

**Clinical
Laboratory
Improvement
Advisory
Committee**

Summary Report

**February 20-21, 2008
Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

**Clinical Laboratory Improvement Advisory Committee
February 20-21, 2008, Summary Report
Table of Contents**

I. Record of Attendance

**II. Clinical Laboratory Improvement Advisory Committee (CLIAC) –
Background**

III. Call to Order and Committee Introductions

IV. Presentations and Committee Discussion

Agency Perspectives and Panel/Committee Discussion

- 20+ Years of CLIA: A Trip Down Memory Lane
- CLIA Past, Present & The Future of Lab Medicine
- A CLIA Carol – FDA Perspectives

Accreditation and Exempt States Perspectives and Panel/Committee Discussion

- AABB and CLIA 2008
- ASHI Standards and Accreditation: Impact on the Quality of Laboratory Testing in the 20 Years of CLIA
- Twenty Years of CLIA, College of American Pathologists
- COLA Accreditation – Working Together for Excellence in Healthcare
- The Joint Commission, Laboratory Accreditation – A Brief History
- New York State, 20 Years of CLIA 40+ Years of the NYSDOH Clinical Laboratory Reference System – Impact on Laboratory Quality
- Impact of Medical Test Site (MTS) Law on Laboratory Quality

Agency and Other Updates and Committee Discussion

- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Centers for Disease Control and Prevention
- Board of Scientific Counselors Report to the Clinical Laboratory Improvement Advisory Committee: NCPDCID Investments for Assuring Public Health Laboratory System Capacity
- CCCLW, Coordinating Council on the Clinical Laboratory Workforce

Quality Management Systems Presentations and Panel/Committee Discussion

- Progress and Process in International Laboratory Quality
- A Quality Management System in a Public Health Laboratory – Why and How?

**Clinical Laboratory Improvement Advisory Committee
February 20-21, 2008, Summary Report
Table of Contents - cont'd.**

- Describing the Incredible Journey in Less Than 30 Minutes -- Implementing a Quality Management System for the Laboratory

Biosafety in Clinical Laboratories – Presentation and Committee Discussion

V. Public Comments

VI. Adjourn

VII. Addenda

Record of Attendance

Committee Members Present

Dr. Lou Turner, Chair
Dr. Ellen Jo Baron
Ms. Susan Cohen
Ms. Joeline Davidson
Dr. Nancy Elder
Ms. Merylyn Francis
Dr. Chip Harbaugh
Dr. Lee Hilborne
Dr. Kevin McNeill
Dr. Dina Mody
Dr. James Nichols
Dr. Gary Overturf
Ms. Elissa Passiment
Dr. Stephen Raab
Dr. David Smalley
Dr. Thomas Williams
Dr. Emily Winn-Deen
Ms. Luann Ochs, Advamed (Liaison Representative)

Committee Members Absent

Dr. Carol Greene
Dr. Geraldine Hall

Executive Secretary

Dr. Thomas Hearn

Ex Officio Members

Dr. Steven Gutman, FDA
Dr. Devery Howerton, CDC
Ms. Judith Yost, CMS

Record of Attendance - cont'd.

Centers for Disease Control and Prevention

Ms. Nancy Anderson	Dr. Alison Mawle
Ms. Shannon Barber	Ms. Isabel McAuliffe
Dr. Louise Barden	Ms. Leslie McDonald
Dr. Joe Boone	Dr. Linda McKibben
Ms. Sal Butera	Dr. Beverly Metchock
Mr. Thanyanan Chaowanachan	Ms. Andrea Murphy
Dr. Bin Chen	Ms. Sandra Neal
Ms. Deborah Coker	Dr. Janet Nicholson
Dr. Suzanne Cordovado	Mr. Michael Omondi
Mr. David Cross	Ms. Anne Pollock
Dr. Jan Drobeniuc	Ms. Emily Reese
Ms. Joanne Eissler	Ms. Diane Ricotta
Ms. Kimberly Foylich	Dr. John Ridderhof
Ms. MariBeth Gagnon	Dr. Shahram Shahangian
Ms. Genny Gallagher	Mr. Darshan Singh
Ms. Sharon Granade	Dr. Susan Snyder
Ms. Tracy Greene-Montfort	Ms. Sharmila Talekar
Dr. Scott Grosse	Mr. Mar Y. Than
Dr. Lisa Kalman	Mr. Howard Thompson
Dr. Rima Khabbaz	Ms. Pam Thompson
Ms. Natasha Khudyakov	Dr. David Turgeon
Mr. Nattawan Lanier	Ms. Glennis Westbrook
Dr. Ira Lubin	Ms. Irene Williams
Mr. Kevin Malone	Dr. Laurina Williams
Dr. Adam Manasterski	
Dr. Robert Martin	

Record of Attendance - cont'd.

