

## **Clinical Laboratory Technology Advisory Committee**

Minutes of the Meeting held on June 6, 2014

Meeting held by videoconference from Richmond campus, CDPH,  
KP Regional Laboratory, North Hollywood and  
Telephone Bridge Line

### **CLTAC members participating**

John Basile, Rhonda Becker, Richard Bennett, Anthony Butch, Patricia Dadone, Lorri Dean-Yoakum (chair), Kathleen Doty, Robert Footlik, Lee Hilborne, Anne Igbokwe, Armand Parada, Jennifer Schiffgens, Fred Ung.

### **Former CLTAC members participating**

Imre Fischer, Tim Hamill, Jerry Hurst, Carmen Maldonado, Solomon Notricia, Les Revier.

### **CDPH staff participating**

Zahwa Amad, Alan Ankerstar, Grace Byers, Gillian Edwards, Elaine Flores, Ron Harkey, Shideh Khashe, Paul Kimsey, Nema Lintag, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Beatrice O'Keefe, Tammy Pahland, Joanne Rowan, Gabriele Sabino, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

### **Public members participating**

Michael Aidan, Jean Amos-Wilson, Barbara Brunell, Marian Castillo, Irene Chen, Hency Chu, John Cordova, Nancy Fraize, Carol Gagne, Dora Goto, Carole Howe, Peggy Kollars, Shiu-Land Kwong, Valerie Ng, Shahrzad Radahd, Rodney Roath, Diana Schillinger, Barbara Sevilla, Shannon Smith-Crowley, Tom Tempske, Ann Tonini, Phyllis Walker.

### **Welcome and general announcements**

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:09 a.m. Ms. Dean-Yoakum thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Dean-Yoakum conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was present for the meeting.

### **Approval of the March 7, 2014 meeting minutes**

It was moved that the minutes from the March 2014 meeting be approved as submitted. Armand Parada seconded the motion and the minutes were approved.

### **Installation of Chair**

Chairperson Lorri Dean Yoakum, who was elected in December to another term, was installed by Beatrice O'Keefe as chairperson. Ms. O'Keefe thanked Ms. Dean-Yoakum for serving another term as chairperson.

### **Commemoration of Jim Ottosen**

Lorri Dean-Yoakum announced the recent death of former CLTAC board member

Jim Ottosen and requested that Mr. Ottosen's seat at the North Hollywood meeting remain empty in his honor. Karen Nickel spoke in memory of Mr. Ottosen. Dr. Nickel described him as an exacting person who was well-versed in the law. A long-serving member of CAMLT, he also served for 12 years on the CLTAC and on various subcommittees. She mentioned his other interests, noting that he was a talented musician and singer. She said that he had been a role model who will be sadly missed by all who knew him. Ms. Dean-Yoakum added that Mr. Ottosen had been a mentor to many, including herself, and that she will miss his presence at CLTAC meetings.

### **Department update**

Dr. Paul Kimsey, deputy director of the Office of the State Public Health Laboratory Director (OSPHLD), gave an update for the California Department of Public Health (CDPH).

Dr. Kimsey expressed his appreciation for the many contributions made by Jim Ottosen to the Department and to CLTAC.

He reported on the governor's interagency Drought Task Force, noting that the task force's surveys have not yet been completed. He reported that OSPHLD is involved in the Drought Task Force's work on indicators for tracking the public health impact of the current drought in California, including the monitoring of mosquito pools in connection with West Nile virus surveillance.

Dr. Kimsey gave an update on the Department's application for accreditation by the Public Health Accreditation Board (PHAB). On February 8, 2014, CDPH Director Dr. Ron Chapman submitted the accreditation package. The next step in the accreditation process is a site visit, which will be conducted by a team of peers who are selected and trained by PHAB. At the end of the site visit a report will be developed and submitted to the PHAB Board. If all goes as planned, the onsite evaluation team is expected to visit the Richmond campus between August 19 and August 21, 2014.

Dr. Kimsey reported that he, Beatrice O'Keefe, and Kathy Williams participated in the COLA Leadership Summit that was held in San Francisco on April 28-29, 2014. He thanked COLA, a laboratory accrediting organization, for sponsoring the conference and for inviting members of his team to participate in stimulating discussions with other leaders in the healthcare and clinical laboratory fields. He noted in particular the discussions of the implications of the Affordable Care Act (ACA) for clinical laboratories and laboratory medicine, including training and payment policies.

Dr. Kimsey also participated in hearings before the California Assembly Health Committee in the spring. He reported that the Department pointed out that its general fund budget across the department had been reduced by 69% in response to the State's budget crisis. There are now public health reinvestment proposals to reestablish the Department's funding. These proposals are still in play, and he will be able to say more once the governor's budget is passed. He noted further that because LFS is specially funded, it is not directly affected by these proposals, although the budget cuts nevertheless had an impact on LFS as one part of the

larger Department.

### **Update from legal counsel**

Tammy Pahland, staff counsel for LFS, reported that details are still being worked out on the implementation of the CLIA crosswalk. The CLTAC crosswalk subcommittee and the Department have drafted a document, which will be sent to the Office of Administrative Law (OAL) once the form of the document has been decided. It could take the form of a letter, a letter with accompanying spreadsheet, a synopsis, or a comparison of the laws. Ms. Pahland will coordinate work on the final form of this document, which has not yet been decided, with Kathy Williams of LFS and the CLTAC subcommittee.

