world. It includes both quality systems and technical competence. The new standard, ISO 17025, includes

more of the ISO 9002 quality systems requirements than Guide 25 did, and also includes changes to technical requirements.

If the new standard is approved, it is expected that accreditation bodies will produce their own documents explaining to assessors how to apply the new standard in specific situations, much as they did with Guide 25.

Guide 25 is available on the Standards Council's Web site at [www.scc.ca](http://www.scc.ca).

More information on possible changes to laboratory accreditation requirements will follow in a future issue of *CONSENSUS*. ■

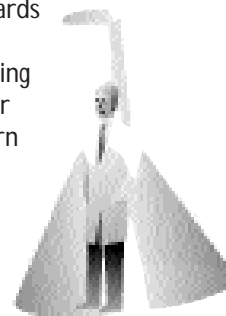
## Calling all lab assessors! Want to become a qualified lead assessor?

You've got the skills and the technical expertise, and now the Standards Council of Canada is providing the training.

This winter our PALCAN program is providing a free, five-day training course that will give you new skills and be your key to an even bigger opportunity – the ability to become a certified lead assessor. In return we'll ask you to participate in technical assessments, giving you the opportunity to use your skills and maintain your expertise.

It's all part of PALCAN's drive to increase our international recognition and expand markets for our accredited labs.

For more information, call the Standards Council at (613) 238-3222.





# *Pacific Rim Accreditation Bodies* MEET IN VANCOUVER

**A**nother member body has signed the multilateral agreement (MLA) of the Pacific Accreditation Cooperation (PAC). The Korean Accreditation Board (KAB) signed the agreement during PAC's plenary meeting, which took place in Vancouver, July 24 – 31.

PAC is an association of accreditation bodies from the Asia-Pacific region, including the Standards Council of Canada. Its MLA calls on participants to recognize one another's ISO 9000 registrar accreditations as equivalent to their own. That's intended to promote the international acceptance of registrations, making it easier for registered companies to do business internationally.

KAB, representing South Korea, is the eighth member body to sign the MLA, which has also been signed by accreditation bodies from Australia and New Zealand, Canada, China, Japan, Malaysia and Singapore.

Here are some other highlights from the meeting:

- PAC will be invited to **sign the MLA of the International Accreditation Forum (IAF)**, following a successful peer evaluation earlier this year. Like PAC, the IAF promotes the international acceptance of ISO 9000 registrations. So far, accreditation bodies from 18 countries have signed the IAF MLA.
- **Canada is playing a leadership role** in PAC with the election of Elva Nilsen, the Standards Council's

manager of conformity assessment, as the organization's vice-chair. Ms. Nilsen replaces Takashi Ohtsubo of Japan. Xiao Jianhua of China was elected chair.

- PAC is **helping its member bodies to develop accreditation programs**. The organization has received funding from the Asia-Pacific Economic Cooperation (APEC) for two seminars. The first, a two-day seminar on the accreditation of product certification bodies, will take place later this year. A four-day seminar on quality management systems registration bodies will take place early next year.
- Accreditation bodies from **Indonesia and Singapore** have applied to join the PAC MLA.
- PAC has set up two new working groups to discuss how to extend its MLA to cover **product certification organizations and environmental management systems registrars**. Factors to be considered by these working groups include the nature of possible extensions to the agreement, differences in scoping practices of members' accreditation programs, and changes to peer evaluation procedures. The working groups will make their recommendations to PAC's technical committee next March. Alan Downe, executive director of the regulatory reform secretariat of the government of the Northwest Territories, will chair the working group on product certification organizations on behalf of the Standards Council.

The next PAC plenary will take place in Indonesia in July 2000. For more information on PAC, please visit its Web site at <http://www.apec-pac.org>. ■

# The CE Mark - a passport for your products



The mark is everywhere – a rounded, stylized “CE” affixed inconspicuously to products like lamps, computers and children’s toys. Chances are, unless you export to the European Union, you have no idea what this “CE mark” means. And if you’ve just started thinking about exporting to the European Union, you may wish you’d never heard of it. Qualifying for the mark is a complicated process, but a little knowledge and a little help can make it a lot easier.

## What is the CE Mark?

“CE” stands for *Conformité Européenne*. Unlike the product certification marks Canadians are most familiar with, the CE mark doesn’t belong to a particular product certification organization – it’s a logo that shows that products have met the requirements of the European Union (EU). It’s part of the EU’s drive to create a single market, allowing companies to access all 15 countries in the European economic area without having to meet separate safety, inspection or customs requirements for each.

To work toward this single market, the EU created a set of directives outlining common European requirements. The directives are based on safety objectives known as the *Essential Health and Safety Requirements* and cover such areas as the safety of children’s toys, machinery, personal protective equipment and medical devices. They also cover customs and excise related matters and transportation of goods between European countries.

European Norm (EN) standards have been developed to support each directive.

It’s important to note that while the goal may be to have a single set of requirements for all EU nations, that hasn’t yet been achieved. Although it is essential to have the CE Mark to access any European market, there may still be other requirements for individual nations. What those requirements are will depend on the product and where it is being sent.