Department of Health and Human Services (Agencies other than CDC)

Ms. Carol Benson (FDA)

Dr. Steven Gutman (FDA)

Ms. Judith Yost (CMS)

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 30 public citizens attended one or both days of the meeting.

Clinical Laboratory Improvement Advisory Committee

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory Committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

The Committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid Services; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions. Due to the diversity of its membership, CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may eventually result in changes to the regulations, the reader should not infer that all of the Committee's recommendations will be automatically accepted and acted upon by the Secretary.

INTRODUCTORY NOTE

The theme for this meeting was “Recognizing 20 years of CLIA.” Whereas typically CLIAC meetings begin with updates from the three agencies with responsibilities under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) – Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) – the meeting format was modified to allow the CLIAC ex officio members to provide unique agency perspectives on the CLIA program since 1988, in addition to the regular agency updates that were scheduled for the second day of this meeting. The agency representatives then served as panelists during Committee deliberations, during which time the members provided comments, asked questions, and shared individual perspectives as part of a guided discussion. This approach was repeated twice more, first as the presenters for the accreditation organizations and exempt states provided information on their individual programs, and finally with speakers from a variety of settings (international, public health laboratory, clinical laboratory) discussing Quality Management Systems. Again, following the presentations, the speakers served as panelists interacting with the Committee via discussion guided by the Chair.

CALL TO ORDER – INTRODUCTIONS/FINANCIAL DISCLOSURES

Dr. Lou Turner, Chair, Clinical Laboratory Improvement Advisory Committee (CLIAC), welcomed the Committee and called the meeting to order. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

Dr. Thomas Hearn, Executive Secretary, CLIAC, and Deputy Director, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), CDC, welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process. He explained that the theme for this meeting, “Recognizing 20 Years of CLIA,” was more reflective than celebratory and the meeting format was intended to provide a framework for considering the changes that have occurred over the past 20 years, examining current issues, and looking ahead with respect to the role of the CLIA program and future work to be done. Four honored guests were recognized by Dr. Hearn: Dr. Toby Merlin, former CLIAC Chair and current Deputy Director, Influenza Coordination Unit, CDC; Dr. Carlyn Collins, former Director, Division of Laboratory Systems (DLS), currently working with the Division as an intermittent expert; Dr. Robert Martin, former Director, DLS, and current Senior Laboratory Advisor in CDC’s Office of Global Health; and finally, Ms. Rhonda Whalen, whose history with the CLIA program spans the greatest number of years and whose very name, according to Dr. Hearn, is synonymous with “CLIA.” Dr. Hearn then introduced Dr. Rima Khabbaz, Director, NCPDCID, CDC. Dr. Khabbaz expressed her pleasure in attending this milestone meeting, and welcomed the members and thanked them for their service to the public.

AGENCY PERSPECTIVES AND PANEL/COMMITTEE DISCUSSION

20+ Years of CLIA: A Trip Down Memory Lane

Addenda A & A-1

D. Joe Boone, Ph.D.
Acting Director, Division of Laboratory Systems
National Center for Preparedness, Detection, and Control of Infectious Diseases
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention

Dr. Boone's presentation recounted notable facts, personal recollections, and historically significant milestones related to CLIA. He began by discussing the 1987 newspaper articles that sparked Congressional hearings leading to the passage of the CLIA statute. In the context of a brief history of CLIA, his presentation reviewed CLIA's impact on the nation's laboratories and laboratorians illustrated by a CLIA regulatory timeline, statistics related to CLIA accomplishments, and listings of CLIA-inspired partnerships, institutes, and CLIA-mandated studies. He provided a chart compiling 77 CLIA-related Federal Register publications. In conclusion, Dr. Boone noted the value of CLIA over the past two decades has been remarkable.