Ms. Pahland gave an update on the draft personnel regulations package DPH-11-012. She noted that the review by the Office of Regulations (OOR) is still in progress, and they are awaiting some documents. The Regulations Process Team (RPT) will meet next month to establish a timeline for the process. The draft of the regulations, which is a large package, is being reviewed by OOR staff for clarity, consistency, necessity, and non-duplication in compliance with the standards set forth in the Administrative Procedure Act (APA). Ms. Pahland anticipates that the review will take some time and that the package will probably be released early next year for public comment.

Ms. Dean-Yoakum thanked Ms. Pahland and the LFS committee and staff for their work on the new regulations.

### **CLIA Crosswalk Subcommittee update**

Robert Footlik, chair of the CLTAC subcommittee on the CLIA crosswalk, reported on the work of the subcommittee and gave an explanation of the process followed by the subcommittee. He stated that a subcommittee was appointed seven years ago to produce a crosswalk comparing the 2003 CLIA laws with existing California law, which was based on the 1994 CLIA law. The subcommittee has reviewed all CLIA documents and has recommended that the 2003 CLIA law be adopted with two exceptions. The committee recommends against the adoption of equivalent quality control because it is less stringent than current law. It also recommends against adopting daily control for titring syphilis serology separately from the titer run of the specimen because it is less stringent than current law. A written document, which is being formulated by Kathy Williams, will be submitted at the next CLTAC meeting. Mr. Footlik thanked the members of the subcommittee, especially Kathy Williams, and all members past and present for their work on the crosswalk.

Tom Tempske noted that California never adopted the personnel standards of CLIA because those are in statute and Mr. Footlik said that will not change. Robert Thomas noted that CLIA states that if state law has more stringent personnel requirements than CLIA, the more stringent state requirements must be met.

### **LFS update**

Beatrice O'Keefe, chief of LFS, apologized for her absence from the March meeting.

She reported that LFS is working on a transition to a new licensing software platform for personnel licensing and eventually for facilities licensing. This transition is

required by a mandate from the State to bring all information technology services in-house, which means that the system supplied by an independent contractor must be replaced by one supplied by a new software vendor, PEGA. There is one year remaining on the old contract, during which time the transition must be completed.

There are three phases to the implementation of this platform. The first phase will introduce an in-house online application and payment system. The second phase will bring online the personnel licensing renewal process, and the third phase will make changes to the facility licensing process and bring it online. She noted that printing may or may not remain with EDD and that the Health Application Licensing System (HALS) will not be replaced. This system, inherited from the Department of Consumer Affairs, is 25 years old and has many limitations. Very few people know the system, which is programmed in Atabase.

Ms. O'Keefe also reported that LFS is working on updating its website. Mary Wogec is working on updates to LFS's webpages, beginning with the personnel licensing section. She will also post recent CLTAC minutes and agendas to the website. It is hoped that these changes will make the LFS website more accessible and more useful.

Ms. O'Keefe reported that Robert Thomas, former section chief of the Personnel Licensing section who now works with LFS as a retired annuitant, is working with examiner Martha Obeso on approval of examinations for clinical chemists, clinical laboratory scientists (CLS), and medical laboratory technicians (MLT).

She noted that LFS is also working on the repeal of the Title 17 California Code of Regulations (17 CCR) §1050 regulations, and on the question of whether new regulations will be required.

Robert Footlik asked if the third phase of the new software platform, which will bring facility licensing online, will include online renewal. Ms. O'Keefe said that it would. She added that LFS is also working on moving tissue bank and then blood bank licensing online, but stated that it will take several years to complete the process, the ultimate goal of which is to handle all LFS licensing online.

Tom Tempske asked if the new examinations for clinical chemists and CLS would be administered by outside organizations. Ms. O'Keefe said that they would, and that some outside organizations have submitted their examinations for our approval.

Dora Goto asked if the verification website would change. Ms. O'Keefe said that the verification website would remain as it is. HALS software will not change, and the new platform will coordinate with HALS.

### **Legislation updates**

Ron Harkey, section chief of the Biologics and Tissue Bank Section, reported on proposed legislation being analyzed by his program. Assembly Bill (AB) 1822, proposed by Assemblyman Rob Bonta, deals with the storage of tissue for implantation into or application onto patients, and would exempt a person or facility licensed to provide health care services from the FDA tissue bank licensing requirement for storage of such tissue when the tissue was obtained from a licensed

tissue bank, stored in strict accordance with FDA regulations, and used for implantation into or application onto a patient. This bill has not changed since Mr. Harkey made his report at the March meeting except for technical, non-substantial changes. He noted one problem with the bill as written. It states that FDA laws will ensure proper storage of tissue in facilities that are exempted under the proposed law, but Mr. Harkey pointed out that FDA laws exempt those facilities from oversight. If the bill passes into law, these facilities will be self-regulating, and able to operate without either federal or state oversight. He explained that improper storage of tissues for transplantation or implantation can have serious and even fatal consequences, and emphasized that proper oversight of tissue storage in all facilities is imperative.

Kathy Williams, Section Chief of Facility Licensing in northern California, reported on AB 2143, a bill that exempts certain chiropractors from clinical laboratory requirements when performing urine specific gravity, urine protein, urine blood, and urine sugar tests that are classified as waived clinical laboratory tests under CLIA for the sole purpose of completing the Department of Motor Vehicles Medical Examination Report. The bill exempts only those chiropractors listed on the most current federal Department of Transportation (DOT) and National Registry of Certified Medical Examiners (National Registry). The bill requires the chiropractor to obtain a valid certificate of waiver and comply with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations and requires a chiropractor who receives an abnormal test reading to refer the applicant to his or her primary care physician.

