

Clinical Laboratory Technology Advisory Committee
Minutes of the December 3, 2009 Meeting

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

Note: For flow purposes; these minutes are documented in the order in which they appeared on the agenda, and not in the order discussed.

CLTAC Members Participating

Laurie Armour, Michael Borok, Leonard David, Lorri Dean-Yoakum, Elizabeth Dequinia, Lee Hilborne, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung.

Former CLTAC Members Participating

Victoria Bello, Sam Chafin, Imre Fischer, Robert Footlik.

DPH Staff Participating

Zahwa Amad, Norma Barocio, Kathleen Billingsley, Grace Byers, Maria DeSousa, Ron Harkey, Robert Hunter, Nema Lintag, Cindy Lloyd, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Janet Otey, Judy Schlosser, Lilia Shumaker, Dale Statley, Genie Tang, Tom Tempske, Robert Thomas, Patricia Toomer, Kathy Williams.

Welcome and General Announcements

The meeting was called to order by CLTAC member Donna Kirven. She announced that Dr. Tim Hamill could not attend the meeting and she was requested to take his place for this meeting.

Approval of the September 10, 2009 meeting minutes

Donna Kirven asked CLTAC members if there were any additions, deletions, or corrections to the minutes. There was a motion and a second for approval. The minutes were accepted.

Department News

Ms. Billingsley apologized for not being at the CLTAC meeting in person. She gave a few updates on the departmental level. She talked about the work that has been done related to H1N1 especially the impact in California. She said that the second allotment of vaccines just went out and there were discussions between the state and local health about the distributions. Ms. Billingsley added that the Center for Health Care Quality (CHCQ) is launching a program in which they will be monitoring hospitals. They will be looking at vaccination rates of healthcare workers in hospitals, ED visits and whether there is any change. The majority of the focus will be on infection control. She announced that CHCQ has conducted two MOC surveys one in Kaiser at Northern California and that both of them went well.

She also announced that CHCQ will be launching a pilot program in which each of the 15 district offices will be conducting three surveys, for a total of 45 surveys that will be performed next week. Ms. Billingsley went on to say that the amended budget did not necessarily help resolve all of the budgetary fiscal issues that may be impacting the state of California going forward. She was happy to announce the passage of SB 744. LFS will have to prepare an 18 month plan explaining what actions will be taken to rebuild this important state licensing program. This plan will need to include what else can they do to link the federal CLIA program with the state activities and she was hopeful to be able to

share that with CLTAC at future meetings. Ms. Billingsley went on to say that she had a message from Dr. Horton that he would like the CLTAC to discuss an agenda item at the next meeting regarding the CLIA laboratory director requirements for the public health laboratories. Material will be sent out before the next meeting in March. Ms. Billingsley will bring back the comments of the CLTAC to Dr. Horton.

Question: The question was asked, so legislation would be at the federal level and not the state level with regards to laboratory director qualifications?

Answer: Yes.

News and Update on LFS

Bea O'Keefe announced that Cindy Lloyd has been promoted to be the lead for administrative litigation which deals with licensing litigation and administrative litigation. Bea thanked Cindy Lloyd for all the legal help and support she has given to Laboratory Field Services (LFS) over the years.

LFS had to give a one year update to The Bureau of State Audits (BSA) which came back with nine recommendations that were not fully implemented. BSA wanted a timeline when they will be fully implemented. Several of the recommendations were discussed.

Recommendations by the BSA Audit

- **To develop the resources to meet all of the mandated oversight responsibilities.** The passage of SB 744 will give the resources that LFS needs to improve staffing which will allow LFS to carry out its mandated activities.
- **To improve current data base systems.** The current system that LFS has is HAL. HAL is an antiquated system. If anything were to happen to the HAL mainframe, there is no backup to the system. LFS has partnered with the department on an online licensing system. LFS has completed all of the initial steps to identify the program processes at LFS. The proposed online system would replace many of the internal data bases currently used by LFS. The BSA audit cited LFS for not having appropriate controls on many of the internal data bases. The proposed online system is expected to be fully implemented by 2013. There could be changes to this timeline and we will keep CLTAC informed.
- **To leverage current resources.** Beginning in November 2008 LFS leveraged the state portion of the federal CLIA surveys to review a certain number of state issues. The checklist includes the major issues, although, it is not fully comprehensive. We had about 823 laboratories that were reviewed for various state issues.
- **To continue the steps to license and register all laboratories.** LFS did an initial project with Victoria Maxwell from the LA office where 100 accredited labs that were required to be licensed were identified and LFS worked to get them licensed. LFS has identified an additional 3,000 laboratories that should be registered. We also have a number of licensed labs to be completed. LFS is planning to move forward in 2010 to identify and notify laboratories inside California and outside California that are testing on California patients. LFS has laboratories that are located outside the country that are testing California patients and the state law requires that they have a California license. We currently have one laboratory outside the United States that is LFS licensed and we have a second one that is providing phenotypic HIV information and drug resistance. LFS is working on licensing that laboratory.
- **To maximize LFS opportunities to impose sanctions.** LFS is looking at various options for meeting this recommendation.