CLIA Past, Present & The Future of Lab Medicine

Addendum B

Judith Yost, M.A., M.T.
Director, Division of Laboratory Services
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

Ms. Yost's presentation focused on past, present, and future technology, personnel, and the oversight/quality of laboratory medicine. Graphs and demographic information were used to illustrate changes in laboratory certificate types since CLIA's inception and the impact CLIA has had on improving the quality of laboratory testing. She discussed increases in waived and point-of-care testing, the status of genetic testing, the growing personnel shortage, the advent of and increased use of digital pathology, the changes in laboratory deficiency citations from 1995 to 2007, proficiency testing (PT) performance over time, and future goals for the CLIA program.

A CLIA Carol – FDA Perspectives

Addendum C

Steven Gutman, M.D.
Director, Office of In-Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Food and Drug Administration

Dr. Gutman chronicled an FDA perspective of involvement with the CLIA program, discussing test categorization, complexity determinations, evolving criteria for waiver determinations, and alternative quality control (QC) (including Clinical and Laboratory Standards Institute [CLSI] projects). He also noted the important collaboration among FDA, CMS, and CDC, and acknowledged the value of sharing information and expertise among the three agencies. Dr. Gutman finished his presentation by discussing future challenges to laboratories and the CLIA program.

The Chair guided the Committee's discussion, asking members for comments and personal perspectives in response to four specific questions. The questions are provided below, followed by relevant points made during the CLIAC discussion.

- *How has the quality of laboratory testing improved as a result of the implementation of CLIA?*
 - *What are the challenges ahead in continuing quality improvement efforts under CLIA?*
 - *Where should the agencies focus their efforts in the future regarding regulatory revisions, test categorization (including waiver), studies, others?*
 - *How can voluntary standards that supplement CLIA be promoted so that they are more widely implemented?*
-
- Laboratories in general have improved; technology has improved and there are more collaborative partnerships. However, major challenges for laboratories include increasingly sophisticated tests, workforce shortages, and implementation of quality management systems (QMS) by laboratories. In some settings, productivity and efficiency may be considered more important than testing quality.
 - There has been a move toward patient-centered medicine. In light of this, improvements are needed in several areas: public information and education regarding laboratory testing is inadequate; when physicians have insufficient time, tests and medical procedures may not be fully explained to all patients; cultural differences between laboratorians and patients may lead to poor communication.
 - There is a need to balance access to testing, cost, and quality. Access to and quality of care can be linked to reimbursements from both CMS and the private insurers. To offset increased testing costs that result from decreased reimbursement for testing, some physician office laboratories are closing, while others are hiring high school graduates to perform testing instead of trained laboratorians.
 - Physicians need to be better informed on how to order, use, and interpret laboratory tests. Laboratories need to be more engaged in education of the medical staff in their facilities. To do so, laboratory directors need to stay informed about new technology and current literature regarding testing. In addition, the Accreditation Council for Graduate Medical Education needs to expand its curriculum requirements in the area of laboratory medicine.
 - Waived laboratories, where adherence to quality standards is voluntary, are often the laboratories most in need of quality standards. Because the numbers and types of waived tests are increasing, it is important that attention be given to improving the quality of waived testing.
 - Consumers need education on the importance and cost of laboratory quality, otherwise, given a choice of laboratories, they will select for cost, not quality.
 - Manufacturers should clarify the information provided in product inserts regarding test performance, such as reference ranges. Test limitations also need to be clearly highlighted in the product insert to ensure tests are used appropriately.
 - CLIAC needs to be more cognizant of accrediting organizations' activities and

knowledgeable of laboratory training and education programs.

ACCREDITATION AND EXEMPT STATES PERSPECTIVES AND PANEL/COMMITTEE DISCUSSION

AABB and CLIA 2008

Addendum E

Holly Rapp, MT(ASCP)SBB
Director, Accreditation and Quality
AABB

Ms. Rapp presented the history of the AABB (formerly the American Association of Blood Banks) commenting that the AABB Standards and Accreditation programs are celebrating their 50th anniversary in 2008. The AABB standards were developed in 1957 to provide consistency in donor and patient care. The accreditation program followed in 1958 to ensure compliance to the standards. AABB was granted CLIA deemed status in 1995 and in 2008 received deemed status for Blood Banking /Transfusion Services (BB|TS) and Immunology Reference Laboratory (IRL) standards. She emphasized that due to the serious consequences of an error in blood banking and transfusion medicine, AABB has always held to a high standard for quality, examples of which are found in the numerous revisions of the AABB standards. Ms. Rapp noted AABB was the first laboratory organization to adopt QMS and that assessment of the facilities mirrors the change to QMS by moving from a checklist approach to systems evaluation utilizing open-ended questions.

