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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Is Lab Industry Ready for Facebook and MySpace?

WHO COULD HAVE IMAGINED, JUST A FEW YEARS AGO, that social networking sites such as **Facebook.com**, **MySpace.com**, and **YouTube.com** would become a useful platform that allows clinical laboratories, pathology groups, and *in vitro* diagnostics (IVD) companies to engage in two-way conversations with patients and customers?

After all, in those days, the preponderance of active users of these social networking services were young people. There were no obvious business reasons why a clinical laboratory might want to establish its own page on any of these sites. If that was the popular wisdom then, it is not accurate today.

In my neighborhood, even the retired ladies now maintain Facebook or MySpace pages and regularly communicate with each other via this medium. Of course, since elderly folks tend to have a variety of health problems, there is plenty of conversation taking place about these topics. I suspect that is why certain lab companies, like **Myriad Genetics** with its predictive genetic test for breast cancer, have established a presence on these social networking sites and find them useful for communicating with women concerned about breast cancer.

On pages 3-6, THE DARK REPORT provides the lab industry's first briefing about why IVD companies and certain clinical laboratories are consciously incorporating social networking activities into their marketing and business development programs. I suspect it will surprise many pathologists and lab managers at how rapidly social networking has become a useful conduit for organizations to directly conduct two-way conversations with patients, customers, and prospects.

In fact, it might be smart for clinical labs and pathology groups to invite their Generation Y pathologists and medical technologists to enlighten the marketing and sales teams at their labs about how social networking works. An even bolder move would be to empower the most enthusiastic of these Gen Y laboratory professionals to help design social networking programs in tandem with the lab's sales and marketing team.

By way of full disclosure, this aging curmudgeon acknowledges that he doesn't surf such social networking sites as FaceBook.com and MySpace.com. However, he has learned that he can go to YouTube.com and easily find entertaining clips of musical performers popular during his youth. With just a couple of mouse clicks, performances by Mitch Miller and Patti Page can be accessed! TDR

Social Networking Is New Lab Marketing Channel

Clinical labs and IVD companies encourage customer dialogue at Facebook, YouTube, Twitter

CEO SUMMARY: Using social marketing sites on the Web allows labs and IVD manufacturers to interact with customers in ways that were not possible years ago. Marketers use these interactive web sites to supplement traditional methods of advertising. Inviting customers to discuss your company and products on a Facebook site can result in powerful word-of-mouth testimonials. But proceed with caution! Negative comments about your company or laboratory can pop up as well.

MEET SOCIAL NETWORKING! This is a growing, dynamic new business concept with perfect appeal to the Generation Y pathologists and laboratory professionals.

In its simplest form, social networking is a way for people, companies, and organizations to interact. Social networking incorporates web sites, cell phones, wireless devices, and similar technologies in ways that allow highly-interactive communication among users.

If you are familiar with such names as **Facebook.com**, **MySpace.com**, **YouTube.com**, and **Twitter.com**, then you know about the most revolutionary forms of social networking. In the clinical laboratory industry, a number of clinical labs, *in vitro* diagnostics (IVD) manufacturers, and other organizations now use social networking as a way to tout the performance of their products, create two-way dialogue with customers and prospective buyers, and learn what people think about their service.

Social networking upends the long-established ways companies use to communicate sales, marketing, and business information. To reach its market, an IVD company traditionally used print advertising and direct mail as a one-way communication to its customers. This one-way form of advertising is often augmented with press releases—another one-way communication channel.

Now social networking sites augment these traditional forms of communication to customers. "Think of social networking as public relations on steroids," commented Rob Kinslow, Vice President, Strategic Communications for **Seidler Bernstein**

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Inc., marketing consultants in Cambridge, Massachusetts. Recently Kinslow and his colleague Nik See talked with THE DARK REPORT about how clinical labs, IVD manufacturers, and other companies are using social networking sites to augment their customer communication efforts.

"Social networking is a way to make conversation easier between an IVD company and its laboratory customers, as well as between a clinical laboratory and its referring client physicians," said Kinslow. "Web sites such as FaceBook, YouTube and similar sites help an IVD company not only create conversations about its products and services, but encourage feedback and comments.

"Smart companies and labs can use social networking to create a community of customers and users," he explained. "This community makes it easier for a two-way flow of information and commentary to move between all the parties.

"At the same time, since it is in the public domain, other people can tap into this information if they are seeking more information about a company or its products," added See, who is Director of Brand Planning and Strategy at Seidler Bernstein. "People can read all the comments, good, bad, or otherwise. Like your personal network of friends, this information can often be highly credible for those who tap into it."

Companies Use FaceBook

"We are helping clients establish FaceBook pages," noted Kinslow. "Companies can create a Facebook page for each of their products, along with a page for their company. Social networking like this allows them to reach incredibly large numbers of people.

"Consider this: if Facebook were a country, it would be the fourth largest country in the world," Kinslow said. "That would rank Facebook between the size of the United States and Indonesia.

"Another example of why social networking is skyrocketing is YouTube," he continued. "Most people know that **Google** is the world's largest search engine. But few people realize that YouTube is now the second largest search engine in the world.

Word-Of-Mouth Advertising

"Any marketing manager at an IVD firm or clinical laboratory has a tremendous opportunity to take advantage of these social networking technologies," Kinslow said. "As they do, it generates word-of-mouth advertising—which is the most powerful form of advertising.

"Everyone wants viral," See agreed. "If traditional forms of marketing such as print advertising no longer seem as effective as they once were, it probably has more to do with whether they've been properly integrated with each other. We are big believers in integrated marketing communications.