The bill does not seek to allow these chiropractors to direct a waived laboratory, but it will exempt them from all California personnel laboratory laws, and Ms. Williams anticipates that it will change the workload for LFS. An urgency clause has been added to the bill, and if it passes it will go into effect immediately. Ms. Williams noted that the practice of chiropractic does not authorize the chiropractor to penetrate tissues of human beings so chiropractors are prohibited from collecting capillary or venous blood specimens, and can only perform dipstick tests.

Ms. Williams stated that the proponents' analysis says that the bill will exempt chiropractors from CLIA law, but added that she has not been able to verify that. She stated that there are 14,000 chiropractors practicing in California. Two hundred fifty chiropractors are trained and certified by DOT and are listed in the federal Department of Transportation and the National Registry of Certified Medical Examiners. For purposes of comparison, there are 800 to 900 physicians and surgeons listed in the registry. She also noted that as AB 2143 went through the Assembly committees there was not a single "no" vote, and it is now on the consent calendar.

Ron Harkey reported for Jan Otey on Senate Bill (SB) 492, proposed by Senator Ed Hernandez. This bill was introduced last year and is still active as a two-year bill. It seeks to expand the scope of practice parameters of optometrists who are certified to use therapeutic pharmaceutical agents by removing certain limitations on their practice and adding certain responsibilities, including the ability to immunize and treat certain diseases. It deletes the specified drugs the optometrist would be authorized to use, and authorizes the optometrist to use all therapeutic

pharmaceutical agents approved by the United States Food and Drug Administration. The last action on this bill took place when the bill was amended on August 6, 2013.

Dora Goto noted that Sen. Hernandez can reactivate SB 492 at any time before the end of September 2014.

Asked for the rationale for the exemption of hospitals in AB 1822, Mr. Harkey said that the bill was introduced by the American Association of Tissue Banks (AATB), which in the past has taken a strong stand on issues related to storage of tissue. Their rationale for the exemption is that current requirements place an excessive burden on hospitals.

Robert Footlik noted that the FDA inspects hospitals for tissue bank storage, and asked what kind of tissue the bill covers. Mr. Harkey said that the FDA law quoted in the bill says that hospitals are exempt for tissue received from licensed manufacturers or distributors of tissue products. He encouraged people to read the pertinent sections of FDA law.

Dora Goto said that according to the Legislative Digest, AB 2143 allows chiropractors to perform and report on only four waived dipstick tests. If they perform these tests, they do not need California registration, but they do need to have a CLIA certificate of waiver. She noted that the analysis in the Legislative Digest says that chiropractors do not need to have a CLIA certificate of waiver. Mr. Footlik said that the Legislative Digest's reports are notoriously inaccurate and unreliable. Ms. Goto noted that the bill contains a safety measure that states that if the results of the dipstick are abnormal, the chiropractor must refer the patient to his or her healthcare practitioner.

Beatrice O'Keefe asked if AB 2143 meets current exemption requirements for forensic testing. Ms. Williams said that in order to be considered forensic, a test must be associated with law, legislation or crime, and must be used to determine if there is a violation of the law. AB 2143 regulates only testing to determine physical condition with regard to fitness to work, so it does not include forensic testing.

### **Guest Speaker**

#### **John Wogec**

Lorri Dean-Yoakum introduced the guest speaker, John Wogec, Senior Emergency Services Coordinator in the Emergency Preparedness Office (EPO) in CDPH. He serves as the Exercise Coordinator for the EPO and has been actively involved in the CDPH Medical and Health Coordination Center and Richmond Campus Coordination Center since 2007. He also serves in the CDPH Duty Officer program, responding to a wide variety of incidents including wildfires, hazardous materials spills, drinking water contamination, and communicable disease outbreaks. He received a Doctor of Osteopathic Medicine degree from Western University of the Health Sciences and a Master of Public Health and Bachelor of Science in Biology from the University of California at Los Angeles. Prior to joining CDPH, he practiced community medicine.

Mr. Wogec addressed the role of clinical laboratories in public health emergencies.

As an example of the challenges that confront California's emergency preparedness system, he described a 13 day period in 1970 during which 16 lives were lost, 700 structures were destroyed, and over one-half million acres were burned in California. This experience prompted the development of the Firefighting Resources for Potential Emergencies (FIRESCOPE) system in Southern California. By 1980, FIRESCOPE had been adapted into the Incident Command System (ICS) and was in use throughout California as a field-level response system for numerous fire responses. In 1991 the Oakland Hills fire resulted in the introduction of SB 1841 by Senator Nick Petris. This bill proposed that the Standardized Emergency Management System (SEMS) be developed to augment ICS with the intent of improving coordination of Federal, State and local emergency management and response. The bill was signed and chaptered into California law as Government Code section 8607. SEMS was adopted by the Federal government and introduced as a national response framework known as the National Incident Management System (NIMS). California was once again the bellwether for emergency response, and the system developed by the state of California was adopted at a national level.

In SEMS emergency management has a defined set of tools that allow response to any type of incident. This is referred to as an "all-hazards" approach. SEMS has been used in CDPH's response to incidents including the 2007 and 2009 wild land fire seasons, the H1N1 Pandemic in May, 2009, the San Bruno gas line explosion in September, 2010, the Chevron Richmond Refinery fire in August, 2012, and the Asiana Airlines plane crash at San Francisco International Airport in July, 2013.

