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SPECIAL!

First Interviews and News!

Two Innovative Laboratories Soon to Achieve ISO 15189 Accreditation

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

Quality Management Systems (QMS) & Healthcare

OFF THE RADAR SCREEN OF THE LABORATORY INDUSTRY is an evolving management approach that gives unity to the mishmash of quality improvement tools that carry a variety of names, but have several common attributes.

Soon lab directors and pathologists will be quite familiar with the concept of the "quality management system" (QMS). *Wikipedia* describes it thusly:

> *Quality Management System (QMS) can be defined as a set of policies, processes and procedures required for planning and execution (production / development / service) in the core business area of an organization. QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. QMS enables the organizations to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance.*

Over recent decades, industry has developed the concept of "quality management systems" as a way to allow *all* business, organizational, and operational functions within the enterprise to utilize the basic management principles identified by W. Edwards Deming, Joseph Juran, Taiichi Ohno, and others, including Henry Ford. These principles are rooted in such shared management precepts as "system of prevention," continuous improvement, "only the customer defines quality," and use of statistical process control (SPC) to improve quality and reduce variation.

QMS is just now reaching healthcare. Within the laboratory industry, it is well known to the *in vitro* diagnostics (IVD) manufacturers and the QA/QC professionals inside clinical laboratories. I predict that soon many labs will have a QMS. Since early in this decade, THE DARK REPORT has been consistently early, if not the first voice in the lab profession, to alert laboratory leaders as to how and why calls for improved patient safety, reduced medical errors and greater use of evidence-based medicine (EBM) will require their laboratories to adopt different management philosophies and methods. So it is with QMS.

ISO 15189:2007 Medical Laboratories is a quality management system. In this issue of THE DARK REPORT, you have the only public interviews by the nation's first two laboratories to adopt ISO 15189:2007. It marks another milestone on the quality management journey of the laboratory profession, and once again, THE DARK REPORT is giving you a front row seat to watch events unfold and position your laboratory for success with QMS! TDR

Two U.S. Labs Pursuing ISO 15189 Accreditation

Nation's first ISO:15189 accreditations will be milestone in use of quality management systems

CEO SUMMARY: In their first public interviews, the nation's only two laboratories to seek ISO 15189:2007 accreditation share insights about the process, along with its challenges and benefits. Both laboratories are in the final stages of implementation and expect to earn accreditation by year end. Their achievement will represent the next advance in how laboratories in the United States use quality management systems and the tools of continuous improvement.

TWO LABORATORIES IN THE UNITED STATES ARE WEEKS AWAY FROM ACHIEVING accreditation under ISO 15189:2007 Medical Laboratories. These will be the first ISO 15189 accreditations in this country.

The two labs working toward their ISO 15189 accreditation are **Piedmont Medical Laboratory** (PML) in Winchester, Virginia, and **Avera McKennan Hospital & University Health Center** in Sioux Falls, South Dakota. PML processes about one million tests per year and Avera McKennan processes almost three million tests per year.

This is a notable development for the laboratory industry in the United States. Because ISO 15189 is designed to be a comprehensive quality management system (QMS), it will provide American laboratories with valuable lessons about the benefits and costs involved to become accredited under ISO 15189:2007.

Lab leaders at both Piedmont and Avera were among the first in the nation to embrace and implement Lean and Six Sigma earlier in this decade. This fact adds interest to the decision by each of these laboratories to devote considerable time and resources to attain accreditation under ISO 15189:2007 Medical Laboratories.

It shows how the original decision to introduce quality management systems, including Lean and Six Sigma, encourages a laboratory to further advance its use of continuous improvement techniques. Additionally, both laboratories believe that ISO 15189:2007 accreditation will make them tougher competitors in the lab outreach marketplace. One reason is that, outside healthcare, many companies are

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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ISO-accredited. They and their employees understand and recognize the value of this achievement, as do many payers.

This issue of THE DARK REPORT contains interviews with leaders of both Piedmont Medical Laboratory *(pages 5-8)* and the Avera McKennan laboratory *(pages 9-11)*. In each case, it is the first time either laboratory has been willing to publicly discuss why they decided to pursue accreditation under ISO 15189:2007, as well as the benefits and challenges of the ISO 15189 accreditation process.

➤Lab Quality Confab Speeches

Lab directors and pathologists have the opportunity to personally meet these lab leaders and hear more about their experience with ISO 15189. Each lab is presenting at the upcoming *Lab Quality Confab* in Atlanta on September 24-25. Piedmont Medical Lab's Quality Management, Compliance and Education Coordinator, Benita Haines, will do the first public presentation about her lab's experience with ISO 15189 accreditation. By the time of *Lab Quality Confab*, PML will have completed the assessment step and will be awaiting confirmation that it has met all accreditation requirements. Also speaking at *Lab Quality Confab* is Leo Serrano, Director of Laboratory Services at Avera McKennon. He will discuss his lab's use of Lean Six Sigma methods and automation, particularly in histology.

➤Growing Role For ISO 15189

THE DARK REPORT recommends that lab administrators and pathologists begin paying closer attention to ISO 15189:2007 and its growing acceptance as an international standard for laboratory accreditation and reimbursement. This international trend is likely to have consequences for laboratories in this country. Two points support this prediction.

First, around the globe, ISO 15189 is being adopted by a steadily-increasing number of countries which, up to now, have never mandated any form of medical laboratory accreditation. That number may be reaching critical mass. For example, the **World Health Organization** (WHO) and the **Centers for Disease Control and Prevention** (CDC) conducted the "Joint WHO-CDC International Conference on Health Laboratory Quality Systems" in Lyon, France, earlier this year, on April 9-11. Upwards of 150 delegates from 69 countries participated at this meeting and there was plenty of discussion about the fitness of ISO 15189:2007 for use as a laboratory quality system *(http://www.who.int/csr/ihr/lyon/-eqauconference/en/index.html)*.