"Social networking and the Internet offer IVD and clinical laboratory marketers useful tools to better integrate their overall marketing campaigns," he added. "These new tools can fill the gaps and knit the marketing effort into an integrated plan."

"We preach to our clients the value of integrating all marketing and information messages to customers and prospects," continued Kinslow. "Print advertising still has a place because the cost per impression is still the most economical way to create awareness.

"But increasingly, you will see print advertisements point readers toward a Facebook page, for example, or to a landing page on the Web where readers can get a white paper or other information of value to them," he explained. "When the reader responds by visiting these sites, the marketer can collect that reader's contact information, which means you've got a lead for your sales force.

"In addition, you can use this information to track how well your print advertising is working," he added. "Running a

Cell Phones, Handheld Technology Foster New Online Communication Techniques

ONE FACTOR DRIVING the use of social networking is the widespread adoption of hand-held and wireless technologies. Individuals can use their cell phones or PDAs (personal digital assistants) to access and surf the Web.

"New technologies are changing everything, everywhere," said Rob Kinslow, Vice President, Strategic Communications for Seidler Bernstein Inc., of Cambridge, Massachusetts. "This is true among physicians, pathologists, laboratory professionals, and many other healthcare professionals.

"For example, it wasn't that long ago that we advised companies against sending e-mail messages to nurses because they didn't have access to computers," he recalled. "That's changing.

"Just a few years back, most physicians did not work on a computer," Kinslow said. "Now a majority of physicians actively use a computer, whether or not their practice has an EMR. Many of them are intense users of Blackberries, iPhones, and the like.

"Manhattan Research studies show that 64% of U.S. physicians own smartphones," he said. "And company analysts predict penetration will increase to 81% by 2012.

"Similarly, radiology has gone digital and now digital pathology is coming into play," observed Kinslow. "These mobile technologies foster social networking. This allows companies to use mobile applications to direct messages to certain users in specific locations.

"As an example, think of real-time tweets and e-mails to attendees at a trade show, alerting them to new product demonstrations or activities at the vendor's booth," he noted. "It's like the buzzer they hand you at the restaurant to tell you your table's ready. It summons you and you can't ignore it."

print advertisement which directs the reader to a Facebook page is just one way to take advantage of social networking.

"Another approach is to use banner ads on select websites that reinforce or supplement the message in your print ads," Kinslow noted. "In this form, the banner ad is again like PR taken to another level because it creates two-way conversations. The customer is able to respond to you, and you can encourage him or her to take a desired action."

See offered **Gilead Sciences Inc.**, of Foster City, California, as an example of how social networking plays a role in marketing a therapeutic drug (and which would increase laboratory testing for that disease). "Gilead has an excellent campaign that combines print advertising and social networking," he explained. "It wants to market its hepatitis B drug, Hepsera, for patients with chronic hepatitis B.

Educating Patients

"Under the theme 'B Here,' Gilead's marketing and social networking campaign is designed to educate patients—particularly those in the Asian-American community—about the disease and the need for testing, monitoring, and education. It's on the web at *www.willyoubhere.com*," stated See.

"The goal of this campaign is to rally second-generation Asian-Americans to get tested and to spread the word about the importance of getting tested for hepatitis B," See explained. "The landing page Gilead created for this campaign is *www.asianliver.com*." In addition, added See, the campaign also uses Facebook and

Twitter, the microblogging site that allows users to send messages of no more than 140 characters to alert followers about trends, news, updates about the web site, or Gilead's products and services.

"Pathologists and laboratory managers are familiar with **Myriad Genetics**, which uses social networking as part of its marketing," stated Kinslow. "Myriad promotes screening for the BRCA1 and BRCA2 breast cancer biomarkers on its Facebook page. The campaign is called 'Just Ask' and promotes awareness about both breast and ovarian cancer."

Rallying Patients Online

"One big difference between a site such as *AsianLiver.com* and other social media initiatives is that *AsianLiver.com* encourages patients to voice their concerns or ask questions of healthcare professionals," said See. "Gilead actively encourages patients to take an action. This is different than what most sites do.

"Another social networking approach is to provide a page on Facebook where patients can comment and interact with other customers," he said. "Through these comments and interactions, customers are generating word-of-mouth endorsements and spreading the word about your company and its products in very powerful ways."

IVD and lab testing companies which use the web for social networking are exploiting technology to their advantage, Kinslow observed. "These pages on social networking web sites create tremendous opportunities for IVD companies to foster conversations between their customers, as well as take advantage of the information they get from customers," he said. "In addition, they get credit among customers just for facilitating these conversations.

"There is a caveat, however," cautioned Kinslow. "Any IVD company or clinical laboratory that markets its products and services through social networking on the web must remember that inviting customers to post public comments can be a double-edged sword.

"These conversations happen in a public forum, which means sales reps—both your own and those of competitors—can listen in. Everyone gets to hear what customers are saying to each other about your products, their experiences, and their opinions of your competition.

"If your company or laboratory wants the free publicity that comes with social media, you also have to accept that sometimes people will say things you won't like," added Kinslow, "which means you will have to put up with some negatives as well. That's because these are real conversations."

"Of course, there are controls," noted See. "There are ways to review patient and consumer comments before they post on the web page, for example."

"There is one final comment I'd make about social networking," Kinslow said. "Companies are beginning to customize information and deliver it with mobile apps technology. We live in a era when people are accustomed to getting custom content—news and information tailored to their specific interests and needs. Many people don't go looking for the news anymore because the news is delivered to them, via a mobile device, for example. That's a big change that's happened surreptitiously and may not be apparent until you stop and think about it."