Mr. Wogec underscored the fact that emergency managers are well aware that they do not have expertise in all the fields that may be required to respond to a specific emergency situation. Emergency managers rely on experts in the various fields, and coordinate the contributions of various experts to the larger response plan. For example, EPO recently designed a tabletop exercise to address the possibility that the entire Richmond campus might be taken offline by an earthquake and subsequent tsunami. During such an incident the need might arise for expertise in clinical laboratory knowledge and procedures. He explained that in any given situation, the central emergency management team has one set of tools, while local agencies, programs, or groups, for example, clinical laboratorians, have a different but equally important set of tools. In an event like the once proposed in this exercise, EPO would consult with experts in all Richmond campus departments to ascertain how their programs work and what must be done to enable the campus to continue to function. These local experts would be incorporated into EPO's process through a Multi-Agency Coordination (MAC) group.

MAC groups are comprised of subject matter experts from a variety of disciplines who are brought together to develop policies and make recommendations for specific issues related to their expertise during emergency incidents. SEMS establishes rules and procedures for the interaction of all partners in a situation, as well as a methodology and framework developed from experience during actual emergencies. EPO in turn uses these rules and methodologies to create a structure that enables an appropriate response in a specific situation. EPO coordinates needs and the availability of resources.

During the H1N1 Pandemic in 2009, for example, EPO required laboratories capable

of performing certain tests, which in turn required certified analysts and specific equipment. EPO worked with various groups, including LFS, to arrange for the necessary personnel and equipment. In any given emergency situation, local agencies and programs continue to do their jobs, but under a framework created by EPO that has been tested over time and in a variety of conditions, in which normal tools and communication pathways are overlaid by structures created with the help of SEMS.

Under SEMS, clinical laboratorians might be called on to participate in a response through an Emergency Operations Center (EOC), providing field level support in the form of certified staff or bench level equipment, or they might be enlisted to provide technical guidance through a MAC group. The Medical and Health Coordination Center (MHCC) coordinates communications between the various working groups using guidelines and procedures provided by SEMS in an all-hazard approach. Mr. Wogec noted that the MHCC has recently been activated to respond to emergencies arising from the drought.

Mr. Wogec encouraged people to consult the California Public Health and Medical Emergency Operations Manual (<http://www.cdph.ca.gov/programs/ccldho/Pages/EmergencyOperationsManual.aspx>) The CDPH Emergency Operations Response Plan is available on the CDPH intranet at <http://cdphintranet/Pages/CDPHEORP.aspx> (available only within CDPH).

Beatrice O'Keefe noted that during the H1N1 Pandemic LFS was informed that the Viral and Rickettsial Disease Laboratory (VRDL) was unable to handle the volume of tests that were required, and the Department needed to know what laboratory specialties could perform the required tests. LFS provided information and the governor then signed an emergency proclamation allowing those specialists to perform the tests. She mentioned other situations in which LFS has stepped in to provide information in connection with laboratorians and facilities. She also encouraged all laboratories and facilities to create their own emergency plans. Mr. Wogec said that under the all-hazards approach, the Office of Emergency Services bears ultimate responsibility, and SEMS provides a framework to facilitate and coordinate any subject matter expertise that is needed to respond to a situation, but he emphasized that SEMS does not replace or take over local agencies or programs. The Emergency Operations Response Plan describes the implementation of responses in such situations.

Zahwa Amad said that she hopes EPO has a plan for dealing with an emergency at the Richmond campus. Mr. Wogec noted that the Richmond campus has unique attributes and a location that would create unique problems in the event of an emergency.

Ron Harkey asked about the hierarchy of coordination of various agencies in an emergency situation. Mr. Wogec said that SEMS follows a logical progression, involving first local agencies, then those located in neighboring counties, the Regional Emergency Operations Center (REOC), the Governor's Office of Emergency Services in State government, and the federal government (first neighboring states, then those at a greater distance from the emergency).

In response to Ms. O’Keefe’s mention of individualized emergency plans for all laboratories and facilities, Tom Tempske noted that accreditation by the College of American Pathologists (CAP) requires an emergency response plan. He also pointed out that if the Richmond campus were to be closed down during an emergency, the EPO’s command center, which is located in Building P on the Richmond Campus, would also be unusable. Mr. Wogec noted that there are three emergency coordination centers with which Richmond would be likely to interact: Richmond, Sacramento, and Station 1 in Rancho Cordova.

### **CLIA Update**

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, reported that through the end of April 2014, the CLIA section performed 41 initial surveys and 344 recertification surveys. No validation surveys were performed due to a shortage of staff. Sixteen proficiency testing desk review sanctions were issued, and there was one onsite complaint.

Ms. McCallum reported that as part of an ongoing effort to empower patients to be informed partners with their health care providers, the federal Department of Health and Human Services (HHS) issued a final ruling on February 3, 2014, to give a patient or a person designated by the patient a means of direct access to the patient’s completed laboratory test reports. This rule was a joint effort between the Clinical Laboratory Improvement Amendment (CLIA), the Center for Disease Control (CDC), and the Office of Civil Rights (OCR). The federal CLIA regulations at 42 Code of Federal Regulations (CFR) Part 493.1291(f) and the California Business and Professions Code (BPC) Section 1288 are affected by this rule.

The final rule was published February 6, 2014 and laboratories must comply by October 6, 2014. Federal law 42 CFR 493.1291(l) states that upon request by a patient (or the patient’s personal representative) the laboratory may provide patients, their personal representatives and those persons specified under 45 CFR 164.524(c)(3)(ii) as applicable with access to the completed test reports that can be identified as belonging to that patient using the laboratory’s authentication process.