- **To update the regulations.** LFS was successful in getting the HIV regulation package approved. Kathy Williams will be talking about the HIV package and what that means for the laboratories. LFS completed a draft on the personnel regulations. Bob Thomas will be talking about it and the process for moving these regulations forward.
- **To strengthen LFS complaint process.** Thomas Tempske will be giving an update on complaints. LFS wants to be able to do more onsite inspections on complaints. LFS was able to do only 4 last year.

Proposed Initiative would change the definition of a person

The term person would apply to all human living organisms from their beginning of their biological development regardless of the means by which they were procreated, method of reproduction, age, race, sex, gender, physical well being, function or condition of physical or mental dependency and/or feasibility. If this initiative were to pass, than any kind of genetic test done on an embryo could be considered a laboratory test. Also, reproductive facilities that are storing embryos might be required to keep the embryos forever in liquid nitrogen. If this initiative passed, LFS would have to look to our legal department for assistance as this could mean those facilities performing clinical testing on embryos would have to meet all requirements of a licensed clinical laboratory, and be subject to laboratory sanctions.

Legislation Impacting Clinical Laboratories

SB 744(Strickland) – Bea O’Keefe said that this bill has been discussed thoroughly at previous CLTAC meetings. However, LFS would like to discuss this important legislation one more time.

- This bill was introduced February 27, 2009 by Senator Strickland.
- It went thorough and survived 4 committee hearings with various amendments. Initial opposition was removed as a result of subsequent amendments.
- Assembly Votes-Ayes 70, Noes 3.
- Senate Vote-Ayes 39, Noes 0.
- Signed by governor 10/11/2009.
- This bill was urgency legislation – this means it went into effect immediately.

Provisions

- Increases fees for waived from \$59 to \$100 and PPMP labs-one set fee from \$88 to \$150.
- Changes clinical lab license fees based on volume of testing. This is different from how we charged fees in the past.
- Increases 2 year certificate fee for phlebotomists from \$54 to \$100.
- Fee for Multiple Sites \$25 for each additional site.
- Allows for proposal of the state accepting Accrediting Organizations.
- Requires report to the Legislature.

Licensed Labs

- Approximately 60% of the labs will see a reduction in fees. Labs with less than 2000 tests will see this reduction.
- Labs with 10,000 tests and up will see a graduated fee increase.
- Cap at 15 million tests. There are some labs doing 150 million tests. Fees will be based on a maximum of 15 million tests.
- Fees will go to the CLIF fund and not to the general fund.

Accrediting Organizations

- Begin accepting applications January 2011. LFS will need to complete a current crosswalk between federal and state law.
- Must be approved by CMS as an accreditation body
- Must be approved by the department
- Must conduct inspections to determine compliance with both state and federal standards
- Laboratories issued a certificate of deemed status by approved accrediting organizations.
- Laboratory must permit the accrediting organization to provide all records to LFS.
- Authorize the release of PT results.
- If accreditation is removed, deemed status retained for 45 days, state would resume doing inspections.
- Certificate renewed annually.
- No every 2yr. routine inspections by the department.
- LFS would do Inspections conducted for initial, complaint and validation purposes.
- Enforcement action for decertified lab taken by the department.
- Regulatory report due by 2013.

Questions: e-mail Bea.Okeefe@cdph.ca.gov

LFS Web Site: <http://cdph.ca.gov/programs/lfs>. You can view PowerPoint at this Web site. We will also post how to calculate test volumes.

Question: How are non profits hospitals or laboratories treated differently under the new law especially in respect with the fees that they pay?