## How do I get a CE Mark?

There are three major steps in acquiring a CE mark. To begin with, you need to find out what requirements you need to meet. That means determining which CE directive applies to your product – for example, there are directives for low voltage products, machinery or personal protective equipment – and then acquiring the appropriate directive and the standards you need to meet it (see box “SourCEs of help” for information on how to do all this).

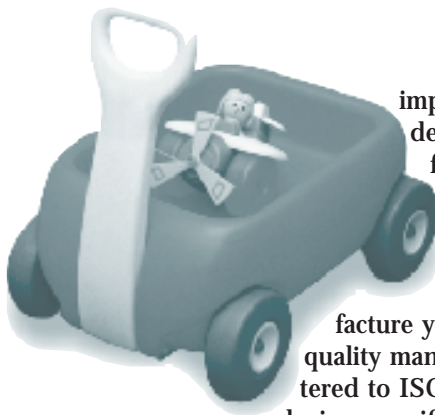
Second, you have to make sure your products are manufactured in accordance with the specified European standard. It is possible to use other standards so long as they meet the safety requirements of the directive. The Standards Council of Canada can help you identify comparable standards.

Third, you need to show that you have met the standard, in a process called attestation. The way that this is done is outlined in the directive, and depends on the type of product being certified and the standards being met. It can be a fairly simple process – many products exported to Europe can be tested in-house to see if they meet the standards in the directive. If they do, you can then simply declare that your product complies. Just remember, you must keep records of technical documents relating to compliance even if you declare conformity yourself.

On the other hand, attestation can be more involved if there is potential risk to health and safety. For instance, companies that manufacture







implantable medical devices like pacemakers face the most stringent requirements. If your company manufactures such devices, you will be required to manufacture your products using a quality management system registered to ISO 13485, the medical devices specific version of ISO 9000.

And you'll have to have test results from a "notified body," an independent testing and certification body recognized by the EU. The reason is simple: the more potential risk to health and safety, the more important it is to have independent confirmation that a product meets the requirements. The delegation of the EU in Canada can provide lists of European notified bodies if they are required, and can also provide names of Canadian certification bodies that can perform tests on behalf of the notified bodies.

Once you have demonstrated conformity to the

## SourCEs of help

- To determine the appropriate directive for you and the appropriate standards to meet the directive, call the Standards Council of Canada at (613) 238-3222, fax (613) 995-4564 or e-mail [info@scc.ca](mailto:info@scc.ca). There may be a fee for this service, but we will notify you beforehand if there is.
- To determine the appropriate directive and obtain it, call the delegation of the European Commission in Canada at (613) 238-6464 or fax (613) 238-1649.
- To purchase the appropriate standards, contact Global Info Centre Canada at 1-888-782-6327 or (613) 237-4250, fax (613) 237-4251 or e-mail [gic@micromedia.on.ca](mailto:gic@micromedia.on.ca).



## Notice of public review

Canadian OSI Registration Authority (COSIRA)

In accordance with CSA International's *Canadian OSI Registration Procedures and Guidelines* (Z243.110 Series-93), the organizations below have applied for authorization to use the following Open Systems Interconnection (OSI) identifiers.

Company	Object Type	Value
Hydro Québec	Object Identifier X.500	2.16.124.10.1000 O=Hydro-Quebec
Entrust Technologies	X.500	O=Entrust O=Entrust.net
The Bank of Nova Scotia	NSAP	305
Capital Health Authority	NSAP X.500	306 O=Capital Health Authority
Institut international des télécommunications	NSAP	307
Canadian National Railway Company	Object Identifier	113555
Loto Québec	Object Identifier	2.16.124.10.1001
Ternanet Land Information Services Inc.	X.500 Object Identifier	O=Ternanet 113556

For details, to comment on this application, or to obtain more information on OSI registration in Canada, please contact the administrator, COSIRA at (819) 956-4848, fax (819) 956-3321, e-mail [cosira@pwgsc.gc.ca](mailto:cosira@pwgsc.gc.ca).

requirements, you can affix the CE logo to your products, allowing them to gain entry to the EU.

### What will the CE Mark do for me?

The most obvious benefit of the CE Mark is that it is like a passport for products, allowing them entry to the entire European market. If a product is covered by a directive, it can't be sold in the EU unless it has the mark.

Once the single market system is in place, companies will be able to take advantage of the common directives and produce only one product model for the entire EU, instead of needing different models to meet varying national requirements. And because the single market eliminates tariffs between EU nations, companies will need only one European base from which they can export to all the EU countries.

Finally, getting the mark and keeping the technical documentation that relates to compliance protects companies from fines or legal problems that may result from non-compliance, not keeping documents, or falsifying documents. ■



# *Building on standards*

*World Standards Day, October 14th, 1999*

**T**he theme of this year's World Standards Day celebration is "building on standards," a recognition of the overwhelming importance of standards in construction and the promise they hold for the future of the industry.

It's a theme Canada can endorse with pride – already, Canada has demonstrated leadership in building standards, and is maintaining its leadership role as we push on to the next millennium. The stories on these pages are a celebration and demonstration of Canada's excellence in building standards.