Second, in the Canadian province of Ontario, mandatory laboratory accreditation is based upon ISO 15189:2007. It is estimated that, by year's end, almost 200 laboratories in Ontario will have earned ISO 15189 accreditation.

➤Laboratory Accreditation

These two examples show that ISO 15189 is gaining international acceptance as a useful approach to laboratory accreditation. This development has not attracted much attention in the United States. That is probably because labs in this country already must comply with long-established state and federal requirements for licensure and accreditation.

ISO 15189:2007 is not likely to rapidly change this licensure/accreditation status quo. But something else may occur. It was earlier in this decade when a handful of pioneering labs began to adopt Lean and Six Sigma methods and used them to realize impressive gains in operational quality, productivity, and financial performance—often generating competitive advantage in the outreach marketplace.

So it may be that a handful of pioneering labs, led by Piedmont and Avera McKennan, choose ISO 15189:2007 accreditation as the quality management system they use: 1) to drive further improvement to their laboratory's quality and performance; and, 2) to gain competitive market advantage at the same time. TDR

Piedmont Med Lab Mixes ISO with Lean & Six Sigma

While working toward ISO:15189 accreditation, Piedmont Med Lab generates increased productivity

CEO SUMMARY: Piedmont Medical Laboratory (PML) could be the only clinical laboratory ever to pursue three quality improvement initiatives simultaneously. Even as it was in the early stages of implementing both Lean and Six Sigma methods, PML also decided to seek ISO 15189:2007 accreditation. Since 2004, the lab has worked diligently to put all three programs in place. The lab is currently preparing for its final assessment that will lead to formal accreditation under ISO 15189:2007.

IN THE NEXT FEW MONTHS, **Piedmont Medical Laboratory** (PML) of Winchester, Virginia, has a good chance of becoming the nation's first laboratory to achieve accreditation under ISO 15189:2007 Medical Laboratories.

This month, PML is preparing for the last step in ISO 15189 accreditation: assessment by independent auditors. This comes after the lab's gap assessment was conducted last April and the pre-assessment audit was completed in July. PML is using the **College of American Pathologists** (CAP) as its accrediting body.

"Achieving accreditation under ISO:15189:2007 is a milestone that caps the quality management strategy initiated here at PML in 2004," stated Benita Haines, PML's Quality Management, Compliance and Education Coordinator. "At that time, the decision was made to simultaneously introduce Lean and Six Sigma methods while laying the groundwork for ISO 15189 accreditation."

The strategy of introducing continuous improvement throughout the laboratory has paid regular dividends for PML. "We see steady gains in productivity, along with comparable improvements in quality, fewer errors, and reduced costs," noted Haines. "Lean, Six Sigma, and our transition to the ISO 15189:2007 standards have worked in combination to produce these outcomes."

Piedmont Medical Laboratory is a joint venture, for-profit, independent laboratory located in Virginia's Shenandoah Valley. Founded in 1991, it is owned by three healthcare systems and two independent pathology groups.

Competitive Strategy

PML launched its quality management program back in 2004 as a deliberate strategy to improve its ability to compete for outreach business in its region. "Like regional laboratories everywhere, Piedmont Medical Laboratory recognized how managed care companies were taking steps to monitor the quality of services provided by physicians, laboratories and other providers," noted Joe Skrisson, CEO at PML. "We wanted to be ready to meet tightening payer criteria covering clinical quality, service performance, patient satisfaction, and similar factors.

"Our quality management strategy was specifically crafted to prepare PML to meet payer requirements that could possibly exclude PML and other local laboratories," continued Skrisson. "Our ISO, Six Sigma, and Lean efforts help us improve quality, sustain high levels of patient and physician satisfaction, and reduce our error rate. These tools are important to make sure that our lab doesn't get excluded from managed care contracts.

Managed Care Contracts

"Obviously, the largest national labs are very good at helping managed care organizations include criteria in their contracts that could exclude competitors like us," he explained. "As a regional lab, you have to be on the alert for such criteria and either stay parallel with these national lab competitors or get ahead of them in some way. That's part of what we're doing here with our ISO, Six Sigma, and Lean initiatives."

Many laboratories now use Lean and Six Sigma methods as a way to improve performance and become tougher competitors. But taking on the challenge of an ISO 15189 accreditation remains a rare event. For PML, the decision to become ISO 15189–accredited actually starts in Detroit, a long way from the verdant hills of the Shenandoah Valley.

"Prior to my arrival at Piedmont Medical Laboratory in 2004," explained Skrisson, "I was at **William Beaumont Hospital** in Detroit where we were one of the first labs to use ISO 9001 standards. At the time, everyone thought we were crazy to do this.

Employers Recognize ISO

"But Detroit was the perfect environment for a laboratory to pursue ISO accreditation," he noted. "That's because the auto companies, the tool and die companies, and other supply firms in Greater Detroit are all ISO-compliant themselves. They recognize the value of pursuing ISO quality standards. Further, as patients, our lab served many employees of these companies. Beaumont lab's ISO status gave us competitive advantage with employers and payers in this market.

"It's difficult to explain to some employers what the **Joint Commission** and CAP (College of American Pathologists) accreditation means to them," Skrisson explained. "But when your lab is ISO accredited, they immediately know what that means because they may be ISO accredited as well. They understand the terminology and know what we had to achieve to become accredited. It is an international language of quality and competence."

PML has a staff of 100, including couriers and billing professionals. It serves 13 patient service centers and eight hospitals in the Shenandoah Valley. It also serves 300 physicians and nursing homes in its outreach program. Its core lab in Winchester handles up to 1,300 requisitions daily and about 750,000 billed procedures (about 1 million tests) annually.

Dramatic Results At PML

Skrisson explained that all three quality improvement efforts have produced dramatic results at PML. "Our Lean initiative supports the ISO effort by helping us continually improve efficiency," he explained. "One example is the change in how we handle specimens. With Lean, we now process specimens in real time, as they arrive in the laboratory. We no longer hold specimens until the afternoon and evening shifts to then test them in batches. This has generated significant improvements in productivity, reduced costs, and faster turnaround times."