Answer: Non-Profits, if they are doing fewer than 15 types of waived or moderate tests, can have one CLIA certificate and if they have multiple sites, they can have multiple sites with one CLIA certificate. Each additional multiple site will be charged a fee of \$25. Hospitals can have one CLIA certificate for the whole hospital campus as long as the ownership is the same, and as long as the director is willing to accept the responsibility for all of the facilities doing laboratory testing.

Question: When are the facility Licensing renewals coming out?

Answer: The licenses were printed November 16, 2009 for expiration date 12/31/10. Laboratories have a 60 day grace period which will be until March 1, 2010. If you get your renewal by March 1, you should be okay.

Question: How much longer will it be before source verification of facility licenses will be available online?

Answer: It will be 2013. The online project is in the consulting phase right now. Each program is going through their systems. There are other programs involved in this project such as Radiological Health, Drinking Water, and Licensing and Certification. LFS wants to bring the personnel licensing program which is currently online for initial application to include online renewals and application for the facility licensing program. Biologics and tissue banks are also included in this program.

Question: Will the cytology assessment fee go away?

Answer: Yes, during the negotiations of SB 744, the cytology assessment fee was removed. Laboratories will no longer be charged that fee.

Question: Are there funded open positions for Examiners in LFS now? How many?

Answer: Yes; however, we have had difficulty in filling positions due to salary. We have 12 vacancies; however, not all are Examiner positions.

SB 482(Padilla) – Kathy Williams discussed this bill.

SB 482 known as the biological data service bill has been relegated to a two year status. This bill was sponsored by 23andME which interprets genetic laboratory data according to algorithm used to determine risk of certain diseases or genetic makeup. LFS has not heard of any new amendments to AB 482 and it has not officially been re-introduced as there are several issues involved. One is the status of whether or not their interpretation is part of the laboratory test. Another concern is the privacy issues involved with producing the individual genetic information and its uses.

AB 221 (Portantino) - Robert Thomas discussed this bill.

AB 221 was an act to amend section 120917 of the Health and Safety Code relating to the public health and declaring an urgency to take effect immediately. This bill was chaptered on November 11, 2009 and is now in effect. The problem had been that this bill affected the Office of AIDS (OA) program and that OA testing counselors were authorized to perform the HIV test but were not authorized to collect the sample. This is a department run program to permit OA test counselors trained by the OA to perform skin punctures for the purposes of withdrawing blood for HIV test purposes. Prior to this legislation, OA was using the oral fluid test which is more costly and created problems with sensitivity and/or specificity. This bill is now in effect and has been chaptered.

Question: How does this relate to OA HIV testing counselors when they are not employed by the department as a testing counselor?

Answer: The OA testing counselors are part of a state run program. They can only do it as part of a department run program and no where else. If the person wanted to do finger sticks or phlebotomy outside the HIV testing counselor program, he or she would need to become a limited or certified phlebotomy technician through LFS.

Personnel Licensing Regulations - Reported by Robert Thomas

Since the Center for Health Care Quality organized the August 24th stakeholder meeting, LFS has received and reviewed numerous comments from organizations and individuals. LFS made modifications to some of the 14 proposals based on the comments in the draft package. The original proposals and the 14 issues are still listed in the LFS website at www.cdph.ca.gov/programs/lfs. If you submitted comments during the unofficial comment period, you will need to review the regulation package when it becomes available for the official comment period. If you have issues, it is important that you address those during the official comment period. On November 18, 2009, the LFS team started working on the personnel licensing regulations and met with the office of regulations to map up the process. The proposed regulations package has been given a number DPH-08-001. The official start date has been established as November 4th. The Center for Health Care Quality and LFS consider this package as priority. This package should be coming up early next year but a date can not be specified at this time. Every effort is being made to move this regulation package forward to the public comment period.

Question: If I go to this website, can I see the proposed regulations?

Answer: No, you can see what was presented at the August 24th stakeholders meeting, which is the 14 key issues of the concerns that has been brought up to LFS in the past 7 to

8 years. LFS has amended some of them but can not discuss what was amended until the package comes up for public review. There may be more changes than the 14 issues listed on the LFS Web site. However, they are not considered as key issues by LFS.

Question: For clinical cytogeneticist scientist and clinical genetic molecular biologist scientist, with the purchase of NCA by ASCP, will California recognize these examinations given by ASCP.