ASHI Standards and Accreditation: Impact on the Quality of Laboratory Testing In the 20 Years of CLIA

Addendum F

Marilyn Pollack, Ph.D.(ABHI)
Department of Pathology, University of Texas Health Science Center, San Antonio
Program Director, ASHI Accreditation Review Board (2007-08)
American Society for Histocompatibility & Immunogenetics

Dr. Pollack presented the early history of the American Society for Histocompatibility and Immunogenetics (ASHI) and told of the organization's development of standards for the accreditation process. Early efforts to ensure testing quality included workshops, exchanges of sera, and comparison of test methods. ASHI was approved as an accrediting organization by CMS in 1999 and continues to meet CLIA deemed status. It was noted that rapidly changing technology requires ASHI to make yearly changes to the standards and that to ensure compliance with CLIA each change is crosswalked.

Dr. Pollack stated that ASHI is of particular importance internationally since it is the only approval body for international bone marrow transplants. Reagents for HLA typing are not FDA approved, therefore the responsibility for their quality lies with ASHI. She suggested the need to

update the CLIA regulations to accommodate changes in technology such as the use of microarray technology that allows more accurate crossmatches and decreases the amount of time from donor to recipient. In conclusion, Dr. Pollack stated that ASHI is an effective CMS partner for lab quality, and that ASHI helps improve test accuracy and clinical outcomes because of its expertise.

Twenty Years of CLIA

Addendum G

R. Bruce Williams, MD
Chair, Commission on Laboratory Accreditation
College of American Pathologists

Dr. Williams presented an historical timeline of the College of American Pathologists (CAP) Inspection and Accreditation Program that began in 1949 with the first chemistry survey and discussed highlights of recent years, including receipt of CLIA deemed status from CMS in 1994. He noted CAP checklists constantly evolve to reflect changes in new technology and announced a CAP pilot implementation of accreditation to ISO (International Organization for Standardization) 15189 in 2008. Dr. Williams also explained the structure of the CAP accreditation program and presented data showing improved performance in PT and inspection results over time, both of these being outcome indicators of improved quality. In considering future opportunities for improving quality in laboratories, he suggested reevaluation of the advisability of increasing the number of waived test approvals and the inclusion of esoteric testing, such as cytogenetics and molecular testing, in the CLIA framework.

COLA Accreditation - Working Together for Excellence in Healthcare

Addendum H

Helena Duncan, MJ
Acting Director, Policy and External Affairs
COLA

Ms. Duncan provided a brief history of COLA, a non-profit organization that accredits physician directed laboratories. She stated that COLA emphasizes education and provides a focus for people lacking a strong background in laboratory testing. The number of laboratories accredited by COLA has increased from less than 6,000 in 1993 to over 7,800 in 2007 with a large influx of laboratories reported between 1993 and 1995. The COLA program structure includes the web-based and interactive on-site survey, accreditation, self-assessment, and PT. By providing hands on communication with the laboratory throughout the survey cycle, COLA can train non-skilled people in good laboratory practice. PT monitoring is used to measure laboratory performance. In 1995, COLA improved their tracking system to allow feedback for continuous monitoring in real time. Ms. Duncan stated that it takes four survey cycles for the laboratories to show evidence of sustained improvement.

The Joint Commission, Laboratory Accreditation – A Brief History *Addendum I*

Margaret Peck, MS, MT(ASCP)
Executive Director, Laboratory Accreditation Program
The Joint Commission

Ms. Peck presented a historical timeline beginning in the mid-1800s and touched on highlights including the Joint Commission (JC) first receiving CLIA deemed status in 1995. She chronicled the name changes from the Joint Commission on the Accreditation of Hospitals (JCAH) to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 1987 to The Joint Commission in 2007. Ms. Peck noted that over time the JC accreditation approach has changed from a survey or inspection process to an improvement process that integrates the laboratory into the continuum of care.