"Work flow analysis using Lean and Six Sigma methods also helped us re-route our couriers to support continuous flow of specimens into the lab," added Haines. "Lean, Six Sigma, and ISO require us to look more closely and more critically at everything we do. Another example is our introduction of scanning software to aid our staff in looking up requisitions, there-

ISO 15189 Accreditation Typically Requires Two Years and Nine Performance Steps

IN THE UNITED STATES, the **College of American Pathologists** (CAP) of Northfield, Illinois, offers a lab accreditation program based on the International Organization for Standardization (ISO) 15189:2007 standard for medical laboratories. CAP advises laboratories that the accreditation process involves the following nine basic steps and typically requires two years to complete:

- One: Gain support from key executives, including senior administrators and medical officers, among others.
- Two: Read an official copy of the ISO 15189:2007 standards. A laboratory must purchase an official copy of the standards to become accredited from www.ISO.org or www.ANSI.org.
- Three: Assign appropriate roles for conducting an internal audit. This step may involve updating the organizational chart with key personnel. Those who would be involved in directing the effort would include the laboratory director, all supervisors, all internal auditors, and the quality manager.
- Four: Apply for 15189:2007 accreditation through CAP.
- Five: For organizations that may be unfamiliar with ISO, CAP recommends a gap assessment done 90 days in advance of an accreditation assessment. This assessment will provide a detailed review to the standards to determine areas of strengths and weaknesses. A pre-assessment is a dry-run assessment that is a high level review for degree of conformity to the standards and will take place within 90 days of the accreditation assessment.
- Six: Conduct an internal audit to ISO 15189, document the findings, perform a root cause analysis, take corrective actions as needed, and continue auditing and taking corrective actions until all major nonconformance issues are resolved.
- Seven: Document participation in external quality assessment schemes and proficiency testing programs for all tests and evidence of participation over the preceding two years.
- Eight: Update the lab's quality manual, including the quality policy and any supporting documentation.
- Nine: After correcting all nonconformance issues identified in the internal audit, schedule an accreditation assessment.

fore improving turnaround time in the customer service department."

ISO was a key part of PML's quality improvement program from the very start. "As we launched implementation in December 2004, our lab had no quality manual," recalled Haines. "With the help of a consultant, we produced our first quality manual by cross-referencing the lab's policies to ISO 15189:2003 standards. That was a huge education for our staff!"

"In fact, one of the biggest insights from this effort has been to better understand the wide variance in how individual employees perform work," she continued. "It's been a major effort to standardize all work processes, document each practice, then help staff perform their duties using these standard work practices. This all happened as a direct result of the document control portion of the ISO standard. Our motto here now is: "Say what you do and do what you say."

Moving Forward With Lean

"Then we introduced other initiatives such as Lean and Six Sigma," continued Haines. "Staff attended classes to become certified as Six Sigma green belts and black belts and to learn about Lean methodologies.

"Overall, it is a challenging and rewarding process that is helping us significantly improve our work processes, quality, and productivity," Haines concluded. "Two important lessons we've learned are, one, the value of standardizing work practices and, two, the documentation of processes and procedures."

ISO Provides Framework

Skrisson agreed, saying, "If your lab has implemented a process improvement program, then ISO accreditation supports that effort very well. It gives the laboratory a framework that gets people at the bench level involved, particularly because they understand these procedures and how it guides their work.

"In fact, during the assessment process, ISO auditors don't spend much time with directors like me," added Skrisson. "They focus on the technicians to confirm that they are following protocols and using standard work. From that perspective, ISO is good for the staff because it reinforces process improvement while helping the lab create a system and culture that guides everyone in their work."

Three Improvement Initiatives

THE DARK REPORT observes that PML is an uncommon example for other labs installing quality improvement models. By introducing three initiatives at the same time (Lean, Six Sigma, and ISO 15189), PML shows what is possible when seeking to improve processes. It also demonstrates that ISO 15189:2007 accreditation supports these other quality improvement initiatives while simultaneously preparing a lab to compete more effectively in its own market and in the increasingly global healthcare market.

Another noteworthy aspect to the quality improvement effort at Piedmont Medical Laboratory is that it demonstrates how even regional laboratories and smaller hospital lab outreach programs can successfully implement quality management programs like Lean, Six Sigma, and ISO 15189:2007. Once the commitment is made to introduce these quality methods, laboratories can quickly generate improved productivity while lowering operational costs. These savings can be then re-invested into further support for ongoing deployment of Lean, Six Sigma, and ISO 15189. TDR

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Piedmont's Timetable for ISO 15189 Accreditation

EXPECTATIONS ARE THAT Piedmont Medical Laboratory (PML) will receive its accreditation under ISO 15189:2007 Medical Laboratories by year end.

"In April, our lab completed its gap assessment," stated Benita Haines, PML's Quality Management, Compliance and Education Coordinator. "Next, in July, our pre-assessment was conducted.

"Now we are preparing for the auditors to conduct our true assessment," she said. "That is scheduled for this week (September 9 to 11). Following this assessment, on September 11, there will be a summation meeting with the auditors. If the laboratory has no nonconformance issues to address, the auditors will submit that information to the accrediting body.

"Should any nonconformance issues be identified, we have 30 days to submit corrective actions. Assessors then have 30 days to submit that information to the accrediting body," noted Haines. "We expect to learn the outcomes of this assessment and our accreditation status anytime between the middle of October and the end of the year."

ISO 15189 Is the Goal At Avera McKennan Lab

Lab is using four years experience with Lean as cornerstone for ISO 15189:2007 accreditation

CEO SUMMARY: Now entering its ninth month on the path to accreditation under ISO 15189:2007 Medical Laboratories, Avera McKennan's lab recently completed its "gap analysis." This important step prepared the laboratory for the pre-assessment and assessment steps that will result in accreditation. Leaders at Avera McKennan expect this achievement will provide competitive advantage to the laboratory, as well as reinforce the health system's public reputation for quality.