Useful Conversations

THE DARK REPORT observes that while IVD companies and some clinical labs have a presence on YouTube and Facebook, most clinical laboratories have yet to take advantage of social networking. That is likely to change as more labs learn how to create useful two-way conversations with their referring physicians and patients via social networking channels. TDR

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Pre-authorization Coming For Pricey Molecular Tests

Health insurers ready to control utilization of expensive genetic and molecular tests

CEO SUMMARY: In response to the steep ramp-up in the utilization of genetic and molecular testing, the nation's largest health insurers are preparing to institute new guidelines for coverage and reimbursement. These will include pre-authorization by physicians, a more effective genetic test coding arrangement for claims submission by laboratories, and implementation of evidence-based medicine (EBM) guidelines. All of these developments create opportunities for clinical laboratories to step up and add value in new ways to payers.

DEMAND FOR MOLECULAR TESTING and the ample reimbursement for such tests is a bright spot for the clinical laboratory industry. But rapid growth in the utilization and expense of molecular tests has caught the attention of the managed care companies who pay the bills.

"Laboratories should prepare to address new coverage guidelines and strict requirements for pre-authorization of molecular tests that the nation's largest health insurers are already implementing," said Michael Snyder, President and Co-Founder of **Laboratory Management Services**, in Hauppauge, New York. "Health insurers are now instituting major policy changes designed to bring utilization of genetic and molecular tests under tighter control.

"This is a consequence of the rapid growth in the volume and related costs of genetic and molecular testing performed each year in this country," he noted. "For 2008, about $5.5 billion was spent on molecular testing. Estimates are that the bill for molecular tests will top $8 billion for 2010 and some predictions are that, in coming years, molecular testing will represent about one-third of all diagnostic testing.

"It is only natural that payers are concerned by this sharp increase in spending for molecular testing," explained Snyder. "Anytime health plans see the cost of certain clinical procedures spiraling upwards, they actively take steps to control this spending growth.

Consequences For Payers

"For payers, the rapid increase in molecular test volumes has two consequences," he observed. "First is the greater cost of the molecular tests. Second, in the practice of personalized medicine, a single molecular test is often paired with a direct therapeutic response. This means the lab test leads directly to spending for treatment.

"This motivates the payer to ensure that expensive molecular tests are only ordered when appropriate, since the right test at the right time on the right patient is essential to determining if that patient qualifies for expensive therapy," he said.

"Another issue of concern to payers is the 'code stacking' laboratories use when

filing claims for molecular tests," continued Snyder. "Code stacking may involve a group of 21 CPT codes combined on one bill and representing more than 1,500 tests. These codes describe the components of the test or the procedures involved, not an actual clinical objective or specific identification of a pathogen or disease state.

Clinical Appropriateness

"Since the CPT code describes the processes performed by the laboratory, it's very difficult for health plans to understand exactly which test was performed," noted Snyder. "Thus, when health plans pay these bills, they do so without knowing the specific laboratory test performed and with no ability to manage clinical appropriateness.

"Health plans would prefer to apply evidence-based policies," he continued, "This is one way they can ensure that the right patient got the right laboratory test. It also allows the payer to match the diagnostic results to the appropriate therapeutic response.

"To control costs and minimize code stacking, health plans are auditing testing practices and implementing new policies requiring pre-authorization and new coding standards," said Snyder. "These steps will result in an increase in the denial rates for molecular lab test claims. In addition, health insurers are ready to apply evidenced-based policies before paying these molecular test claims.

Evidence-Based Care

"Of course, most pathologists and lab administrators know that evidence-based medicine (EBM) is not new," he explained. "All clinical policies are based on medical evidence. The problem comes when health plans have no knowledge of the molecular lab test performed because it means they cannot apply the appropriate policy. In such cases, the health insurers' recourse will be to deny payment of that laboratory test claim.

"And, in fact, payers will have good reasons for not paying for these tests," he continued. "A well-known example involves the administration of Herceptin, a chemotherapy agent for the treatment of breast cancer. Herceptin is indicated only when there is a positive HER2/neu test. Therefore, it is absolutely imperative for a managed care company to know whenever a HER2/neu was performed.

"That's because the results of the HER2/neu test generate successive steps that both the physician and the health plan must take," added Snyder. "This example demonstrates the positive effect of appropriate laboratory test utilization in support of the medical policy that payers want physicians to follow. In fact, health plans want labs to perform the HER2/neu test for several important reasons.

Essential Uses of Lab Data

"First, health plans want the molecular lab test results to support the reporting of data for the Healthcare Effectiveness Data and Information Set (HEDIS) to the **National Committee for Quality Assurance** (NCQA) and others," noted Snyder. "Second, this test data is essential for disease management. Third, these test results are necessary for the health plan to help patients manage their pharmacy benefits. Fourth, as managed care plans establish patient health record (PHR) repositories, they want the molecular test data to be part of the patient's PHR.

"All of these elements bear directly on how a managed care plan directly covers the care of an individual patient," he observed. "But health insurers have other extremely valuable ways to use molecular test results.

"Managed care plans need the molecular lab test data: 1) to identify the target populations; 2) to select outcomes measures; 3) to risk-stratify the target population; and, 4) to implement interventions," stated Snyder. "Here is a place where clinical laboratories can step up and add value to the managed care plans.

"Payers' need for full and complete sets of molecular test data is what opens the

door for clinical labs to work more closely with health plans," he advised. "It is possible for laboratories to develop partnerships with payers. In these partnerships, labs can work with health plans to give them the laboratory test data they need in the format that is most efficient for them.

Pre-Authorization Returns

"To manage molecular testing, health plans will introduce new policies regarding notification, prior authorization, and revised coding standards," explained Snyder. "There are at least three ways that payers are about to change current coding and billing practices for genetic and molecular tests.