The JC continues to meet CMS requirements for CLIA deemed status, participates in CMS' Partners in Laboratory Oversight Project, and shares relevant survey findings with the JC Cooperative Partners, as well as CMS. New and revised Accreditation Participation Requirements establish processes for employees and the public to identify quality or safety concerns and outlines protection for whistleblowers. The Joint Commission has improved its 'Immediate Threat' reporting processes to CMS. In the future, Ms. Peck stated the JC will focus on new, emerging technologies, identify best practices, and concentrate on reduction of errors in pre- and post-analytical processes and improved oversight of point-of-care testing.

New York State, 20 Years of CLIA 40+ Years of the NYSDOH Clinical Laboratory Reference System – Impact on Laboratory Quality *Addendum J*

Richard W. Jenny, Ph.D.
Clinical Laboratory Reference System
Wadsworth Center

Dr. Jenny gave an overview of the New York State Department of Health (NYSDOH) Clinical Laboratory Reference System established by Public Health Law (PHL) in 1964. He talked about the three components of the clinical laboratory reference system and oversight and licensure activities required by PHL. He also mentioned that NYSDOH licenses 960 laboratorians, of which one third are outside the state. Dr. Jenny used several case studies to illustrate how standards of practice and PT processes in New York have improved testing or led to changes in patient care. He concluded with a summary of how the components of the NYSDOH Clinical Laboratory Reference System contribute to overall laboratory and public health care quality, and acknowledged the important partnership among laboratory professionals/organizations, industry, accrediting organizations, and government.

***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

Impact of Medical Test Site (MTS) Law on Laboratory Quality *Addendum K*

Susan Walker, MT, MA (HEd)
Program Manager, Office of Laboratory Quality Assurance
Washington State Department of Public Health

Ms. Walker began her presentation with an overview of the history and background of the Medical Test Site (MTS) Law in Washington state. The overview described the passage of the Washington state MTS law, the first licenses issued and surveys beginning in 1990, and Washington becoming the first state granted CLIA exempt status in 1993. Currently, there are 3,105 licensed laboratories with the majority categorized as waived. Laboratory fees and categories are the same as CLIA. Ms. Walker stated the numbers and types of deficiencies are tracked; the most frequently cited deficiency relates to the competency and training of all laboratory personnel. Although the numbers are declining, 30% of laboratories continue to have deficiencies.

Ms. Walker discussed the Coordinate Clinical Laboratory Council and described the Internal Quality Improvement Program. She discussed a study that showed technical assistance visits significantly reduced deficiencies of newly regulated laboratories. Ms. Walker projected that in the future emphasis will be on more newsletter articles, distributing Good Laboratory Practices handouts, and more training classes for waived testing and provider performed microscopy.

Committee Discussion

Addendum L

The Chair guided the discussion, asking the panelists and Committee for comments related to the following questions:

- *How has laboratory testing quality been impacted by accrediting organization and exempt state standards?*
 - *Are there differences between these standards and CLIA requirements that contribute to this impact?*
 - *Where should accreditation and state standards focus in the future?*
-
- A member stated concern for patients' safety and health due to the problems surrounding the proliferation of waived testing and emphasized a continuing need for discussion. The member also remarked on the need for standardization in quality improvement, assessment, and terminology.
 - Another member agreed with the need for standardization and commented on a personal experience in a study comparing in-laboratory and nursing point-of-care blood glucose level testing which reflects the fallibility of testing. The two compare favorably for the most part, however, the member cited several instances where critically high glucose levels were reported by point-of-care testing and found to be incorrect upon in-laboratory confirmation, while a few low point-of-care values were found to be high upon retesting in the laboratory.
 - A member expressed concern over the lack of improvement in waived testing, even though much discussion has ensued over many years and recommended the laboratory and medical communities move forward with some positive actions.
 - Dr. Turner asked the accrediting organizations and exempt states whether they used the

Morbidity and Mortality Weekly Report Recommendations and Reports (MMWR R & R) publication that addressed good laboratory practices for waived testing. She also asked if the guidelines spelled out in this document were part of their training, education, and outreach to laboratories.