## Canada's building standards

Since 1941, Canada has had the *National Building Code of Canada* – a unified national model building code upon which provincial and municipal codes are based. That code replaced the multiple codes that used to exist for each province, and allowed greater trade and compatibility for the construction industry within Canada. Standards play an essential role in that code – the 300 standards referenced in the most recent edition account for over half of its technical content, and many more standards are referenced indirectly in the text. Those standards deal with diverse matters, from architectural design to ventilation, from the structure of the ceiling to the length of nails. They go a long way to ensuring the health and safety of Canadians.

The building code, which is developed by the Canadian Commission on Building and Fire Codes and published by the National Research Council, is revised approximately every five years. It is complemented by the *National Fire Code of Canada*, the *National Plumbing Code of Canada*, the *National Farm Building Code of Canada* and the *National Housing Code of Canada*. These codes are developed in a manner very similar to the development of standards – the final product is a result of balanced committees working to achieve consensus. All the codes rely heavily on standards to remain effective and up-to-date.

## Building our economy

The construction industry doesn't just build material things – it also helps build our economic well-being. According to the Canadian Construction Association, the total construction expenditure in Canada in 1998 represented about 12 per cent of Canada's total GDP – a whopping \$99 billion.

Employment in the construction industry grew in 1998, too – some 762,000 Canadians held office or field jobs in construction compared to 747,000 in 1997.

Although the industry is big, it's made up of small businesses – between 90 and 95 per cent of firms in the construction industry have fewer than 20 employees.

## Building on success

The harsh conditions some Canadian builders have to deal with have made them come up with interesting and innovative solutions to building problems. Now, Canadians are taking advantage of that innovation to export our knowledge abroad.

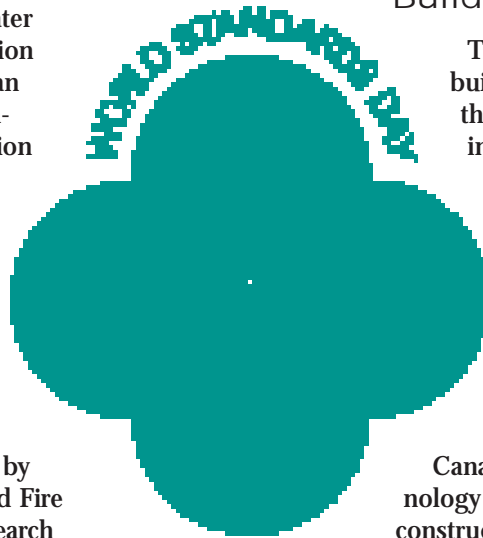
Bob Doherty is the principal of Canada North Projects, a company that promotes construction in the North and marketing of Northern construction know-how abroad. He says that Canadian cold weather construction technology – an adaptation of Southern construction standards and methods to meet the more rigorous climactic conditions of the North – is a major selling point for foreign buyers.

"All these challenges are faced in other emerging

markets like Russia and Asia," says Mr. Doherty. "Because Canada has developed such high standards in products and building systems, it has become highly desirable around the world."

Canada's standards are so highly regarded that they are being used as the basis for ongoing projects in Russia – projects that aim to harmonize codes and standards for wood frame construction, basing them on Canadian standards and thereby facilitating entry of Canadian construction products into Russia.

Canada's innovative work on wood standards has proven very interesting to the Japanese as well. When Japan decided to come up with a two-by-four building code, they didn't have to start from scratch – they



There is a Canadian content minimum, so the architects are obliged to specify Canadian products if they wish to build an “Anne” home.

## Building for the future

The Canadian construction industry is showing no signs of slowing down in its inventiveness. We're leading the way, for example, in having codes that are based on objectives rather than on prescriptive instructions. The codes would lay out what needs to be done, and construction companies would be free to find their own ways of doing it, opening the door to even more innovation. There would also be guidelines for evaluating whether a given solution meets the requirements. Final versions of the codes are expected to be published in 2003, following extensive consultation with the users of the codes and subsequent public review of draft versions (for more information, visit the Web site of the Institute for Research in Construction at [http://www.nrc.ca/irc/newsletter/v4no2/objective\\_code\\_e.html](http://www.nrc.ca/irc/newsletter/v4no2/objective_code_e.html)).