The final rule as announced by HHS amends the CLIA 1988 regulations to allow laboratories to give a patient, or a person designated by the patient as his or her “personal representative,” access to the patient’s completed test reports upon the patient’s or patient’s personal representative’s request. At the same time, the final rule eliminates the exception under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to an individual’s right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients’ privacy. The rule was issued jointly by three agencies within HHS: the Centers for Medicare and Medicaid Services (CMS), which is generally responsible for laboratory regulation under CLIA, the Centers for Disease Control and Prevention (CDC), which provides scientific and technical advice to CMS related to CLIA, and the Office for Civil Rights (OCR), which is responsible for enforcing the HIPAA Privacy Rule. The rule will affect 42 CFR 493.129(f) and California BPC 1288.

Ms. McCallum discussed changes to the HIPAA Privacy Rule, which include amendments to 45 CFR 164.524.524(a)(1)(i-iii), removal of the exceptions that relate to CLIA and CLIA-exempt laboratories, and alignment of the Privacy Rule with changes to the CLIA regulations. She explained that a laboratory is considered a HIPAA-covered entity if it performs one or more “covered transactions” electronically. A laboratory is a non-covered entity if it does not conduct covered transactions electronically, and therefore is not subject to the HIPPA Privacy Rule at 45 CFR parts 160 and 164, subparts A and E. These laboratories would have the discretion to provide patients with direct access subject to State laws that may constrain access, but are required to follow State rules if they are more stringent than federal rules.

Ms. McCallum noted that test reports maintained by or for a covered entity laboratory are considered part of a “designated record set” as defined at 45 CFR 164.501. Under 45 CFR 164.521(a)(1) a patient has a right to all public health information (PHI) in a designated record set as long as the information is maintained by the laboratory. A covered entity laboratory is not required to purchase new software or systems to accommodate a request for an electronic copy in a form they cannot produce. Covered entity laboratories must satisfy the verification requirements of 45 CFR 164.514(h) before providing an individual with access. Laboratories will not be required to interpret the test results for the patient. Reference laboratories are covered entities under HIPAA and will also be required to provide access in compliance with 45 CFR 164.524 of the Privacy Rule. Covered entity laboratories have 30 days to comply with the request for access. Test results are not considered part of the designated record set until they are completed. Ms. McCallum noted that an exemption is provided when a licensed health care professional has determined based on professional judgment that the access request is reasonably likely to endanger the life or physical safety of the individual or another person. Laboratories can charge a reasonable fee as specified at 45 CFR 164.524(c)(4) of the Privacy Rule.

Ms. McCallum reported on her recent attendance at a partner’s meeting. Meagan Sawchuk, a Health Scientist at CDC, encouraged laboratory professionals to be actively involved with a new publication sponsored by the US Center for Disease Control and Prevention, “The Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Records System.” The purpose of this paper is to provide an overview of the key areas in which laboratory professionals can contribute their expertise to the development of the accurate exchange and display of laboratory data in Electronic Health Record (EHR) systems. The paper illustrates the seriousness of laboratory data-related interoperability issues and displays discrepancies in EHR systems. It proposes focus areas for action by laboratory professionals to support resolving those issues. It is hoped that through collaboration, laboratory professionals, clinicians, healthcare executives, medical professional societies, health IT developers, and federal agencies like the Office of the National Coordinator for Health Information Technology (ONC), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA), can work together to develop effective solutions to reduce identified patient safety risks in and improve the safety of EHR systems. She encouraged interested people to visit the CDC website at <http://www.cdc.gov/labhit> for more information. The paper can be found at

Ms. McCallum also addressed the issue of waived blood glucose meters (BGM). She noted that currently waived blood glucose meters cleared by the Food and Drug Administration (FDA) carry statements in the manufacturers' instructions indicating that the system is not intended to be used for the critically ill patient population. Such use is considered off-label use. Off-label use of a test means that the test defaults to high complexity under CLIA regulations and the testing laboratory must meet all applicable CLIA high complexity requirements. Hospitals and physicians must define "critically ill" and decide if this limitation applies to their patient population.

There are various options for hospitals for point of care testing of critically ill patients. A hospital may:

1. Convert to Certificate of Compliance or Accreditation and comply with high complexity test requirements for off-label use.
2. Use a test system without the limitation.
3. Send tests to another laboratory.

Laboratories will have a reasonable amount of time to make their choice, implement it, and achieve compliance, unless immediate jeopardy to patient health and safety is identified. The FDA is working with some manufacturers on a draft guidance for the industry and FDA staff regarding Blood Glucose Monitoring Test Systems for prescription point of care use. Ms. McCallum encouraged people to visit the FDA website for updates on this guidance on the use of glucose meters in critically ill patients.

Lorri Dean-Yoakum asked if biometric screening done by an employer for insurance purposes is included under the rubric of health fairs. Ms. McCallum said that if the screening is non-diagnostic and the patient is not treated on the basis of the screening results, it doesn't fall under CLIA, and so it is not covered by these regulations, but rather by the regulations governing forensic or employee physicals.

Karen Nickel said that if one manufacturer does this, everyone will want to do it.