HAVING INTRODUCED LEAN INTO THE LABORATORY more than four years ago, achieving accreditation under ISO 15189:2007 was viewed as a desirable next step in the laboratory's quality management efforts at **Avera McKennan Hospital and University Health Center** in Sioux Falls, South Dakota.

Competition was another important factor motivating laboratory leadership to seek accreditation under ISO 15189:2007. "I expect that having the ISO 15189:2007 accreditation will provide us with a competitive advantage," observed Leo Serrano, Director of Laboratory Services for Avera McKennan. "Here in South Dakota, we have an unusually competitive environment, and we compete not on price but on quality of care! In fact, we compete very aggressively on quality."

Meeting High Standards

"The market here in eastern South Dakota is the most competitive healthcare environment I've ever seen in my 44 years of working in healthcare," noted Serrano. "There are two major healthcare systems: Avera and **Sanford Health**. Particularly in the Sioux Falls metro, these health systems have a strong community orientation toward quality and both healthcare systems are top notch. Quality is such an important element here that it's not enough to be average, or even good.

"For that reason, Avera McKennan has pursued quality and won a number of quality awards," he added. "We were the first magnet hospital and the first burn center in the Dakotas. We were the first and only transplant center for bone marrow, kidney, and pancreas. The Sanford system has also emphasized quality."

Such an emphasis on quality helped Serrano gain approval for the laboratory's goal of achieving ISO 15189:2007 accreditation. "There's been incredible support from the administration and the board of directors at Avera," said Serrano. "The Presentation Sisters and the Benedictine Sisters are equally supportive of our lab's pursuit of this accreditation.

"Avera's support for improving the quality of health services can be seen in how this proposal was approved," he continued. "It did not require board approval. I proposed this to my boss, the COO and,

in a meeting with the COO and CEO, they both said, 'Go for it!' A cost-benefit analysis wasn't required because the benefits of this accreditation were obvious to an organization focused on quality.

"At Avera, we are in our fourth year as a Lean laboratory and we've taken Lean to the Nth degree," Serrano continued. "We've also been a Lean showplace and have hosted more than 100 to 150 site visits in this facility over four years. That's an average of more than 25 site visits a year.

"We might even have a slight advantage over other labs in that our lab is accredited not only by the **College of American Pathologists** (CAP), but also by the **American Association of Blood Banks** (AABB) and, because we are a transplant center, we have the **Foundation for Accreditation of Cellular Therapy (FACT)** accreditation," Serrano said. "Several of these certifications—particularly FACT's accreditation—mimic the ISO 15189 format in many ways. It is one reason our laboratory has very high quality results and low error rates.

"But ISO 15189:2007 accreditation takes quality to a whole different level," he explained. "From our perspective in the lab and here at Avera McKennan, achieving accreditation under ISO 15189:2007 is the ultimate badge of laboratory quality.

"But no lab director or pathologist should underestimate the level of effort required to achieve accreditation under ISO 15189:2007," said Serrano. "Our laboratory already had high standards of quality. However, since last January, when we started the process of applying for ISO 15189:2007 accreditation, this experience has caused us to see quality and work processes in the lab from a different and valuable perspective.

Revising Process Maps

"These insights have led us to revise and rewrite all of our policies, procedures, and documentation to make them more robust," he added. "We also revised, distilled, and clarified our process maps, which is a significant step.

"The lab already had process maps, but they weren't in the ISO-required format," stated Serrano. "The extensive time spent reformatting these process maps turned out to be quite useful because it helped us identify and improve gaps in our existing processes.

Staff Involvement

"Throughout this process, we've been teaching our staff to understand what we were doing and how quality management is improving many aspects of our laboratory," he explained. "This step was possibly the most challenging part of the process because we have a staff of 125 to 130 people and every individual needs to understand every part of the process.

"Sustaining this high level of communication and interaction is a significant challenge," Serrano observed. "Laboratory staff ranges from phlebotomists, clerks, and couriers to professionals with graduate and doctoral degrees, along with all the physicians in our pathology group. Every member of the laboratory staff needs to be on the same page, which is challenging for any lab. And, because our staff pathologists are an independent group practice, we needed their commitment for the ISO 15189:2007 accreditation effort to succeed.

"This educational process is about both competency and ensuring the entire staff is involved and understands what ISO 15189:2007 accreditation means to the lab, to our patients, and to their work environment," Serrano explained.

"Since our laboratory had completed that step, our next step was the gap assessment," he said. "For that, the assessors talked to the staff in the lab—and did not just talk to the directors—to verify that staff conducts their work daily in a manner that follows written policies and procedures. Simply stated, the gap assessment is a check to confirm that we do and act every day consistent with the quality management methods and principles articulated and defined in our written materials.

"ISO 15189:2007 accreditation assessments are highly detailed and thorough," stated Serrano. "We expected our lab's gap assessment to be different from all the other inspection visits we have had over the years, and it was.

"The gap assessment is the first indication of how we measure up against the standards," he explained. "It gave the lab an understanding of its level of readiness and what corrections need to be made to prepare for the next step, which will be pre-assessment. Pre-assessment is a dress rehearsal before the actual accreditation assessment. The gap assessment permits us to revalidate our process, make corrections, and move forward to the accreditation assessment with greater confidence.

Beyond Policies, Procedures

"For this reason, everyone on staff needs to understand the policies and procedures, the resources, and the mechanisms that we have throughout our laboratory's operation," he explained. "The entire ISO process focuses on operational activities.

"This is a notable difference from most other healthcare accreditations that generally involve a review of our lab's policies and procedures to make sure we have dotted all the 'i's and crossed all the 't's," Serrano added. "ISO does that as well, but then ISO goes several steps further by verifying that: 1) your staff knows exactly what the policies are; 2) your staff understands why these policies are in place; and, 3) assessors confirm your lab's staff consistently follow these procedures each day.