## Building Pride

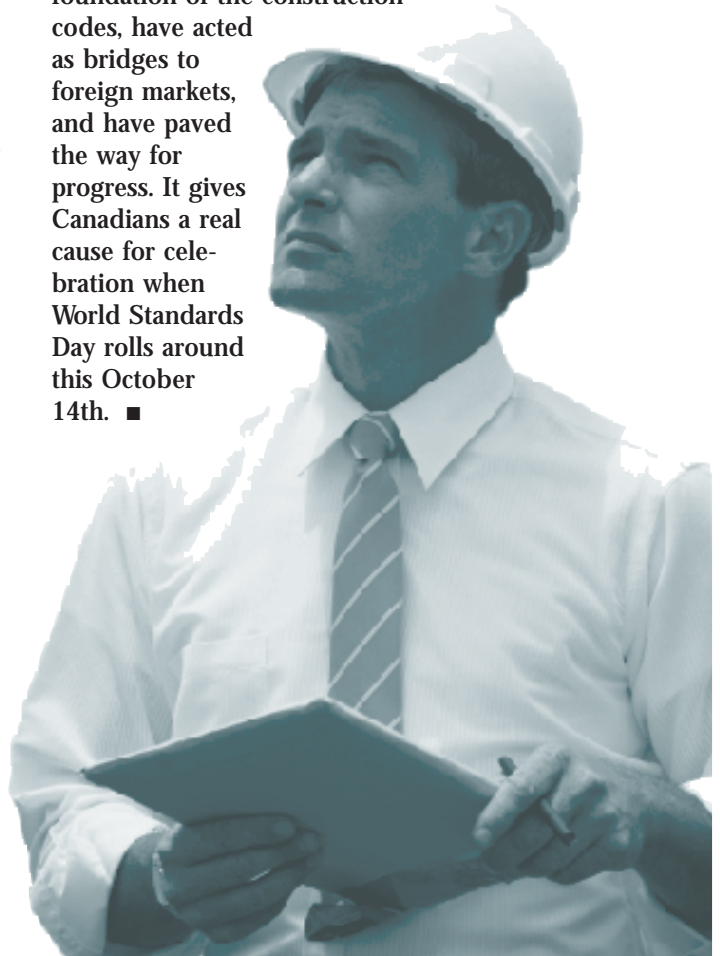
Canada's construction industry is one of the great success stories of standards – standards have formed the foundation of the construction codes, have acted as bridges to foreign markets, and have paved the way for progress. It gives Canadians a real cause for celebration when World Standards Day rolls around this October 14th. ■

used Canada's building code as a basis. They also adopted Canadian dimension lumber and softwood sheathing specifications. That's led to a healthy trade between Canada and Japan in wood products – since our standards and specifications are comparable, Canadian products can easily be sold in Japan.

It's not just a technical attraction to Canada, either. The Japanese are famous for their love of Atlantic Canada's fictional heroine, Anne of Green Gables – or *Akage No Anne* (red-haired Anne) as she is known in Japan. An East Coast construction firm took advantage of that love to start exporting houses modeled after those in the Anne books.

Rob Oakie, president of Atlantic Canada Home, says the houses have caught on. “We've sold over a dozen ‘Anne’ homes since last year in locations all over Japan from Tokyo to Takamatsu,” says Mr. Oakie.

Mr. Oakie says his company has experienced very few problems meeting Japanese building standards, in part because the houses are designed by Japanese architects and then approved by an architect from Charlottetown to make sure they meet the criteria of an “Anne” home.



# A new link in the confidence chain

## Accreditation provides more support for ISO 14000 audits and registration

Organizations that register their ISO 14000 environmental management systems (EMS) do so because of an invisible “chain of confidence” linking them to some of the most respected standards institutions, documents and management systems experts in the world.

Since we looked at the confidence chain in the March/April 1999 issue of *CONSENSUS*, a new link has been added. In July, the Standards Council of Canada accredited the Canadian Environmental Auditing Association (CEAA) as a certification organization for EMS auditors and lead auditors.

Auditors play a central role in ISO 14000 registration. They're the people who assess an organization's EMS to ensure that it conforms to the requirements of ISO 14001, both as part of the registration process and on an ongoing basis afterwards. They do that by interviewing personnel, reviewing documents and verifying the organization's compliance with its stated policies and procedures.

An EMS auditor has to be part private investigator, part legal expert, part scientist and part diplomat. Certification organizations such as CEAA ensure that would-be auditors have the necessary experience and credentials to do the job. CEAA is a non-profit association dedicated to furthering the development and professional practice of environmental auditing.


Its EMS auditor and EMS lead auditor certification programs are based on ISO 14012, an international standard that provides requirements for education, work experience and training. To earn their CEAA certificate, candidates have to demonstrate that they have taken part in the required number of audits, have completed an environmental auditing training course, and have on-the-job experience in the environmental field.

CEAA is the first EMS auditor and lead auditor certifier to be accredited by the Standards Council. Auditor certification is an important link in the confidence chain.

The Standards Council's accreditation criteria for EMS registrars require registrars' audit teams to include auditors who are certified to ISO 14012 by an accredited or recognized certification organization. That requirement helps to ensure that Canadian registrations will be recognized outside Canada.

CEAA's activities aren't limited to EMS auditor certification, however. Since 1995, the association has operated a Certified Environmental Auditor (CEA) certification program. Intended for environmental auditors working in industry, government or environmental consulting firms, the CEA program has more demanding criteria than the EMS program: CEA applicants must have more audit experience than EMS applicants, for example. A related program certifies sustainable forest management (SFM) auditors who carry out the audits required by SFM standards such as those developed by CSA International.

For more information on CEAA's certification programs, including a registry of certified auditors, please contact CEAA at (905) 814-1160, fax (905) 814-1158, e-mail [administration.ceaa@sympatico.ca](mailto:administration.ceaa@sympatico.ca) or visit their Web site at <http://www.ceaa-acve.ca>. ■



“Auditing Opportunities Beyond ISO 14001”, the Canadian Environmental Auditing Association's annual meeting and technical conference, takes place in Toronto November 1 and 2. For details, contact the CEAA (see main text) or visit their Web site at <http://www.ceaa-acve.ca>

# ISO 14000 IN JAPAN

Japan leads the world  
in ISO 14000 registrations.  
We look at the reasons why

When Canadians think about Japan, they usually picture cherry blossoms, busy cities, sophisticated electronics, *manga* (comic books), *anime* (animation), Hello Kitty or Pokémon. Most don't think about ISO 14000.