"First, laboratories will be required to notify the health plan when they perform molecular diagnostic testing," he predicted. "The notification will help payers to identify the actual molecular test being performed and determine utilization patterns. It will also allow the payer to engage the medical management process.

"Second, pre-authorization guidelines will require a doctor to obtain permission for the genetic or molecular test *prior to performance of that test*," he stated. "Currently, pre-authorization is commonly handled by telephone and fax. Until electronic or fully-digital ways of handling pre-authorization of molecular tests between physician and payer are in place, this will be a challenge for the laboratory which is to perform the molecular test.

"Third, managed care plans will manage utilization of genetic and molecular tests by the introduction of new coding requirements," continued Snyder. "Molecular test codes are needed that can function as an adjunct to the current codes. As this happens, the claims systems used by payers can then precisely recognize which genetic and molecular tests are being performed.

"Pathologists and lab directors should expect payers to roll out all three of these changes during the next 24 to 36 months," predicted Snyder. "It will be important for every lab team to keep tabs on this, because each of these coming changes will be incorporated into the managed care contracts the laboratory signs with payers."

There may be additional surprises for laboratories as health insurers take deliberate actions to control utilization of genetic and molecular tests. "Conversations I am having with managed care plans indicate that they intend to issue standards of participation to clinical labs," he commented. "One aspect will be standards of care based on scientific evidence. The second aspect will be credentials for each laboratory that go beyond CLIA and CAP certification.

"After managed care plans educate laboratories on how to meet these new guidelines, they will police these policies," he added. "Their goal is to ensure that all genetic and molecular testing is appropriate and ties back to personalized medicine. As part of this effort, there will be automation and digital reporting tools, because these new systems need to work uniformly for everyone."

Snyder believes all of this represents an excellent opportunity for laboratories which respond quickly and efficiently to the changing needs of their payers. "This evolutionary path gives the lab industry an opening to be a partner at the table with respect to the application of clinical evidence and its proper effect on utilization.

More Claim Denials Ahead

"However, it's in the cards that laboratories will see more denials of claims for genetic and molecular tests," predicted Snyder. "After all, it's going to take time for health insurers to refine their policies and procedures for each type of molecular test. Labs must be prepared to obtain patient acknowledgement of financial responsibility. And that means getting patient waivers signed. For these reasons, labs need to be prepared to see an increase in bad debt that is associated with claims for genetic and molecular tests." TDR

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Pioneering Clinical Labs Prepare to Tackle ISO 15189

ISO 15189 Accreditation Requires Specific Steps For Global Recognition

➤➤ *CEO SUMMARY: This intelligence briefing is the third in an ongoing series about quality management systems (QMS) and their role in advancing the performance of clinical laboratories and improving the quality of the testing services they provide. ISO 15189 is a set of standards for medical laboratories based on the ISO 9001 quality management system. It provides a way for medical laboratories to demonstrate to outside examiners both conformance to the QMS and competence in the performance of laboratory testing services.*

In the United States, ISO 15189 is making inroads with those clinical laboratories wanting to implement a quality management system (QMS).

One factor contributing to this new interest in QMS is the fact that many of the nation's clinical laboratories and anatomic pathology groups are harvesting ongoing benefits from their use of Lean, Six Sigma, and similar methods. Adoption of a quality management system is a natural progression for these laboratories.

For its part, The Dark Report was the first lab industry publication to call attention to these developments and write about the experiences of the nation's earliest laboratories to certify under ISO 9001 (1998—*see TDR, July 6, 1998*); to implement Lean Six Sigma (2003—*See TDR, September 8, 2003*); and, to become accredited under the requirements of ISO 15189 (2008—*See TDR, September 8, 2008*).

The world's biggest player in QMS is ISO, which stands for the **International Organization for Standardization** (Organisation Internationale de Normalisation). The organization's headquarters is in Geneva, Switzerland. From here, it coordinates development of technical standards in virtually every area of international trade and professional activity. It supports the development of specific quality management systems for every relevant activity, including all areas related to laboratory testing and calibration.

➤Terminology Used By ISO

In response to the growing interest in QMS by pathologists and lab managers, The Dark Report interviewed QMS expert Lucie Berte of **Laboratories Made Better!**, based in Broomfield, Colorado, about the definition of a quality management system. Berte explained how laboratory quality control (QC) and lab quality assurance (QA) functions differ from a true QMS. *(See TDR, October 12, 2009.)*

In its next installment about QMS, The Dark Report interviewed Daniel Tholen, M.S., founder and owner of **Dan Tholen Statistical Consulting**, based in Traverse City, Michigan. Tholen has extensive experience with QMS. He serves in various roles with a number of national and international standards development organizations, including the group that recently developed the standard for laboratory proficiency testing, ISO/IEC 17043.

➤Terminology Used By ISO

Tholen provided information about ISO 9001, ISO 15189, and ISO 17025. He also explained the importance of understanding the terminology relating to certification to ISO 9001 requirements and accreditation to ISO 15189 requirements. *(See TDR, November 23, 2009.)*

This third installment about QMS deals with the practical steps a clinical laboratory or pathology group should take as it prepares to implement a quality management system. Globally, the QMS most widely used by clinical laboratories is ISO 15189: Medical Laboratories—*Particular Requirements for Quality and Competence*, which was first introduced in 2003 and updated in 2007.

Since 2003, many countries passed laws requiring laboratories to meet the requirements of ISO 15189 in fulfillment of their national scheme of accreditation or licensing. For example, Australia has used ISO 15189 since July, 2005, administered by its **National Association of Testing Authorities** (NATA). In Canada, Ontario Province similarly mandates ISO 15189 as the requirement medical laboratories must use to meet accreditation laws.