Robert Footlik said that the reality is that the test is categorized as a waived test. He asked why, if there is little or no chance of causing harm if the test is performed incorrectly, the FDA would be concerned about critically ill patients. Mr. Footlik said that there is almost no test that, when performed incorrectly, will not cause harm to the patient. Ms. McCallum said that all of these issues were raised at the meeting that she attended, and that CMS does not assume responsibility for defining critical illness, but leaves it to hospitals, laboratory directors, and professionals under whose scope of practice such definition comes. She noted that the major concern is patient outcome. She also noted that this is not an issue for CMS, but for the state of New York and the state of Washington, where inspection rules are different. She noted that in California, everyone comes under inspection, and so this ruling will have a greater effect on California.

Karen Nickel pointed out that Dr. Jim Faix and Dr. Tim Hamill are going to present a discussion, "Can Glucose Meters Be Used for Critically Ill Patients? A Pro/Con

Debate,” at the AACC Northern California Section Chapter Meeting in San Francisco on June 10, 2014, and encouraged people to attend.

Beatrice O’Keefe said that it was her experience when she was inspecting laboratories that these tests tend to be accurate at normal ranges but are skewed at critical levels, and that because these tests have been in use for a long time, it may be late for the FDA to become involved. Ms. McCallum agreed, and noted that this will force people to reconsider use of tests and think about patient outcomes. She added that this question affects LFS when examiners perform inspections and hospital validations.

Peggy Kollars asked if it is the case that nothing needs to be done until CMS releases the letter. Ms. McCallum said that the important points to be considered are the definition of a critically ill patient and following the manufacturer’s instructions. This is already in the law, so facilities must be in compliance now, without waiting for the FDA’s letter.

Tim Hamill asked, with regard to patient access to laboratory test results, if this is to be taken on a case by case basis, pointing out that geneticists, for example, should not release the results of genetic tests without providing genetic counselling. Ms. McCallum said that it is on a case by case basis.

### **Facility Licensing - Richmond**

Kathy Williams, Section Chief of Facility Licensing in northern California, reported that in the past three months, from March 1, 2014, through June 1, 2014, her section received 34 new applications for licenses and 218 new applications for registrations. There were no new applications from pharmacists or optometrists; there was one application from a naturopathic practitioner, and one from a CLS-directed waived laboratory, both of which were approved.

Ms. Williams discussed the need to reprogram HALS, the LFS computerized licensing system, to accept new director classifications as well as email addresses.

Ms. Williams reported that between March 1, 2014 and June 1, 2014, her section received 45 major complaints. Four of these involved test errors, four involved test management and quality control, one involved state licensing, and two involved tests being performed by unauthorized personnel. LFS also received 31 miscellaneous complaints. Thirteen complaints were referred to the Licensing and Certification program, nine were referred to other departments, and nine were resolved by LFS staff. Ten complaints concerned phlebotomists and their techniques, and three involved billing issues. Ms. Williams noted that Direct Access Testing using the Internet is becoming a major issue.

Robert Footlik asked how many applications were for laboratories outside California. Ms. Williams said that her program received many, many inquiries about out-of-state laboratories setting up draw stations in California, but she is not sure how many applications have actually been received. She thinks that the CDPH requirement that phlebotomists work under the supervision of a lab director and provide monthly competency tests may discourage applications for California draw stations from out-of-state laboratories.

## **Facility Licensing – Los Angeles**

Joanne Rowan, Section Chief of Facility Licensing in southern California, reported that the Los Angeles Facility Licensing Section continues to conduct routine inspections of the accredited labs, applications for initial licensure, and complaint investigations

Between March of 2013 and May of 2014, Ms. Rowan's section received approximately 139 applications for initial licensure or upgrades (approximately nine per month, but some months there are more and other months fewer). About a dozen applications were terminated or the labs canceled due to inactivity, that is, the laboratories were still not ready to test after 6 months of receipt of the applications in the Los Angeles office.

For laboratories applying for initial licensure, the most common specialty identified with all new applications was hematology (400). Many of the facilities associated with this specialty are either fertility clinics performing semen analysis or cancer centers testing for Complete Blood Counts (CBCs); there are a few other types of facilities as well: a donor center for testing platelets, vascular centers testing for Protimes and Partial Thromboplastin times (PT/PTT), a pediatric center using the QBC Instrument, and clinics with multiple subspecialties, hematology being just one of them.

The next most frequently subspecialty was histopathology (610), requested primarily by sole practitioner dermatologists, with some pathologists performing MOHS procedures, and some pathologists requesting the subspecialty of cytology (630) as well. Endocrinology (330) was the next most common subspecialty. This subspecialty is sometimes associated with fertility centers; however, there appears to be a growth of free standing hormone clinics (for example, the Lo T Center, which tests for PSA and testosterone).

Finally, a large number of facilities requested the subspecialty of toxicology (340) for drug screen testing. This was usually coupled with a request for routine chemistry (310) for creatinine testing to ensure the validity of the drug screening results.

Ms. Rowan reported that her staff is continuing to perform routine inspections of accredited laboratories as routine state inspections. They are focusing on accrediting organizations (AOs) other than COLA, since COLA now has been approved by the State to inspect laboratories for the State. She is compiling their findings, and will report on these at a later date. From May of 2013 to the present, Ms. Rowan's section has inspected 53 laboratories accredited by COLA, 2 accredited by the American Association of Blood Banks (AABB), 9 accredited by the American Osteopathic Association (AOA), 6 accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), 39 accredited by the College of American Pathologists (CAP), and 15 accredited by the Joint Commission (TJC).

She reported that, for 2014, approximately seven complaints were received in Los Angeles. These complaints involved phlebotomy certification, the use of unlicensed personnel, patient test management (test ordering and reporting issues), and training schools.