"For lab administrators and pathologists considering this accreditation for their laboratory, I can state that one important difference about ISO 15189:2007 is that it is not simply a paper exercise," advised Serrano. "ISO 15189:2007 is a true, thorough, and deep evaluation of your facility to make sure that quality is ingrained in the very essence of the laboratory."

Serrano also emphasized that it requires staff time and other resources to undertake the goal of achieving ISO 15189:2007 accreditation. "To get our laboratory to the point where we could conduct the gap assessment, I estimate that we've had two full-time equivalent staff on this project since January," he said. "It's a full-time job for our Quality Systems Manager, Sheryl Wildermuth. It's also required considerable involvement by our Medical Director, Raed A. Sulaiman, M.D.; our blood bank Medical Director, Henry Travers, M.D.; and our technical specialists and supervisors. Of course, the entire staff has contributed an inordinate amount of time to support this accreditation effort."

Serrano hopes that the pre-assessment and the accreditation assessment can be completed before year's end. His laboratory is working with the **College of American Pathologists** (CAP) as the ISO 15189:2007 accreditation body.

"As a laboratory committed to continuous improvement, in a health system committed to quality and patient care, our decision to become accredited under ISO 15189:2007 represents our desire to move to the next higher level of performance," summarized Serrano. "With healthcare transforming into a patient-centered care model in which outcomes are closely monitored, we want our lab to raise the competitive bar. To do that, we must be bold at introducing new quality management tools and methods that allow our lab team to achieve more."

More Labs May Chose ISO

THE DARK REPORT observes that it is significant that Avera McKennan sees a competitive advantage in pursuing ISO 15189:2007 accreditation. While the Sioux Falls market may be different from most, it may nonetheless foretell what is to come in other regions across the United States. If laboratories in such markets need to demonstrate that they can deliver high quality lab results and lab services, then they may also opt to pursue ISO 15189:2007 accreditation. **TDR**

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Health Record Databanks Are Different Than RHIOs

➤Health Record Banks (HRBs) are designed to be patient-controlled central data repositories

➤➤CEO SUMMARY: Forget CHINS from the 1990s and RHIOs from this decade. The future of regional health data repositories may turn out to be a patient-controlled model, often called a "Health Record Bank" (HRB). Here is the lab industry's first look at this nascent movement. HRBs are under development in Louisville, Kentucky, the State of Oregon (for the state's Medicaid beneficiaries), and the State of Washington. Other notable HRB advocates investing in the concept are Microsoft and Google.

ANY DISCUSSION OF SHARING HEALTHCARE DATA at the community, regional, or state level portends major threats and opportunities for laboratories serving patients within that geography. After all, laboratory test data comprises the overwhelming majority of information in a patient's long-term clinical record.

There is widespread agreement from most healthcare stakeholders that healthcare would benefit from some form of a single health repository. In the 1990s, the favored term was CHIN—Community Health Information Network. In this decade, the most common term is RHIO—Regional Health Information Organization. HIE—Health Information Exchange—is another way to describe this data repository model.

However, progress on creating such health data repositories at the community or regional level is proving problematic. The first challenge is to develop a funding model that sustains the data repository. The second challenge is to gain agreement among the participants on the technology to assemble, store, and make data available, along with the operating protocols of the HIE. The third challenge is getting all classes of providers, including hospitals and large clinics, to participate in the healthcare data repository. Many entities see their heath data as a proprietary asset. Thus, these providers are cagey about "supporting" the RHIO in their area while working to retain control over how data they hold are used.

➤Health Record Bank

Enter the "Health Record Bank" (HRB). This is a healthcare data repository concept which borrows from the financial banking model. Both patients and providers choose a health record bank, pay a fee and establish an account. Next, each time a patient visits a provider, the provider would feed information from that encounter into the patient's HRB. Of course, patients can also submit their own health data into the HRB.

Credible efforts are already under way to create the nation's first HRBs. For the past two years, in Louisville, Kentucky, the **Louisville Health Information Exchange** (LouHIE) has raised funding and developed a business plan. It expects to select a vendor this fall and initiate the first pilot

project in the second quarter of 2009. It is targeting system build-out for 2010.

In Oregon, during 2007, the state received a $5.5 million federal grant specifically to develop an HRB for the 400,000 patients covered by the **Oregon Health Plan**, which is the state's Medicaid Program. The data warehouse for this HRB is under development.

HRBs In Washington State

Next door to Oregon, the State of Washington is providing $3.4 million in seed money to help several communities organize and operate their own HRBs. Several large health systems are involved in this project. State officials hope to have the first community HRBs operational by February 2009.

The three examples presented above represent just one dimension in the gathering effort to make HRBs the dominant form of regional health information exchanges. As clients and long-time readers of THE DARK REPORT know, **Microsoft Corporation** and **Google** both launched well-financed, much publicized health record banks during the past 12 months. Because Microsoft and Google are both respected as strategic leaders in business uses of the Internet, their decision to enter the healthcare informatics marketplace by developing health records banks gives this concept added credibility. *(See TDR, May 27, 2008.)*

Both Microsoft and Google see the HRB business model as a natural extension of their primary businesses. Further, Microsoft and Google have a sophisticated understanding of how consumers currently use the Internet and why a health records bank service is likely to be both successful and financially lucrative down the road.

There are simple and obvious reasons why interest in the HRB approach is growing. The complexities of creating RHIOs, frustrate RHIO organizers and those healthcare providers in a region who must participate if the proposed RHIO is to function effectively. RHIOs need to get agreements on technology, to create operating rules, and to interface with all participating providers.