In the United States, a medical laboratory that wants to implement a QMS like that contained in ISO 15189 will still need to comply with the statutory requirements of federal and state laws. For example, U.S. medical laboratories must meet the accreditation requirements of the **Centers for Medicare and Medicaid Services** (CMS) in order to provide services to most government health

programs. Medical laboratories in the U.S. must also meet the licensing requirements as defined by the federal Clinical Laboratory Improvement Act (CLIA).

QMS Starts With ISO 9001

Internationally, the quality management system represented by ISO 9001 forms the basis for the other ISO standards, including ISO 15189. "ISO 15189 includes the QMS requirements in ISO 9001, but it also includes technical requirements for competence that are general for all medical laboratory testing situations," stated Tholen.

"In most countries where ISO 15189 is applied, there are specific requirements from the medical or health regulatory authority, as there is in the United States under the CLIA regulations," he noted. "Every application of ISO 15189 requires consideration of the specific program requirements in the laboratory's country."

"It is important to understand that in the ISO system, 'certification' means that the company's QMS meets the requirements of ISO 9001, while 'accreditation' means that the testing laboratory not only meets the QMS requirements, but also meets the requirements for *competence of specific technical activities,*" explained Tholen. These points were discussed in detail in THE DARK REPORT's second installment on quality management systems.

"For that reason, certification is actually a very limited designation," he continued. "To avoid confusion about certification and accreditation, ISO and the two main players in the application of QMS—the **International Accreditation Forum** (IAF) and the **International Laboratory Accreditation Cooperation** (ILAC)—have all agreed that testing laboratories should be accredited and not certified."

"There is unanimity on this principle within ISO and any organization holding an agreement with ISO," added Tholen. "I should also point out that, in the medical community here in the United States, the terms 'certification' and 'accreditation' are often used interchangeably, generally in reference to long-standing state and federal laws for licensing of health providers.

"That is why readers should be aware that my statements here use the terms 'certification' and 'accreditation' according to international usage as it relates to quality management systems, and specifically to the numerous ISO standards," he noted.

"Clinical laboratories in the United States take note," continued Tholen. "This difference in certification versus accreditation is why the testing laboratory accreditation process for ISO standards—including ISO 15189—are more rigorous than for an ISO 9001 certification.

Safeguarding The Public

"Any type of testing laboratory delivers a service that may directly affect public health and safety," he added. "This is why ISO and ILAC develop and refine standards so that accreditation of a testing laboratory is a meaningful measure of competence."

"The second fundamental involved in the ISO accreditation process is integral to the goal of conducting a meaningful assessment of a testing laboratory," he added. "In practical terms, if a clinical laboratory wants to achieve accreditation under ISO 15189, the clinical lab needs to utilize a third-party organization which has itself met the standard of ISO 17011: Conformity Assessment—*General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.*"

Tholen stresses the importance of understanding this requirement. "Memoranda of Understanding between ISO, ILAC, and IAF state that a testing laboratory—such as a clinical laboratory seeking accreditation to ISO 15189—should be accredited by a body which is itself recognized to ISO 17011, the standard for accreditation bodies," he said. *(See sidebars on pages 13 and 15.)*

"ISO 17011 is a well-established requirements document," added Tholen. "It is the cornerstone of the accreditation

Who Accredits the Bodies Doing the Accrediting? It's Complex, But Important to Understand

SINCE ITS INCEPTION, the ISO system has evolved steadily to support the concept of a single, internationally-accepted process for assessing the adherence to standards by companies, organizations, and recognition bodies.

"The role of ISO is very specific. It develops, publishes, and maintains the range of standards applicable to different industries, services, and products," observed Daniel Tholen, owner of Dan Tholen Statistical Consulting. "Implementation of ISO standards is independent of ISO itself.

Who Accredits Accreditors?

"To the question 'who accredits the accrediting bodies?', there is a fascinating answer: no one and everyone," said Tholen."The International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) arrangement calls for each accreditation body within a country to be recognized by its peers as being in compliance with ISO 17011.

"Thus, an accrediting body will undergo a rigorous assessment by its peers to demonstrate that it operates in compliance with ISO/IEC 17011: Conformity Assessment—*General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*," he explained. *(Editor's note: IEC is the International Electrotechnical Commission—a sister organization to ISO that has a scope of obvious importance, and is directly involved in the ILAC/IAF agreements, but is not concerned with medical laboratories.)*

"For a body that wants to provide accreditation services, the process of recognition by peers is extremely rigorous within ILAC and IAF," noted Tholen. "It involves an on-site assessment by a team of peers from at least two other regions (Asia Pacific, InterAmerican, Europe). The assessment requires observation of the candidate body as it conducts accreditation assessments of testing laboratories and other organizations in its country.

"These on-site assessments involve a team of three to five individuals and typically take at least a week," he added. "The process includes citations of non-conformances and a resolution process before recognition of that body's compliance to ISO 17011 is extended by peers. This process is repeated every four years. Members are admitted to the IAF and ILAC Mutual Recognition Arrangement (MRA) upon a 75% majority vote of peers.

"Of course, an agency of that nation's government can recognize or designate a body to determine the competence of medical or other testing laboratories in its country," he added. "The key point here is that, within the ILAC and IAF systems, accrediting bodies are *recognized by their peers* to be competent and to operate in compliance with ISO/IEC 17011.

"Also, both IAF and ILAC have Mutual Recognition Arrangements (MRAs) that require every full member to recognize—as equivalent—accreditations by other members, even in different nations," stated Tholen. "Under this system, any testing laboratory accredited by one nation's ILAC member body will have that accreditation recognized by the ILAC member organizations of any other country.