But perhaps they should. Japan is the world leader in adopting this international family of environmental management standards. The country boasts more than 2,000 registered environmental management systems (EMS) – about 20 per cent of the worldwide total.

A remarkable variety of Japanese organizations have obtained registration, from factories to government offices to supermarkets. And information and financial support are widely available for organizations establishing or registering an EMS.

## Going by the numbers

By May of this year, Japan had recorded 2,124 ISO 14000 registrations, according to figures from the Japan Accreditation Board for Conformity Assessment (JAB).

Current figures from other countries aren't available, but earlier surveys have consistently identified Japan as the world leader, followed by Germany and Great Britain.

That trend is likely to continue. In a February 1998 survey, about a third of the companies listed on the Japanese stock exchange said they planned to register. According to some forecasts, the number of registered organizations will double in the next three years.

Canada's achievements and ambitions are more modest. According to the Globus Registry, a directory of ISO 9000 and 14000 registered organizations, there were 62 ISO 14000 registrations in Canada as of late August. A research study conducted earlier this year by the Standards Council of Canada's Canadian National Committee of ISO and Industry Canada (please see our March-April 1999 issue for details) found that 18 per cent of the non-registered Canadian companies surveyed planned to seek registration.

While the numbers are interesting, they don't neces-

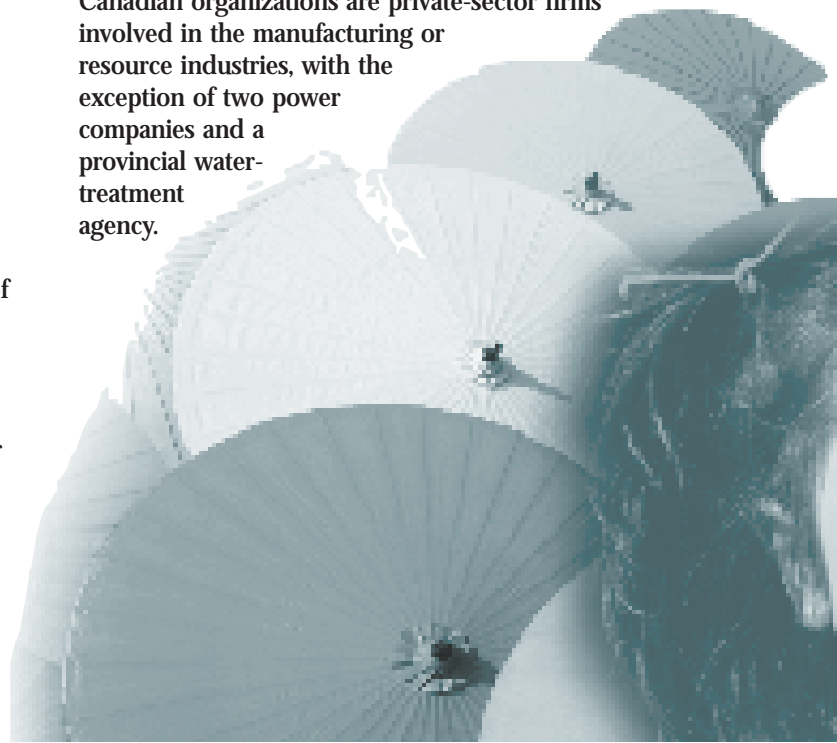
sarily provide a complete or accurate picture. Not all registrars submit information to Globus, for example, so the actual number of Canadian registrations is believed to be higher. The Canadian and Japanese economies differ considerably in size and composition. And registrations can be issued on an organization-wide or site-by-site basis, so the numbers can often be misleading.

But numbers aside, there are some genuine differences in Canada's and Japan's ISO 14000 experiences.

For example, Japan is notable for the variety of organizations that have achieved ISO 14000 registration. As in most other countries, the manufacturing industry accounts for a significant proportion. But other sectors have also adopted ISO 14000. The list of registered organizations includes schools, universities, banks, trading houses and even supermarkets.

Governments are also establishing and registering EMSs. The country's Environment Agency, for example, is seeking registration, as are an estimated 80 local governments. About 14 more are already registered.

So far, Canada's ISO 14000 users are less diverse. According to the Globus Registry, most registered Canadian organizations are private-sector firms involved in the manufacturing or resource industries, with the exception of two power companies and a provincial water-treatment agency.



## The why and wherefore

What accounts for Japan's enthusiasm for ISO 14000?

The reasons for implementing an ISO 14000 EMS are much the same in Japan as they are in the rest of the world. Companies see an EMS as a means of improving their environmental performance and public image, reducing costs by conserving energy and resources, motivating employees, distinguishing themselves from the competition, and expanding their pool of potential clients.

But observers also point to a number of influences that are uniquely Japanese. One of these is the Japanese experience with ISO 9000. Because of their confidence in their own quality control systems, Japanese companies were slow to adopt ISO 9000. As a result, they were caught short when European and North American clients began to insist that their suppliers be registered.