Ms. Rowan reported that CDPH director Dr. Ron Chapman accompanied examiner Victoria Maxwell on a clinical laboratory inspection during his tour of the different departments. Ms. Maxwell did an exemplary job and Dr. Chapman was highly complementary about his visit with the southern California program and his experience with the LFS representative.

### **Personnel Licensing Update**

Zahwa Amad, Section Chief of Personnel Licensing, reported on the change of policy on walk-in applications for personnel licenses and asked for the cooperation of CLTAC in disseminating information about this change of policy to laboratory directors and staff. Dr. Amad explained that it takes 90 days to process applications for certification or licensure. She asked laboratory directors and supervisors to remind their staff to submit renewal applications 90 days in advance of the expiration date on their licenses and certificates, and to make sure that their applications are complete. She noted that the final date for accepting walk-in applications at LFS in Richmond will be September 1, 2014. This date was changed from May 1, as previously announced, in order to give sufficient time for notification about the change in policy. She explained that walk-in applications are not given priority over applications submitted by mail. In fairness to the thousands of applicants served by LFS every month, applications are processed in the order in which they are received. A hand-delivered application is date-stamped and must go through the same process as an application that is received by mail. It is not moved ahead of other applications in the processing queue.

She further emphasized that phlebotomy technicians may not work past the expiration of their certificates, unlike other licensed personnel who are allowed a grace period after the expiration date of their licenses. LFS does not offer temporary certificates or licenses, so it is imperative that phlebotomy technicians submit their renewal applications in time to allow processing before the expiration date. Renewal is posted on the LFS verification website, which is updated once a week on Wednesdays. Dr. Amad encouraged people to view the revised personnel renewal webpage on the LFS website at <http://www.cdph.ca.gov/programs/lfs/Pages/ContinuingEducation.aspx>, where they can find information about continuing education, renewal fees, and links to the renewal application form LAB 177 and the verification webpage. The renewal page also offers information about change of name or address. Dr. Amad noted that the California Code of Regulations (CCR) requires that a change of name or address be reported to LFS within 30 days of the change.

Dr. Amad reported that LFS has hired two new receptionists and a new supervisor for the reception desk, and that this has enhanced the efficiency of the reception desk. She also encouraged people to communicate by email to allow for tracking by LFS evaluators, and to utilize the information on the LFS website.

Lee Hilborne noted that renewal notices are sent 120 days in advance of expiration, and asked if it would be possible to say that the submission deadline is 90 days in advance of expiration. Ms. O'Keefe said that according to the CCR, 90 days is the median time for processing an application, and pointed out that these timelines are established in regulations.

Barbara Brunell pointed out that this timeline cuts 90 days off the applicant's continuing education period. Dr. Amad said that as long as applicants submit an application and check before the license expiration date, they can submit continuing education documentation later.

Peggy Kollars asked why LFS does not accept faxes or emails with a scan of supporting documents. Dr. Amad said that the issue is the requirement of an original signature on certain documents. Dr. Amad and Robert Thomas said that LFS can revisit this issue and look into the possibility of accepting electronic signatures. Beatrice O'Keefe said that according to California law LFS is required to have an original signature on supporting documents, and so LFS cannot accept faxed or scanned documents with signatures, and that any change must be cleared by our legal counsel as well as the CDPH IT department. It will also be necessary to deal with this in our new personnel regulations package. Jerry Hurst noted that there are software programs that can verify electronic signatures, which will update in minutes. Use of such programs would allow a person to send a PDF of a document with a verified electronic signature.

### **Biologics and Tissue Bank Program update**

Ron Harkey, Section Chief of the Blood and Tissue Bank Section, reported that the field of blood and tissue banking is rapidly expanding and changing. There are more than 200 blood banks in California, with dozens of stationary collection sites and thousands of non-stationary collection sites. This web is growing as a result of numerous changes in technology over the last two decades. He noted that California regulations on blood banking are more than 50 years old. This program initially had three examiners. The number of facilities in California has increased by 40%, due in large part to the emerging technologies associated with cord blood and stem cells. LFS currently has only one examiner who deals with cord blood and stem cells. This examiner, Robert Hunter, is working with facilities on issues surrounding stem cells, and on numerous press releases and press contacts around these issues. In particular, Mr. Harkey noted that his section provided information for an article that appeared in the Wall Street Journal on April 26, 2014, titled "Inside the Private Umbilical Cord Blood Banking Business."

Mr. Hunter is also working on the safe transfer of cords when tissue banks go out of business. Mr. Harkey noted that tissue banking, especially banking of cords, is an industry worth millions of dollars, and this development has resulted in a large increase in the number of Public Records Act (PRA) requests processed by his section.

Mr. Harkey reported that the number of facilities under the jurisdiction of LFS has grown tremendously, but the LFS staff has not. There are more than 750 tissue banks licensed by LFS, many of them located out of state, and he noted that LFS does not have authorization to travel in order to inspect these facilities.

Robert Footlik remarked on the fact that there is only one biologics field examiner for the entire state, and asked if there is any prospect of funding additional biologics staff. Beatrice O'Keefe said that LFS had recently conducted a Recruitment and Retention study which pointed out that State salaries are well below those offered by

private industry. An examination for examiner positions with LFS will be held on June 17 and interviews will be held soon. She said that LFS has open positions for examiners, but is finding it difficult to fill them. She added that this is the case for scientists throughout State programs, and does not affect only LFS.