Compliance With ISO 17011

ILAC members are also obliged to promote the ILAC system within their countries, especially among 'specifiers'—usually, government agencies for trade or health," concluded Tholen. "Although there is no accreditation body for ISO 17011, IAF and ILAC have formal Memoranda of Understanding with each other and with all authoritative international organizations. These include the **United Nations**, **World Health Organization**, ISO, and IEC, and many others."

process for those countries which use ISO standards for conformity assessment. It applies to organizations that accredit conformity assessment bodies. That includes testing, calibration, and medical laboratories. It also includes inspection bodies, reference material producers, proficiency testing providers, and organizations that certify QMS."

"Let's stop for a moment and review," stated Tholen. "Accreditation is more rigorous than certification because accreditation indicates the testing laboratory has a management system which *conforms* and the testing laboratory is *competent* in its performance.

"Accreditation is more rigorous than certification because accreditation indicates the testing laboratory has a management system which conforms and the testing laboratory is competent in its performance."

"Further, because the testing laboratory has been audited by a registrar or body that is, itself, recognized by its peers as meeting the requirements of the ISO 17011 QMS, the examiners possessed the technical competence to evaluate both the testing laboratory's management systems and the competence with which it operates," he noted.

"Remember, the examiners are assessing both *conformity* to the QMS requirements and *competence* in the performance of testing services," observed Tholen. "This requires the examiners to have extensive training, including knowledge of the science and technology involved in the testing activities taking place within the candidate testing laboratory."

Tholen notes that the body offering accreditation must itself meet a high standard. "When an organization wants to offer accreditation services to laboratories, it must meet key (and very difficult to achieve) provisions of ISO/IEC 17011," he explained. "Included are requirements for impartiality (such as separation of accreditation and proficiency testing); training assessors and monitoring assessor competence; and operation of a QMS in their own organization.

Accrediting Your Lab

"Think about it. Shouldn't an organization that accredits your clinical laboratory's QMS, also operate under an ISO-compliant QMS?" asked Tholen. "Shouldn't an organization that assesses the competence of your laboratory, demonstrate that it has documented the competence of its assessors in the areas of technical knowledge, experience, and competence in the skill of assessing? After all, this accreditation process must have teeth so that consumer and patient safety can be assured.

"In the United States, there are no accreditation bodies that offer 'full service' to clinical laboratories seeking the dual goals of approval by CMS for CLIA activities and accreditation to ISO 15189 by an organization that complies with 17011," he commented. "For example, the **American Association for Laboratory Accreditation** (A2LA) is a full member of ILAC and is recognized to be compliant with ISO/IEC 17011. But, at this time, A2LA is not approved by CMS. It has an application pending with CMS for this authority.

"By contrast, the **College of American Pathologists** (CAP) is a CMS-approved accreditation body. And CAP does offer 'CAP ISO 15189'. But it is not itself recognized as being compliant with ISO/IEC 17011," said Tholen. "CAP is an affiliate member of ILAC and has not applied for recognition by other members.

"There are other CMS-approved laboratory accreditation bodies here in the United States," he added. "However, none of these bodies offer accreditation to ISO 15189 and none of these bodies are mem-

Understanding the Hierarchy of the ISO System and Accreditation of Testing Laboratories

THERE IS A DEFINED HIERARCHY within the international conformity assessment system. It includes not just laboratory accreditation, but also quality management systems, personal certification, inspection services, and product certification.

There are three levels in this hierarchy. It is important that companies and clinical labs understand the structure of this hierarchy when considering whether to seek certification to ISO 9001 or accreditation to ISO 15189.

"What underpins this hierarchy are standards developed by the International Organization for Standardization (ISO)," stated Daniel Tholen, founder and owner of Dan Tholen Statistical Consulting. "ISO writes the requirements for the different ISO systems. The top level of the hierarchy are the members of ILAC and IAF. These are the accreditation bodies that accredit conformity assessment bodies. These organizations must operate in conformance with ISO 17011 and be recognized by their peers in this regard.

"The second level in the hierarchy is made up of the conformity assessment bodies that are accredited to be competent," he continued. "On the ILAC International Laboratory Accreditation Cooperation side, this includes laboratories involved in testing and calibration, (including medical/clinical testing). On the IAF (International Accreditation Forum) side, included are organizations that certify quality management systems.

"Included are: 1) organizations that certify QMS (accredited to ISO 17021); 2) inspection bodies (ISO 17024); 3) reference material producers (ISO Guide 34); 4) proficiency testing providers (ISO/IEC 17043); 5) testing and calibration laboratories (ISO/IEC 17025); and, 6) medical laboratories (ISO 15189)," said Tholen.

"In the third level of the hierarchy are found: 1) certified organizations or companies (as under ISO 9001); 2) people or products—including manufacturing and service organizations—that have a QMS; and, 3) professionals or products that are tested or inspected for compliance with specifications," noted Tholen. "For medical laboratories the third level of the hierarchy are the *patients*, since their specimens were inspected, tested, or measured in some way, for conformance with some expectation, or inquiry.

Accreditation Hierarchy

"We can see how this hierarchy works by looking at our country," continued Tholen. "The sole IAF member for the United States, is the **American National Accreditation Board** (ANAB), which is a cooperation between the **American National Standards Institute** (ANSI) and the **American Society for Quality** (ASQ). ANAB is the entity in the U.S. which represents IAF at the first level. On the ILAC side of the first level in the hierarchy, there are seven accreditation bodies recognized as full members of ILAC.