That's beginning to turn around. ISO's latest survey of ISO 9000 registrations worldwide, conducted at the end of 1997, found Japan lagging behind the major European countries, and only slightly ahead of China, South Korea and Canada. But it also pegged Japan as the country with the fastest growth in registrations.

Japanese firms don't want to repeat their ISO 9000 experience with ISO 14000. In fact, Japan was one of the first countries to embrace the standards. According to one estimate, by the time the final version of ISO 14001 was published in September 1996, about two-thirds of the country's electrical equipment industry had already registered.

Observers also point to Japanese concern over the environment. During the country's rapid growth in the 1950s and 60s, several high-profile incidents, including over 80 deaths due to mercury poisoning, led to widespread concern about pollution. More recently, events such as the United Nations' 1997 Kyoto Conference on global warming and new environmental legislation have

prompted Japanese organizations to review their environmental practices.

It's not surprising that the Japanese would be concerned about the environment. As a small island nation with limited natural resources, Japan has to import most of the raw materials and energy it uses. Japan is also densely populated, with four times Canada's population in an area one-third the size of Ontario. As a result, pollution, resource conservation and land use are serious concerns.

Strong endorsement from government and from the country's leading industries may also have contributed to ISO 14000's success in Japan.

The national government, for example, has supported the implementation of EMSs since 1993, when its Basic Environmental Plan recommended them as an effective tool for dealing with environmental issues. Besides pursuing their own registrations, governments at the national, prefecture and local levels offer grants and loans to organizations establishing or registering an EMS. Tokyo's metropolitan government, for example, will cover half the cost of registration, to a maximum of 1.3 million yen (about \$17,000 Canadian).

Japan's major corporations are also on board, both setting an example and encouraging other firms to become registered. The list of registered companies includes well-known names like Sony, Hitachi, Toshiba, Sanyo, Fujitsu, Sharp and NEC. Most of Toyota's manufacturing facilities around the world are registered, including plants in British Columbia and Ontario. Matsushita Electrical Industrial has announced that it is giving priority to suppliers who have an EMS, and is even considering offering financial assistance to suppliers who want to improve their environmental performance.

## Japanese lessons

Japan's experience shows the growth potential for ISO 14000 in Canada, and suggests what will have to happen in order for that potential to be realized.

Governments can foster the growth of the standards by endorsing and applying them. Major companies can also help by implementing the standards and by encouraging their suppliers to use them. Most importantly, however, an EMS needs to be widely regarded as an effective tool for managing an organization's impact on the environment. ■

*Some background material for this article was provided by the Toronto office of the Japan External Trade Organization (JETRO). For more information about JETRO, please visit their Web site at <http://www.canada.jetro.org>*

# ISO 9000: Health Canada's prescription for medical devices

*Quality system requirements in new medical device regulations are just what the doctor ordered*

**F**rom the simplest tongue depressor to the most complex cardiac pacemaker, medical devices play an important role in assessing, maintaining and improving the health of Canadians.

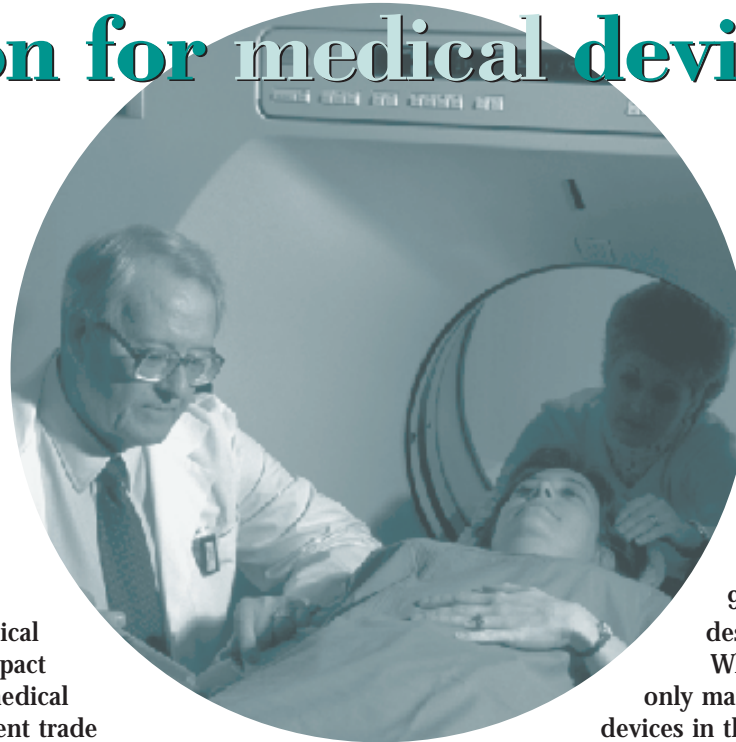
Medical devices also play an important role in Canada's economic health. About 1,000 firms across the country manufacture, import or distribute medical devices. Their cost has a significant impact on provincial health-care plans. And medical devices are a key element in some recent trade agreements.

With both physical and economic health in mind, Health Canada recently revised its *Medical Devices Regulations*. The new rules promise to increase scrutiny over medical devices without significantly increasing costs. Two important ingredients in this new prescription are ISO 9000 and the Standards Council of Canada.