Answer: NCA was recognized in California law by regulation as the administering organization for California clinical cytogeneticist scientist and clinical genetic molecular biologist scientist examinations. A regulation change will need to be made before California can accept the ASCP exams. LFS is working with its legal office and the Office of Regulatory Hearings to see if we can get a change in the law without having to hold hearings based on this change being a non-substantive change. This is one of our top priorities. However, we do not yet have a time line for this to be approved. Hopefully, we will have more to report at the next CLTAC meeting.

H1N1 Flu (swine Flu) Preparedness – Reported on by Paul Kimsey, Ph.D.

This Pandemic started in the spring and had less impact over the summer and did come back in the fall. One of the major issues has been vaccine availability. So far, California has received 7million doses of the H1N1 vaccine; both the nasal and the injectable. This is only 1/3 of what CDPH expects to get in the period of the pandemic. There are 13,000 providers across California. This is a local issue. If you have questions on the availability of the vaccine, first contact your local health department.

- The severity of the illness is dropping. No hard data to support that but its more in the epidemiologists view.
- There have been a total of 6,474 hospitalizations, ICU cases and deaths.
- 354 deaths in California.
- Information is available in the CDPH website at www.cdph.ca.gov, click on the H1N1 influenza link.
- Hot line was set-up in November and their number is 1-888-865-0564. So far there have been a total of 6,000 calls. For now, the hot line will continue.
- Bob Thomas said that we have been trying to cover all aspects of H1N1. We will have an agenda item on this at the next CLTAC meeting in March 2010.

Waived Lab Testing – Discussion led by Paul Kimsey, Ph.D.

Purpose is to let people know there is quite a bit of information on the CLIAC Web site.

- Number of analytes for which waived tests systems are available has gone from 9 in 1993 to 84 in 2008.
- Number of waived test systems has gone from 203 in 1993 to 3,228 in 2008.
- Number of laboratories with a certificate of waiver went from 67, 294 to 129,219 in 2008.
- Percentage of laboratories with a certificate of waiver went from 44% in 1993 to 64% in 2008.

Questions for CLIAC consideration

- Where are the gaps in what we now know about the waived tests performance and its impact?
- How Should CDC address the gaps?
 - How can waived testing performance be assessed in nontraditional testing sites?
 - Should waived test performance be assessed for particular analytes or test systems? If so, which should we focus on?
 - Should a waived test study focus on specific types of testing personnel? If so, what groups should be assessed-nurses, medical assistants, other?
- How can the impact of waived testing on patient care be measured?

During discussion, it was stated that the original definition of a waived test is being studied. Clearly, technology changes and increase in laboratory testing has provided opportunities for obtaining a Certificate of Waiver.

Donna McCallum of the LFS CLIA program said that LFS routinely surveys 2% of waived labs. CMS has concluded that there is a need for more oversight of waived labs. How to increase the number of waived labs surveys? No decision has been made in terms on how to proceed in that direction. Since California has state licensure law, testing personnel and laboratory directors must meet the state's requirements mentioned in the business and professions code sections 1209 and 1206.5 under testing personnel. Proficiency testing is not routinely required for waived testing. If a facility chooses to enroll in proficiency testing for waived labs, all of the proficiency testing rules apply. If there is PT sharing, there can be a sanction.

Question: Has the federal government provided funding to continue the waived surveys for the coming fiscal years? How many labs will that be?

Answer: Yes they have. Approximately 200 labs, plus about 50 follow ups, it all depends when LFS starts performing the onsite surveys.

Question: I noticed that this is broken into a 5yr period with a four fold increase in the first 5 years and less than a two fold increase in the next 5 years. In 2008, there were only 10 tests added. Does the committee feel this is because we have reached a peak in the number of analytes that can be put into the waived testing category? Are we going to see many more in the future?

Answer: The committee did not address this question, the issue with the data that was presented to the government. It has to do with the technology, the interest of the manufacturers and so on. The FDA put out guidelines in January 2008 with recommendations for applications for manufacturers' in-vitro diagnosis related to waived testing. They are now soliciting written or electronic comments. This is taking in consideration that the manufacturer is providing the clients with enough information to keep them in compliance. For people interested in doing comments you can go to their website at <http://edocket.access.gpo.gov/2009/eq-25177.htm> . This is available for making comments until December 21, 2009.

Question: Is it being considered to look at the type of analyte?