For example, as officials looked at progress to create RHIOs in the Pacific Northwest, these daunting challenges drove the decision in Washington State to develop health record banks. "To be frank, we don't think that [the RHIO model] is sustainable or feasible," says Juan Alaniz, Manager of the HRB project for the **Washington State Health Care Authority** in Olympia. "We think the real change will come from consumers having control over their healthcare information and sharing it with whomever they want to. The health record bank could be the disruptive technology to change the paradigm."

One leading advocate for health record banks argues that simplicity is the strength of HRBs. "You don't have endless meetings and discussions and data-sharing agreements and millions of dollars in legal fees," declared William Yasnoff, M.D., Ph.D., and the Founder of the **Health Banking Alliance**. "By using this simple construct—which is consistent with individual medical privacy—you are able to eliminate this whole layer of just maddeningly complex policy discussions about who should see what when."

Critics of HRBs

There are plenty of critics of HRBs, who say that consumers must step up and take responsibility for establishing their patient record in the HBR if this data model is to succeed. There must also be a large enough proportion of patients in a region participating in the HRB to motivate providers to access their patients' health records from the HRB.

Another criticism of HRBs is the possibility that some patients would manipulate the data in their personal health record. For example, how would a physician know whether a patient was withholding information that, if known by the physician, would influence treatment?

"The idea of giving control to the patient, for a lot of my colleagues, was a really hard one for them to wrap their heads around," stated James Hereford, who chaired the **Health Information Infrastructure Advisory Board** (HIIAB) that was created to advise Washington State legislators on options for creating a regional electronic patient health record solution.

➤Treating Data Appropriately

In developing the HRB concept, Washington State will provide ways that physicians can see the sources of data in a patient's record so that they can treat that data appropriately. Yasnoff suggests the HRB can be structured so that providers can deposit data into the health record bank that cannot be modified by the patient—but the patient could add notes in the record which providers would view when they access that data.

Because the concept of the health records bank represents one more approach toward creating a centralized repository of patient health data, laboratory directors and pathologists will need to track its emergence and progress. That's because laboratory test data comprise an overwhelming proportion of the long term patient medical record. Thus, the HRB model will directly change both how physicians and patients access laboratory test data and how they use it.

➤CHINs, Then RHIOs

Further, as noted earlier, CHINS in the 1990s proved unworkable and too complex. In this decade, RHIOs, the next generation in thinking about how to create regional health repositories, are proving equally challenging and expensive.

Thus, it should be no surprise that a consumer-centric approach to regional health repositories is emerging. However, the health record bank (HRB) model will generate its own controversies until a real-world demonstration project shows that this concept can work. TDR

Health Info Exchange Has Three Business Models

FOR SEVERAL DECADES, efforts to organize regional health data repositories have used the distributed (federal) model or the centralized model. Health record banks represent a third business model.

Distributed (Federal) Model: Writing in the *Group Practice Journal* (Vol. 55, No. 2, Page 38, February 2006) authors Victor Plavner, M.D., and Peter van der Grinten wrote about the distributed model common to RHIOs (regional health organizations), stating that "typical RHIO architectures rely on the use of a central data repository that, in turn, requires extensive integration and mapping of data from disparate systems to allow end-users to access and view the data across the network. For providers who have endured expensive data integration projects in their own organizations, the prospect of repeating the process in a network setting can appear daunting."

Centralized Model: In a story for the **American Health Information Association** (AHIA), writer Chris Dimick describes the centralized model as where "...participating organizations store a patient's data on a centralized data base. They form a community that links to the data base for health information exchange, submitting and withdrawing records. Though the centralized repository is similar to that of the health record bank model, control over the record lies with the providers, who own and manage the record."

Health Record Bank Model: Advocates of the health record bank (HRB) point out that organizing the health data repository along similar lines as a commercial bank greatly simplifies the technical complexity and expense. Because one format is used to keep patient data in the HRB, it is simpler for providers to build the interface to the HRB. That single interface allows them to access the patient's record when needed, and to pass new clinical data into the patient's health record.

Labs in British Columbia Meet Tough PT Standards

Successful mandated proficiency testing in BC incorporates tissue array-based surveys

CEO SUMMARY: Facing a crisis due to several highly publicized deficiencies in lab testing, pathologists in Canada are using proficiency testing (PT) to improve standards. In British Columbia, PT is mandatory and every lab is evaluated every quarter. Pathologists in BC recommend that every province and territory adopt mandatory proficiency testing. Currently only British Columbia has such requirements. Labs in the rest of the nation can participate in a newly developed voluntary PT program.

FOR MOST CLINICAL LABS IN CANADA, proficiency testing (PT) is voluntary. But in British Columbia and Ontario, it is mandatory. Documented successes of the Diagnostic Accreditation Program in British Columbia are spurring calls for health regulators in all provinces in Canada to adopt a similar mandatory PT program.

In Canada, proficiency testing for clinical laboratories has been a high-profile issue. In recent years, serious deficiencies in several laboratories were discovered and attracted unfavorable media attention. In response to these events—and to restore public confidence in breast cancer testing—the **Canadian Association of Pathologists** (CAP) developed a voluntary PT system for hospital labs.

Dr. Emina Torlakovic, at Royal University Hospital in Saskatoon, Saskatchewan, manages this program for CAP. It is well subscribed but does not cover all labs that perform these tests. It also has been successful in terms of compliance and reporting. The goal of the program is 100% participation and 100% accuracy by seeking to improve the accuracy and reproducibility of breast cancer markers including estrogen receptor (ER), progesterone receptor (PR), and other clinical immunohistochemistry tests. *(See TDR, Aug. 18, 2008.)*

One Canadian province which has avoided these problems is British Columbia. Not coincidentally, it has a rigorous, mandated program for laboratory proficiency testing. To get the inside story, THE DARK REPORT caught up with Robert Wolber, M.D., Medical Discipline Leader For Anatomic Pathology at **Vancouver Coastal Health** in Vancouver, British Columbia. Wolber said a program similar to the Diagnostic Accreditation Program (DAP) in British Columbia should be required in every lab in every province or territory.