One of the most significant changes in the regulations is the introduction of a risk-based classification system. Medical devices are assigned to one of four categories based on the level of risk they present to the patient. Class I, the lowest-risk category, consists mainly of devices used outside the body. Devices that are used inside the body or that provide important diagnostic information belong to the progressively higher-risk Class II, III or IV.

Another new feature is the requirement that manufacturers of certain types of medical devices must have a registered quality system in place as of July 1, 2001.

Class II devices must be manufactured under a quality system that complies with ISO 13488. This international standard provides particular requirements for the application of ISO 9002 to the manufacturing, processing, pack-



aging, refurbishment and modification of medical devices. Class III and IV devices must be manufactured under an ISO 13485 quality system. This standard, based on ISO 9001, also includes design requirements. While ISO 13485 is only mandatory for devices in the highest-risk categories, Health Canada is encouraging all manufacturers to use it.

Independent quality system registrars will look after auditing and registration. Health Canada and the Standards Council of Canada are in the process of developing an accreditation program that would allow Standards Council accredited registrars to include ISO 13485 and 13488 registration as part of their scope of accreditation.

Requiring manufacturers to implement quality systems is expected to bring about several benefits, including greater scrutiny of medical devices before they go to market. Before the new regulations went into effect last July, only five to ten percent of medical devices required Health Canada's approval before going on sale. By the time the quality system requirements take effect in 2001, that will have increased to about sixty percent. Since registrars will evaluate manufacturers' quality systems, however, the greater scrutiny will require only minimal additional resources on the part of the department.

The quality system requirements may also help to

Please see "ISO 9000", on page 18

## For more information...

- More information on the new *Medical Devices Regulations*, is available from Health Canada at <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/>
- *The ISO 9000 and 13485 Essentials: A Practical Handbook for Implementing the ISO 9000 and 13485 Standards for Medical Device Manufacturers* (PLUS 9001MD-98), is available from CSA International at 1-800-463-6727, fax (416) 747-

2475, e-mail [sales@csa.ca](mailto:sales@csa.ca)

- *ISO 14969, Quality systems — Medical devices — Guidance on the application of ISO 13485 and ISO 13488* is available from Global Info Centre Canada at 1-888-782-6327 or (613) 237-4250, fax (613) 237-4251, e-mail [gic@micromedia.on.ca](mailto:gic@micromedia.on.ca).



# National Standards of Canada

Since the last issue of *CONSENSUS*, the following standards were approved as National Standards of Canada by the Standards Council of Canada. For information on availability and prices, or to order copies of these standards, please contact the appropriate standards development organizations below. Some documents may be available in only one language.

## Canadian General Standards Board (CGSB)

Telephone: (819) 956-0425 or  
1-800-665-CGSB (Canada only)  
Fax: (819) 956-5644



- CAN-CGSB 1.122** Anticorrosive Vinyl Primer
- CAN-CGSB 1.135** Flat Alkyd Enamel for Equipment
- CAN-CGSB 1.146** Cold Curing, Gloss Epoxy Coating
- CAN-CGSB 1.164** Solvent for vinyl pretreatment coating
- CAN-CGSB 1.193** High-build epoxy marine coating
- CAN-CGSB 1.195** Interior Latex Semigloss Paint
- CAN-CGSB 1.61** Exterior and interior marine alkyd enamel
- CAN-CGSB 1.70** High-solvency Thinner

## CSA International

Telephone: (416) 747-4044  
Fax: (416) 747-2475



- CAN-CSA C1264-99** Ceramic pressurized hollow insulators for high-voltage switchgear and controlgear
- CAN-CSA C22.2 No. 236** Heating and Cooling Equipment - Consumer and Commercial Products
- CAN-CSA ISO 14020-99** Environmental labels and declarations - General principles
- CAN-CSA ISO/IEC ISP 10609-33-99** Information Technology - International Standardized Profiles TB, TC, TD and TE - Connection-mode Transport Service over connection-mode Network Service - Part 33: Definition of profile TC4211
- CAN-CSA ISO/IEC ISP 10609-34-99** Information Technology - International Standardized Profiles TB, TC, TD and TE - Connection-mode Transport Service over connection-mode Network Service - Part 34: Definition of profile TC43111
- CAN-CSA ISO/IEC ISP 10609-35-99** Information Technology - International Standardized Profiles TB, TC, TD and TE - Connection-mode Transport Service over connection-mode Network Service - Part 35: Definition of profile TC43112
- CAN-CSA ISO/IEC ISP 10609-36-99** Information Technology - International Standardized Profiles TB, TC, TD and TE - Connection-mode Transport Service over connection-mode Network Service - Part 36: Definition of profile TC43211
- CAN-CSA ISO/IEC ISP 10609-37-99** Information Technology - International Standardized Profiles TB, TC, TD and TE - Connection-mode Transport Service over connection-mode Network Service - Part 37: Definition of profile TC43212
- CAN-CSA ISO/IEC ISP 10609-38-99** Information Technology - International Standardized Profiles TB, TC, TD and TE -