Answer: The issue is do we have good data. The best data was done by LFS about 15 years ago. This study seemed to verify that people who know what they are doing do a better job than those that do not.

Summary of Complaints received by LFS – Reported on by Thomas Tempske
Since the last meeting we have had 32 complaints and closed 20. 12 are still pending. Year to date we have had 192. We have closed 148.

LFS has referred a total of 66 complaints to other agencies as these were not in LFS's jurisdiction. LFS receives an assortment of complaints for cosmetology, barbering, Licensing & Certification (L&C), etc, which implies that the LFS web site has been effective.

The LFS Web site has been effective as we see complaints coming to us involving pedicures and cosmetology.

Question: Is there a summary on the LFS Web site? How are complaints separated out? Is it classified based on whether it involves a Physician Office Lab (POL), hospital, or commercial lab?

Answer: No, the summary is in the CLTAC minutes. Complaints are classified as quality, billing, unlicensed personnel, phlebotomy, etc. A priority is assigned based on whether immediate jeopardy, etc.

It was suggested that there should also be classification based on whether the act was reckless (criminal) or negligent. For example, there may be lessons learned for the whole community regarding negligence by learning from a mistake.

Tom Tempske stated that complaints are not usually public information. They are confidential. Licensing agencies do not release information.

Question: What is reported to CLIA?

Answer: In cases where there are quality issues, LFS coordinates with the CLIA Section Chief to add the complaint to the routine survey if one is being scheduled. This is consistent with the BSA audit where it was suggested for LFS to leverage resources. Also, there are complaints that do not involve federal issues as with phlebotomy. About one-third of the complaints are phlebotomy related. The next highest number of complaints we receive involve billing issues. There are also complaint cases that can not be substantiated.

Tom discussed a case that is an example of the type of complaint that shows up on our radar screen. It began with an airing on CBS 5 news. It was labeled as hook worm therapy for auto-immune disorders. As background, it was mentioned that the Institute of Tropical Disease in London noticed that people in developing countries do not have a large amount of auto-immune disease and it may be due to the fact that they have parasitic disease.

LFS received information that a person was selling band-aides with hook worms over the internet. The FDA asked LFS is there is anything we can do because the

Department of Public Health is involved with infectious diseases. LFS contacted and communicated with the local Public Health Laboratory Director and they followed up. The television spot was recently still playing and titled as "Some Turn to Hookworms to Treat Ailments." One thing that was of concern was the individual selling the infected band aids made the statement that the worms go through a rigid purification and screening process before being prescribed to humans.

Personnel Licensing Section Report – Presented by Bob Thomas

At the September 9, 2009 CLTAC, LFS reported on the LFS Personnel Licensing activities for phlebotomy, CLS, and MLT. Today, Personnel Licensing Section will be reporting on license renewal processing, certifying organization exam approvals recognized for California clinical laboratory personnel licensing, CLS training schools, and update on MLT training school approvals.

Regarding personnel licensing application processing production, we are closely monitoring our activities with the Center for Health Care Quality to measure effects of reduced work days. For license renewals, we have seen a 2% decrease (improvement) in production turn around times. LFS is aware that persons working with a license would be affected if we could not issue them their renewal before the end of their license valid date, and that employers and the public receiving lab services would also be affected. LFS has put a great deal of focus on processing license renewals in a timely way.

Regarding certifying organization exams, LFS has recently approved the American Board of Bioanalysis exams for licensing of Clinical Laboratory Bioanalysts. This completes a goal which LFS began in 2006 to switch from California administered examinations to accepting national certifying organization exams that meet California requirements of Title 17, California Code of Regulations (17CCR), Sections 1031.7 for phlebotomy and 17CCR Section 1031.8 for all other licensing exams. LFS has approved 22 different certifying organization exams for various personnel licensing categories, and 6 organization exams have been approved for phlebotomy technician certification.

Regarding training schools, in the handouts today you should have the current list of CLS approved training schools. It includes three new ones in 2009. LFS has 5 pending CLS training school applications under review currently.

Regarding Medical Laboratory Technician (MLT) programs, we have approved one program since the September 9 CLTAC meeting. This is Southwestern College with an approval date of 12/1/2009. There are two pending; Saddleback College and AMA clinical lab.

Question: Is there an error on the list of certifying organization exams because it appears that one organization is listed on the list that identifies certifying organizations by name, and this same organization does not appear on the second list that sorts by license type?