Identifying Deficiencies Early

"If you want proficiency testing to work, you have to make it mandatory in each of the provinces," observed Wolber, who is a member of the DAP's Anatomic Pathology Advisory Committee. Wolber notes that one key to this proficiency testing program's success is the provincial law that allows the Provincial College of Physicians to revoke the medical license of any physician who operates a lab that fails to meet the DAP's standards.

"Under the DAP, we have proficiency testing for the important tissue biomarkers for breast carcinoma," Wolber explained. "Significantly, as part of this program, all tissue specimens in the province used for testing are verified with what is considered to be the gold standard method, which is fluorescence *in situ* hybridization (FISH) testing. All 11 clinical laboratories in British Columbia that perform breast cancer testing for clinical purposes participate in this PT program.

Tissue Array-Based Survey

"Each quarter, we provide tissue array-based surveys to each of the 11 laboratories," he added. "After we review the results, we send feedback to those laboratories within two weeks. In each array, we include between 40 and 50 tissue specimens. In effect, we have about 200 tests per immunohistochemical marker per year from each of the 11 laboratories. This is meaningful statistical analysis of each laboratory's performance, allowing us to state, with a fair degree of certainty, whether or not any laboratory is reaching appropriate levels of sensitivity and specificity for that marker.

"That degree of certainty is very important," continued Wolber. "For example, we can state, with a high degree of specificity, that every estrogen receptor (ER) test done in British Columbia is performed with a minimum accuracy rate of 95% or greater. In fact, as of the last survey that we did, I can also make this same statement about HER2 (human epidermal growth factor receptor 2) testing.

"Because of this comprehensive quality assurance program in British Columbia," he noted, "if any lab is going off the rails, we can quickly identify the error. If a lab fails one test, then we make recommendations. If that lab fails to perform the second time, we report the results to the DAP and the lab is told to shut down the test until the problem is fixed. That's the strength of the program. It is based on the very strong legislation in British Columbia that requires labs to participate in an external PT program for specific tissue biomarkers.

"These aspects of DAP grew out of a program we had here in our own health region—one of six health regions in British Columbia," Wolber said. "Since about 2003, we have conducted this testing to monitor our own performance. DAP was made mandatory 37 years ago, but it wasn't until the early 1990s that the provincial government put teeth into this legislation. The requirement for labs to participate in PT for specific tissue biomarkers was introduced last year, as a result of lobbying by pathologists." TDR

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BC Pathologists Join in National PT Effort

IN ADDITION TO WORKING on the mandatory proficiency testing (PT) program in British Columbia, pathologists at Vancouver Coastal Hospital are also working with the Canadian Association of Pathologists (CAP) to improve the voluntary PT system being introduced nationwide for hospital labs.

Pathologist Dr. Robert Wolber and others are collaborating with Dr. Emina E. Torlakovic, who heads the CAP's National Standards Committee. "We send Dr. Torlakovic tumor array specimens for evaluation and have participated in the national program on a voluntary basis," Wolber said. "I'm very supportive of their program. I particularly like how they post the results on the Web so that the participating labs can access this information.

"However, I have also recommended that this national PT committee score the results from the various labs," Wolber added. "When we get results from labs in British Columbia, the pathologists use a multiheaded microscope and score all the slides. Then, we send the labs their scores. That shows whether the results reported by each laboratory met the criteria."

Low Vitamin D Linked To Greater Risk of Death

Just-published study indicates how patients with vitamin D deficiency have higher risk of death

CEO SUMMARY: A new report in the* Archives of Internal Medicine *is likely to further spur demand for vitamin D testing. Already, labs are dealing with a dramatic increase in testing for vitamin D deficiency, with test volumes more than doubling in the past 12 months. This new research is considered the most definitive to date. Media reports are educating patients about these findings. Laboratories have an opportunity to ensure that they are running the most appropriate tests for vitamin D deficiency.

PATIENTS WITH LOW LEVELS OF vitamin D appear to have a higher risk of death from all causes, according to a new study published in the August 11/25 issue of *Archives of Internal Medicine* (AIM). These, and similar findings, are expected to fuel greater demand by patients and physicians for vitamin D testing.

In what is believed to be the most conclusive evidence to date, researchers reported that inadequate levels of vitamin D lead to substantially increased risk of death and can be a contributing factor in cardiovascular disease, diabetes, cancer, and death from other causes. This research was given wide play in newspapers across the nation last week.

The research was conducted and published by clinicians at the **Albert Einstein College of Medicine**, in the Bronx, New York, and **Johns Hopkins University** in Baltimore, Maryland. Researchers said the optimum blood level of 25-hydroxyvitamin D (25[OH]D) should be 30 nanograms per milliliter (ng/ml) or higher. According to the study, about 41% of men and 53% of women in the United States have levels lower than 28 nanograms per milliliter.

This incidence of vitamin D deficiency is consistent with the experience of **ARUP Laboratories** of Salt Lake City, Utah. According to A. Wayne Meikle, M.D., Medical Director of the Endocrinology and Automated Endocrinology Laboratory at ARUP, data in the ARUP database shows 58% of the vitamin D 25 assays done last year were below 30 ng/ml level. Meikle also is a Professor of Medicine, Endocrinology, and Pathology at the **University of Utah School of Medicine**.

58% Below 30 ng/ml

Like other labs across the United States, ARUP has seen the volume of vitamin D tests increase over the past 12 months. In the last issue of THE DARK REPORT, Meikle noted that numbers in ARUP's database reveals that vitamin D testing shot up by 248% from an average of about 33,000 vitamin D deficiency tests per month in 2007 to an average of about 82,000 vitamin D deficiency tests per month in 2008.

Meikle has advice for labs that offer vitamin D deficiency testing. "There are assays in the market that do not accurately measure D2, 25OH, so be careful," he noted. "ARUP uses an assay that measures both D2 and D3 25OH accurately to give a reliable total vitamin D 25. For patients who are deficient, we usually measure vitamin D 25OH two to three months after we begin correcting the deficiency."