- Connection-mode Transport Service over connection-mode Network Service - Part 38: Definition of profile TC4331
- CAN-CSA ISO/IEC ISP 10612-3-99** Information technology - International Standardized profile RD - Relaying the MAC service using transparent bridging - Part 3: Token Ring LAN sub-network-dependent, media-dependent requirements
- CAN-CSA ISO/IEC ISP 10612-6-99** Information technology - International Standardized profile RD - Relaying the MAC service using transparent bridging - Part 6: Profile RD54.54 (FDDI LAN - FDDI LAN)
- CAN-CSA ISO/IEC ISP 10612-7-99** Information technology - International Standardized profile RD - Relaying the MAC service using transparent bridging - Part 7: Profile RD51.53 CSMA/CD LAN - Token Ring LAN)
- CAN-CSA ISO/IEC ISP 10612-8-99** Information technology - International Standardized profile RD - Relaying the MAC service using transparent bridging - Part 8: Profile RD53.53 (Token Ring LAN - Token ring LAN)
- CAN-CSA ISO/IEC ISP 10612-9-99** Information technology - International Standardized profile RD - Relaying the MAC service using transparent bridging - Part 9: Profile RD53.54 (Token Ring LAN - FDDI LAN)
- CAN-CSA ISO/TR 10014** Guidelines for managing the economics of quality
- CAN-CSA ISO/TS 16949** Quality systems - Automotive suppliers - Particular requirements for the application of ISO 9001:1994
- CAN-CSA Z795-96** Coding of Work Injury or Disease Information

## Underwriters' Laboratories of Canada (ULC)

Telephone: (416) 757-3611 or  
Fax: (416) 757-8915



- CAN-ULC S612 CAN/ULC-S612-99** - Standard for Hose for Flammable and Combustible Liquids
- CAN-ULC S620 CAN/ULC-S620-99** - Standard for Hose Nozzle Valves for Flammable and Combustible Liquids
- CAN-ULC S633 CAN/ULC-S633-99** - Standard for Flexible Underground Hose Connectors for Flammable and Combustible Liquids
- CAN-ULC S634 CAN/ULC-S634-99** - Standard for Hose Swivel Connectors for Flammable and Combustible Liquids

For a searchable database of all National Standards of Canada, please visit the Standards Council's Web site at <http://www.scc.ca>.

# Accreditation and Recognition News

The Standards Council of Canada's accreditation and recognition programs formally acknowledge the competence of organizations to carry out specific standards development and conformity assessment services. This provides a basis for national and international acceptance of products and services.

Standards Council accreditation or recognition is limited to particular scopes or fields of activity. For complete scope and contact information on any organization listed here, or for information on the Standards Council's accreditation and recognition programs, please visit our Web site at <http://www.scc.ca> or contact our information division.

## New accreditations and recognitions

### Calibration and testing laboratories

- CGI Information Technology Security Evaluation and Test Facility, Ottawa, Ontario
- Newalta Corporation, Newalta Oilfield Industrial Laboratories, Dayton Valley, Alberta

- Maxxam Analytics Inc., Niagara Laboratory, Niagara-on-the-Lake, Ontario
- Wellington Laboratories Inc., Guelph, Ontario
- A.E.A. Management Inc., Testing Laboratory, Windsor, Ontario

### Good Laboratory Practice (GLP)

- Vaughn Agricultural Research Services Ltd., Branchton, Ontario
- Uniroyal Chemical Co., Guelph, Ontario

## Voluntary withdrawal of accreditation

### Calibration and testing laboratories

- Métallurgie Noranda Inc., Rouyn-Noranda, Québec

## Closure of Application for Accreditation

### Certification organization

- Factory Mutual Research Corporation, Norwood, Massachusetts

# Public review Notices

Listed below are standards being proposed (p), revised (r), withdrawn (w) or amended (a). Copies are available from the designated accredited standards development organization. Normally there will be a minimum charge for each copy of a document ordered. Please note that these documents are intended for review and comment, not for application.

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**ULC-D60855** + Corrigendum, Insulating foam-filled tubes and solid rods for live working (p)

**ULC-D61235** + Corrigendums, Live working – Insulating hollow tubes for electrical purposes (p)

**ULC-CEI/IEC 60984** + Corrigendums, Sleeves of insulating material for live working (p)

**ULC-S511**, Standard for lined fire hose for interior standpipes and municipal and industrial fire protection services (p)

**ULC-S602**, Standard for aboveground steel tanks for heating oil or used oil as a fuel (p)

**ULC-CEI/IEC 61243-1** + Amendment 1 + Corrigendum, Live working – Voltage detectors – Part 1: Capacitive type to be used for voltages exceeding 1 kV a.c. (p)

"ISO 9000", continued from page 16

improve the quality and performance of medical devices. According to Health Canada, studies have shown that many recalls and other serious problems associated with the devices are caused by poor design or manufacturing controls – problems that quality systems have proved to be effective at alleviating.

Finally, the new requirements will open up the international market for medical devices by making Canadian

requirements similar to those in some of our major trading partners, particularly the United States and the European Union (EU). Combined with mutual recognition agreements like one recently signed with the EU, this will allow Canadian manufacturers to sell their products in foreign markets without having to undergo multiple tests or assessments. It should also increase the variety of devices available on the Canadian market. ■

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