### **Report on Digital Pathology**

There was a request at the March meeting for a presentation on digital pathology, and Lee Hilborne offered to find someone to speak on this topic at the June meeting. He reported that he is still working to arrange such a presentation. For the present meeting, Beatrice O'Keefe prepared a report on the requirements of California statutes and regulations regarding persons authorized to process specimens. She reported that according to BPC 1269.3, a pathologists' assistant must be certified by the American Association of Pathologists' Assistants (AAPA) or the Board of Registry of the American Society for Clinical Pathology (ASCP) or another national accrediting agency approved by the Department.

Ms. O'Keefe reported that a pathologists' assistant performs his or her duties under the supervision and control of a pathologist. The duties of a pathologists' assistant include preparation of human surgical specimens for gross description including description of gross features and selection of tissue for histological examination. Others authorized to describe gross features and select tissues for histological examination under the direct supervision of a pathologist if they also meet CLIA requirements are a pathologists' assistant who is not certified, a histologic technician, or a histotechnologist.

Ms. O'Keefe explained that "direct supervision" means that a pathologist is physically present onsite in the vicinity of the clinical laboratory while pathologists' assistants who do not meet the certification requirements of subdivision (a), histologic technician or histotechnologist, are engaged in the dissection of specimens. For tissue processing other than dissection, a pathologist must be available by telephone or other electronic means.

She noted that in digital pathology, tissue specimens may be processed at one site and then electronically transmitted to another site where the specimens are read by a pathologist. A pathologist reading slides remotely from the place where the tissue was processed should ensure that the slide area that is electronically transmitted is selected by a person who qualifies for gross description of tissue. Gross description is classified as high-complexity testing under CLIA which, at a minimum, requires an AA degree in a science.

Lee Hilborne said that he would continue to try to arrange for a speaker on this topic at the September CLTAC meeting.

Karen Nickel noted that if a digital image is read by a licensed person at a remote site, that site needs to be licensed. Ms. O'Keefe said that both the site where the tissue and image is prepared and the site where the report is being prepared require licensure.

The point was made that while digital pathology is a promising development, at this

point it takes considerably more time to process and read a digital slide from a computer than to read a slide directly.

Jennifer Schiffgens asked about the definition of a histotechnician certified by the State, and asked if histotechnicians need to be certified. Ms. O'Keefe said that California law does not require histotechnicians to be certified, and there is no definition of histotechnicians in current law, but that the law authorizes LFS to clarify such issues by regulation. Dr. Nickel said that while current regulations do not cover this, the proposed draft regulations on personnel licensing clarify this issue.

Robert Footlik noted that the law under discussion was sponsored by the California Clinical Laboratory Association (CCLA), and that the Department can establish regulations to clarify such issues. Karen Nickel said that this clarification has been added to the draft personnel licensing regulations using the authority cited by Mr. Footlik.

Chairperson Lorrie Dean-Yoakum thanked Dennis Tavares, Mary Wogec, Don Miyamoto, and Laboratory Field Services for their work on preparation for CLTAC meetings.

### **New business**

Lorri Dean-Yoakum asked if anyone had new business to discuss.

Robert Footlik said that he would like to make a clarification of the report he gave earlier in the meeting on the Subcommittee on CLIA 2003. In his report he said that CLIA 2003 was adopted in its entirety except for two items. Regarding personnel standards, he clarified that he should have stated that the recommendation by the subcommittee to adopt CLIA 2003 does not include any personnel standards. The subcommittee does not make any recommendations on personnel standards because they are excluded from CLIA 2003.

Karen Nickel requested an opinion from CLTAC regarding patient service centers, noting that laboratories used to list their patient service locations, but this is no longer being done. She asked that time be set aside at the next meeting for a discussion of these locations, specifically, who should be responsible for them and what the stakeholders think about them.

Lorri Dean-Yoakum asked for a discussion of IQCP. Topics could include reports from anyone who has started the risk analysis on how the work is proceeding, the availability and usefulness of templates, and whether California will be able to use IQCP.

Karen Nickel asked if there have been any problems with health fairs. Kathy Williams listed regulations that cover health fairs, which appear at the end of BPC 1244. She noted that she has not received any complaints about health fairs. The statute says that health fairs can be held under a brick-and-mortar laboratory license, and all regulations that apply to such a laboratory apply at a health fair. State and CLIA license numbers must be provided, a licensed laboratory director must be present on site, testing may be performed on site or sent back to the laboratory. A brief history must be taken to establish the medical necessity of any

tests, and test results must be reviewed by a licensed person before being reported to a patient.

Beatrice O'Keefe asked for further discussion of glucose meters. Specifically, she asked if the manufacturer inserts state that they are for monitoring rather than screening, and asked how this will affect the use of glucose meters for purposes of non-diagnostic health assessment and health fairs. Kathy Williams said that all manufacturer inserts say that they are only to be used for purposes of monitoring. Ms. O'Keefe noted that this could be a potential problem, and asked that this topic be placed on the agenda for discussion and clarification at the September meeting. Kathy Williams suggested postponing such a discussion until the FDA document on glucose meters had been sent.

Ms. Dean-Yoakum asked for further recommendations for topics for future discussion. There were no suggestions.

Ms. Dean-Yoakum asked that if anyone had other suggestions for new business, they be forwarded to herself or to Ms. O'Keefe.

#### **Next meeting**

Lorri Dean-Yoakum announced that the next meeting of the CLTAC would be held on Friday, September 5, 2014. The final meeting in 2014 is scheduled for December 5.

#### **Adjournment**

Rhonda Becker moved that the meeting be adjourned, the motion was seconded by Armand Parada, and the CLTAC voted to adjourn at 12:29 PM.