13,331 Patients Studied

For the article in the *Archives of Internal Medicine*, Michal L. Melamed, M.D., M.H.S., of the Albert Einstein College of Medicine, Bronx, N.Y., and colleagues analyzed vitamin D levels in 13,331 individuals who participated in the Third National Health and Nutritional Examination Survey (NHANES III), conducted by the federal **Centers for Disease Control and Prevention**.

Vitamin D levels were collected between 1988 and 1994, and participants were tracked through 2000, the researchers said. The other researchers were Erin D. Michos, M.D., MHS; Wendy Post, M.D., MS; and Brad Astor, Ph.D., of the Johns Hopkins University, School of Medicine and the Johns Hopkins Bloomberg School of Public Health, in Baltimore, Maryland.

Tracking Patient Outcomes

Over a median (midpoint) of 8.7 years of follow-up, 1,806 of the participants died, the article said. When the patients were divided into four quartiles based on their vitamin D levels, those in the group with the lowest level (meaning they had less than 17.8 ng/ml) had a 26% increased rate of death from any cause compared with those in the group with the highest vitamin D levels. The authors concluded that the category of patients with less than 17.8 ng/ml is associated with a higher risk of all-cause mortality in the general U.S. population. At the same time, researchers found no significant associations when vitamin D levels were assessed against the risk of death from cardiovascular disease or cancer alone.

"Low vitamin D levels may be associated with death through their effect on blood pressure, the body's ability to respond to insulin, obesity, and diabetes risk," the authors said. "Several lines of evidence support vitamin D's role in risk of death, including the fact that cardiovascular events are more common in the winter, when vitamin D levels are lower, and that cancer survival is better if the disease is diagnosed in the summer when levels are higher.

"Further observational studies are needed to confirm these findings and establish the mechanisms underlying these observations," the researchers added. "If confirmed, randomized clinical trials will be needed to determine whether vitamin D supplementation at higher doses could have any potential benefit in reducing future mortality risk in those with 25(OH)D deficiency."

A Rising Wave Of Testing

THE DARK REPORT observes that the increased volume of vitamin D testing reported by labs across the country may be only the front edge of an expanding demand for such tests. Evidence, such as the just-published clinical study referenced in this intelligence briefing, is accumulating that, as the researchers identified earlier wrote "the lowest quartile of 25(OH)D level (<17.8 ng/mL) is independently associated with all-cause mortality in the general population."

How the American healthcare system responds to this situation will be informative for lab directors and pathologists. First, will evidence-based medicine (EBM) guidelines be quickly developed and introduced to guide clinicians? Second, will payers reimburse laboratories adequately, even in the face of a doubling and tripling in the volume of vitamin D tests being performed? TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an update on the issue of why pathologists working in independent laboratories will not be paid under the Medicare Physician Quality Reporting Initiative (PQRI). *(See TDR, August 18, 2008.)* Last week, Donald McLeod, a spokesman at the federal **Centers for Medicare & Medicaid Services**, returned our call to discuss the issue and explain why CMS would not make PQRI bonus payments this year to independent labs currently reporting quality information for breast and colon cancer cases. According to McLeod, under federal statute, independent labs were not entitled to the PQRI bonus payments "because they do not treat patients." McLeod stated that PQRI bonuses go only to physicians in group practices who treat patients.

BIO-REFERENCE REPORTS EARNINGS

Last week, **Bio-Reference Laboratories, Inc.** (BRLI) of Elmwood Park, New Jersey, reported earnings for its third quarter ending July 31, 2008. BRLI posted an impressive 18% growth in revenue, at $77.8 million in Q3-08 versus $66.0 million in Q3-07. Patient volume was up by 9% and esoteric testing comprised 48% of revenues for the quarter. BRLI saw revenue per requisition increase to $68.08, which is 9% larger than revenue per requisition in Q3-07.

ADD TO: BRLI

BRLI has grown at a double digit pace for almost a decade. What sets it apart from its much larger national competitors is that BRLI is generating most of this growth from the combination of a productive sales force and the introduction of specialized esoteric tests. Lab acquisitions have played a lesser role in BRLI's growth over the years. In the New York City metropolitan area, BRLI provides routine and esoteric testing services to office-based physicians. It also has a separate sales program that sells its esoteric testing programs nationally.

TRANSITIONS

• Next week, Rick Panning becomes the new Vice President, Laboratory Services for **Allina Hospitals and Clinics** in Minneapolis, Minnesota. Panning was most recently CEO of the **American Red Cross** Region based in St. Paul, Minnesota. Prior to that, Panning was President, Laboratory Services at **Fairview Health Systems** in Minneapolis.

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DARK DAILY UPDATE

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That's all the insider intelligence for this report. Look for the next briefing on Monday, September 29, 2008.

It's New!

PREVIEW #4

Lab Quality Confab

September 24-25, 2008 • Hilton Hotel • Atlanta Georgia

Tina Krenc of Abbott Diagnostics on...

FMEA and FTA Analysis: Why It's Coming to Your Hospital and Your Laboratory

FMEA (Fault Mode and Effects Analysis) and FTA (Fault Tree Analysis) are important quality management tools working their way into healthcare accreditation. FMEA is a procedure used to analyze the potential failure modes within a system and classify these failure modes by severity or the failure's affect upon the system. FTA is a method for modeling and analyzing failure processes of engineering and biological systems. In recent years, hospitals certified under the Joint Commission have been required to conduct one FMEA annually. As laboratories become more sophisticated about eliminating the source of errors and improving patient safety, FMEA and FTA will play a growing role.

For program details and to register:
visit www.labqualityconfab.com

UPCOMING...

- ***Why Next-Generation Laboratory Automation Solutions Are Likely to Transform Lab Operations.***
- ***Benchmarking Pathologist Productivity: Surprising Insights from World-Class Labs.***
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