"At the second level in the hierarchy, ANAB accredits 46 organizations to offer certificates of compliance with ISO 9001 and other ISO management system standards here in the United States," stated Tholen. "At the same level in the hierarchy, ILAC members accredit over 5,000 testing and calibration laboratories, inspection bodies, proficiency testing providers, and reference material producers. Clinical laboratories are included, although the number is very small (only two clinical labs in the U.S. are accredited to ISO 15189 by an ILAC-recognized body, and a growing number are accredited by CAP under their proprietary system, which is not recognized by ILAC or IAF).

"The third level in the hierarchy is very diffuse for medical laboratories—they are the *patients* whose specimens have been sampled, inspected, and measured," explained Tholen. "Or, more broadly in ILAC, the products that have been tested, measured for acceptability, and products that have been inspected. On the IAF side, the third level is filled by the thousands of organizations with certified quality management systems as well as certification of products and personal competence."

How Ontario Province Uses ISO 15189 for Accreditation

LOOKING NORTH TO CANADA, the laboratory licensing program in the Province of Ontario shows how ISO 15189 functions as an internationally-accepted standard for medical laboratory accreditation.

The **Ontario Medical Association** (OMA), as an agent of the **Ministry of Health and Long-Term Care** (MOHLTC), created a quality management program for licensed medical laboratories in Ontario. It is called QMP-LS, for **Quality Management Program-Laboratory Services**.

The **Ontario Laboratory Accreditation** (OLA) is one component of QMP-LS. With the publication of ISO 15189:2003 Medical Laboratories, OLA adopted those standards as the way for clinical laboratories in Ontario to meet licensing requirements.

OLA's web site (*http://www.qmpls.org*) describes how it meets ISO/IAF/ILAC requirements:

QMP–LS identifies, designs and delivers external quality assessment (EQA), accreditation and education services and related products that meet its regulatory mandate, relevant international standards and client and stakeholder requirements. QMP–LS has been issuing accreditation certificates since 2003.

Clients from other jurisdictions in Canada or other countries may voluntarily apply for accreditation and/or participate in EQA surveys.

Accreditation processes are aligned with ISO 17011:2004 Conformity Assessment—General requirements for accreditation bodies accrediting conformity assessment bodies and International Laboratory Accreditation Cooperation (ILAC) guidelines for assessor qualifications, training and competence.

EQA surveys are conducted in accordance with ISO standards and ILAC guidelines for competent proficiency testing schemes. For more information on EQA surveys, see "Program Information" at http://www.qmpls.org/eqa/eqa.html.

bers of ILAC. There are also other accreditation bodies in the U.S. recognized to comply with 17011, but they do not offer 15189.

"It should be of interest to medical laboratories in the United States that several important U.S. federal agencies fully recognize the integrity of the ILAC system involving accreditation of testing laboratories," he continued. "For example, A2LA accredits all of the FDA's laboratories in the **Food Safety Inspection Service** (FSIA).

U.S. Federal Agencies

"Similarly, the **U.S. Department of Defense Environmental Laboratory System** consists of 260 laboratories which are accredited by four different U.S. members of ILAC," added Tholen. "The same is true of testing laboratories involved in the **U.S. Consumer Product Safety System** (CPSS).

"The area of consumer product safety shows how ISO creates a uniform international standard," offered Tholen. "In the United States, hundreds of ISO-accredited testing laboratories are involved in this field. These labs are accredited by six different U.S. accreditation bodies.

"The accreditation of these U.S. laboratories to ISO 17025 is recognized by any ILAC Full Member anywhere in the world," he emphasized. "That works in reverse. For test methods of interest to the U.S. Consumer Product Safety Commission, test results from accredited consumer safety testing laboratories in other countries are recognized in the United States."

ISO 15189 Goes Global

Growing global acceptance of ISO 15189 is one example of the internationalization of clinical laboratory testing. This may be one factor that encourages more clinical labs in the United States to pursue accreditation under ISO15189. TDR

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Competitive Bidding Update

Two Years Later, CMS Still Holds Labs' Competitive Bid Documents

IF ACTIONS SPEAK LOUDER THAN WORDS, then the federal government sends a clear message by its repeated refusal to return bidding documents to laboratories involved with the now-defunct Medicare Clinical Laboratory Services Competitive Bidding Demonstration project.

That's because, more than two years after a federal judge in San Diego made a ruling that stopped the federal **Centers for Medicare & Medicaid Services** (CMS) from proceeding with the laboratory services competitive bidding demonstration project, the government still refuses to return the bid documents.

THE DARK REPORT has learned that negotiations are taking place between lawyers for the federal government and lawyers representing the plaintiff labs in San Diego that participated in the competitive bidding demonstration project two years ago. The two sides are negotiating over whether CMS should return, destroy, or do something else with the bidding documents the labs submitted on February 15, 2008. *(See TDR, April 15, 2010.)*

CMS Seeks to Dismiss Case

The labs that sued in federal court to challenge the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project are **Sharp Healthcare**, **Internist Laboratory**, and **Scripps Health**. Other plaintiffs in the lawsuit are the **American Association of Bioanalysts** (AAB), and the **American Clinical Laboratory Association** (ACLA).

Last month, on March 18, Judge Thomas J. Whelan of the U.S. District Court for the Southern District of California, denied a motion by CMS to dismiss the amended complaint originally filed by the plaintiff labs to challenge CMS' retention of the bid information from three San Diego labs and to dissolve the preliminary injunction against CMS that the labs had won in April 2008. The preliminary injunction prevented CMS from proceeding with the bidding project. Also in 2008, Congress repealed the competitive bid demo by statute.