Answer: Bob Thomas said that LFS would take another look at the lists and verify if any correction is needed.

Question: It was stated that LFS should not identify the different license categories along with an academic degree in the titles.

Answer: Both Bob Thomas and Bea O’Keefe stated that although references to degrees are made in the law associated with different license categories, LFS will research this more closely to see how the title may be listed without stating the academic degree.

Facility Licensing Report-Kathy Williams

- Facility Licensing is getting about 100 applications per month. 10 for new labs and 90 for registrations.
- Year-to-date Facility Licensing has done 59 new licenses and 1592 registered. This does not include the applications that are just changes in owner, director and address.
- The renewal fees are based on the volume of laboratory testing. LFS will be using what is currently in the HAL System. When you report your volume, if there is an increase or decrease in volume than balance billing will be done.
- A handout of the regulation revisions titled “Important Notice” was distributed at the meeting. This letter will be posted in the website. This letter states that a laboratory no longer needs LFS written approval to do HIV testing. There is a requirement for competency assessment of the personnel, training and quality assurance program via retesting, blind specimens, subscribing to a commercial PT organization or sharing specimens between labs like informal programs.
- There are some additions to the list of reportable diseases by laboratories. In 2004 the department of CDPH received permission to promulgate regulations by printing only without going thru the regulation process package for reportable diseases. On September 22nd there were some changes to the list that the laboratories have to report. The following were added.
 - ✓ Poliovirus
 - ✓ Coccidioidomycosis
 - ✓ Anaplasmosis linked with Ehrlichiosis
 - ✓ Chlamydia Infections were rephrased to Chlamydia trachomatis infections
 - ✓ An electronic reporting system is in development. All laboratories will need to report electronically within one year of implementation.

CLTAC CLIA subcommittee will be resuming their meetings by the end of January. The accomplishments are: The crosswalk between California law, which includes CLIA as of 1/1/1994 in the areas of facility administration, general lab systems, pre-analytic systems, analytic systems as applied in microbiology and chemistry, the post analytic systems and the correct of action area. The subcommittee is yet to do: The EQC portion of Chemistry, Cytology, histopathology, immunohematology, and proficiency testing.

Tissue Bank and Biologics Report

Ron Harkey introduced speaker Dr. John Rosenberg to discuss Senate Bill (SB) 1058. He said that SB 1058 is the most relevant for labs. It requires all general acute care hospitals in California to report specified health care infections to the department. Those infections include MRSA blood stream infections, VRE blood stream infections, central line associated blood stream infections, and Clostridium

difficile defined infections. These are laboratory defined infections. The blood stream infections have to have a positive lab culture. The Clostridium difficile infections have to have positive test for Clostridium difficile to be considered an infection. The ones that occur in a hospital after the third day of hospitalization are defined as health care associated and those are the ones that need to be reported. All hospitals must report the infections on a quarterly basis.

- ✓ The goal is to have all the diseases reported thru the NHSN (electronic web based system)
- ✓ They will be getting 12 state positions
- ✓ The goal is to have an entire electronic reporting system
- ✓ To motivate the hospitals to prevent infections and reduce their rates
- ✓ 75% of all hospital required infections are preventable
- ✓ Most hospital can get their rates under zero
- ✓ Data Validation to make sure the rates are valid

CLIA Update Report

- There will be a new appendix C interpreted guidelines coming out. These guidelines are going thru the approval process. The guidelines still need to go thru the legal and managerial reviews. Once it's available to the public it will be posted in the CLIA website.
- There was a basic training for new surveyors in Baltimore from November the 16 thru November 20th. LFS has three new surveyors that attended the training.
- On December 4, the CLIA department added a new surveyor. She had previously worked for LFS and has been CLIA approved.
- There are two examiners on sick leave.
- There will be a delay on receiving CLIA bills for compliance or certificate fees and some delays in receiving the certificate due to a new ASPEN 9.5 that recently came into effect.
- The federal fiscal year is from October 1, 2008 thru September 30, 2009. In this period CLIA performed
 - ✓ 823 surveys this includes re-certification and initial surveys.
 - ✓ 15 onsite complains
 - ✓ 49 PT sanctions-due to PT desk review
 - ✓ Total workload review came to 897

Meeting Adjourned: The meeting was adjourned by Donna Kirven at 12:20 PM.

Next Meeting Dates for 2010: March 26, June 25, September 24 and December 2010 TBA.