CMS Retains Lab Bid Papers

Prior to Judge Whelan's ruling on March 18, one of the plaintiffs' attorneys told THE DARK REPORT that "federal lawyers are taking a hard line on this case so far. Even though there is a new administration in place at CMS, we speculate that they may not like the precedent represented by this case, since it could potentially establish terms or limits on their discretion to use this kind of information."

CMS officials suffered two major setbacks in their efforts to introduce competitive bidding for laboratory testing services. First, as noted above, the federal judge's ruling in 2008 effectively stopped the demonstration project from moving forward. Then, in the summer of 2008, Congress repealed the mandate for the laboratory competitive bidding demonstration as part of the Medicare funding legislation.

Yet despite both setbacks, Medicare officials refuse to return the laboratories' bidding documents. Is this a sign of the substantial value that such confidential cost and price information has for Medicare officials? At this point, there is no evidence or public comment that would indicate CMS has used any of the bid information for any purpose. TDR

Lab Quality

Errors in Surgical Pathology Surface in the United Kingdom

Starting 10 years ago, physicians in Bristol, England alerted NHS officials about problems in lab test accuracy

ERRORS IN SURGICAL PATHOLOGY DIAGNOSES made the newspapers in the United Kingdom earlier this month. The accuracy of histopathology results at the **Bristol Royal Infirmary** (BRI) in Bristol, England was the subject of a news story in *The Sunday Telegraph* on April 10.

Under the headline "Doctors fear that cases of cancer have been regularly missed in a scandal over botched diagnoses which goes back a decade," *The Sunday Telegraph* reported that physicians in the **University Hospitals Bristol NHS Foundation Trust** (UHB), which operates the Bristol Royal Infirmary, have raised concerns about "repeated and critical blunders" occurring in BRI's anatomic pathology laboratory. According to the newspaper, these concerns date back as far as 2000.

The Telegraph wrote that "submissions by specialist doctors said other serious errors [in pathology diagnoses] had caused the death of a child, while other patients were treated for the wrong disease, received a late diagnosis, or were given needless toxic treatment."

NHS Launches Audit

Evidently these allegations had enough merit to cause officials at the **National Health Service** (NHS) to launch an inquiry last summer. An audit of a random sample of 3,500 tissue specimens that were originally evaluated by BRI's pathology department is being conducted.

The public has learned that one patient who was misdiagnosed was an employee of the UHB trust. Jane Hopes was a 55-year-old senior manager in Bristol. She died in 2004, three years after an NHS biopsy failed to detect her breast cancer.

Hopes' family has said neither Hopes—while she was alive—nor anyone in her family had ever been told that physicians at the hospital where she worked believed that the lump in her breast had been wrongly diagnosed as benign, at a time when her disease was in its earliest stages.

What caught the attention of the *The Sunday Telegraph* is the fact that NHS officials do not appear to have taken effective action in response to concerns raised by physicians about the failures in the accuracy of pathology services at BRI, dating back as far as 10 years.

It is not yet known what specific problems in the diagnostic accuracy of pathologists and/or laboratory testing problems may have occurred at the BRI histopathology service since 2000. What *The Sunday Telegraph* published on April 10 were multiple examples over the past decade of physicians stepping forward to notify NHS administrators of their belief that inaccurate pathology test results had been reported on their patients.

By itself, this fact is notable. Physicians are well-positioned to gauge the reliability and consistent accuracy of the lab test results produced by a specific laboratory. What remains to be seen is whether NHS officials at the UHB health trust will be forthcoming once the findings of their audit of the 3,500 BRI pathology cases is finished. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Laboratory testing in India continues to attract the attention and investment dollars of western companies. News reports indicate that **Apax Partners** is negotiating to buy a stake in **Metropolis Healthcare** of Mumbai, India. Metropolis Healthcare has business activities ranging from clinical laboratory testing to home health services. Metropolis operates 55 testing laboratories in India, Sri Lanka, United Arab Emirates, South Africa, Bangladesh, and Seychelle and is said to process more than 10 million tests annually. Metropolis has been an aggressive acquirer of clinical laboratories in recent years.

MORE ON: *India, Apax*

Apax Partners has a track record of investments in clinical laboratories in several different countries. Alert readers may recall that Apax Partners recently sold its interest in **Spectrum Laboratory Network** (Greensboro, North Carolina) in December 2009. Apax had also been an investor in **Unilabs** of Switzerland. It sold that interest in 2007. These transactions indicate that Apax is bullish on the future of clinical laboratory testing and sees opportunities in other countries besides the United States.

FIRE DESTROYS TACOMA FACILITY OF STERLING LABS

Last month, a specimen collection site owned by **Sterling Laboratories, Inc.**, of Tacoma, Washington, was heavily damaged by fire. Arson investigators stated that the blaze was deliberately set. Firefighters were called to the scene at 2:45 a.m. on Friday, March 27. Sterling Laboratory officials said laboratory testing services, located at another site, would continue without disruption. This incident is a reminder that clinical laboratories and pathology groups should review current fire insurance coverage and take steps to secure and protect important documents and equipment from these types of unexpected events.

HBO BIOPIC ABOUT JACK KEVORKIAN TO AIR ON APRIL 24

Actor Al Pacino will play the role of pathologist Jack Kevorkian in a movie to be aired by **HBO** on April 24. The film is called "You Don't Know Jack." Kevorkian, now 82, was released from prison on parole in 2007. He had been convicted of second degree murder for assisting in the suicide of Thomas Youk in 1998.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...**Procter & Gamble's** purchase of **MDVIP**, a concierge medicine company. It employs 350 physicians in 28 states. Ownership of this physician practice firm gives P&G a window to learn about patient needs.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 10, 2010.