- Dr. Jenny replied that several years ago the NYSDOH, through a CDC cooperative agreement, assessed the use and quality of waived testing. As a result, it was apparent that there was a need for intervention. CLIAC's activities in developing recommendations published in the *MMWR* were greatly appreciated. New York provided the *MMWR* document to their limited service laboratories that only conduct waived testing. After distributing the *MMWR*, a survey conducted on its utility yielded a very high and positive response rate. He said there is opportunity for accrediting organizations to assist waived laboratories in improving the quality of their services.
- Ms. Duncan stated in COLA's primary market, physician office laboratories (POLs), there is a movement from moderate complexity to waived testing and COLA has developed numerous educational products related to testing and QC. However, it is difficult to encourage laboratories to participate in educational activities unless required by regulation. POLs favor waived testing because there is less oversight.
- Ms. Peck commented the JC requires oversight of all of their laboratories that conduct point-of-care or waived testing. She stated, however, errors still occur. It is difficult to teach the concepts of quality control and train non-laboratorians to recognize when quality control is out of range.
- Dr. Jenny remarked it would be interesting to have a discussion on how waived tests impact the quality of patient care. Several individuals agreed access to these tests is critical to patient care, which in turn speaks to the need for manufacturers to ensure that there is little likelihood that the test will ever fail and that the conditions for a waiver are continually met. The lack of laboratory testing expertise of individuals using waived devices further emphasizes the need for manufacturers to provide clear instructions for their use.
- A member complimented the JC for working to revise standards in a way that will make them much more useful for members. The member also commented on CAP data presented at an earlier CLIAC meeting that showed laboratories that conduct both waived and non-waived testing perform better on waived tests than POLs that only performed waived tests. The conclusion was that people who receive the appropriate training perform more successfully than those who do not, thus demonstrating the need for education and feedback.
- Ms. Ochs, AdvaMed liaison representative to CLIA, reminded everyone that there are many people who are helped by waived testing conducted every day in POLs. They get treatment that they might have missed if they had to wait a week for their test results. In addition, Ms. Ochs stated that manufacturers are responsible for providing the best instructions and the most accurate, robust product possible, whether it is a waived, moderate, or high complexity test. She added there is much room for improvement and encouraged laboratories to view manufacturers as partners.
- Numerous members agreed that cooperation and teamwork among all members of the healthcare team, as well as manufacturers, is essential for healthcare quality and for patient safety, as no individual group has the full picture.
- With respect to waived tests, Dr. Jenny commented that NYSDOH processes about 200 complaints each year levied against laboratories by clients, laboratory personnel, patients, or

physicians and that he could not remember any complaints involving the use of a waived device. A CLIAC member noted the State may not receive complaints about waived tests because the patient may not be aware of a problem unless an unintended consequence occurred.

- Ms. Ochs asked Dr. Jenny about New York State's requirement for analytical and clinical performance review of laboratory developed tests and if he thought New York State's validation is similar to the level of rigor of an FDA review. Dr. Jenny stated that NYSDOH reviews all FDA documents on validation protocols, but the State's rigor is not equivalent to the FDA's review.
- A member referred to Ms. Peck's slide titled 'The Future' and asked how the JC plans to accomplish 1) a reduction of error in the pre- and post-analytical stages and 2) improved oversight of point-of-care testing. The member commented that many guidelines are not likely to be followed unless required by regulations or the accrediting organizations. Ms. Peck responded the JC is currently engaged in the "Standards Improvement Initiative" in which all programs, including the laboratory program, are reviewing their standards, revising language, and making standards more relevant. The JC is receiving input from professional organizations and online field reviews that have been posted on their website, and is moving toward a more integrated approach to the laboratory as part of the continuum of care. They are looking at the patient care/clinical laboratory interface, including pre- and post-analytical processes that occur outside the laboratory in an attempt to define risk areas and improve the quality and safety of laboratory care.
- Dr. Williams stated CAP accredits some waived point-of-care laboratories but finds that they do not have a large subscription because those laboratories are held to the same standards as their other accredited laboratories. In a recent initiative, CAP looked at every requirement and eliminated some that were not applicable to the point-of-care setting. However, many requirements that lead to a higher quality laboratory, remained. Ultimately, few point-of-care laboratories opt for the stricter inspection process.
- One member asked Ms. Walker several questions about the Washington state training programs, including who attended and where they were held. She responded that initially all personnel types attended, including laboratory directors. Over the years, fewer physicians have attended classes, citing a lack of time to participate. She added that much of the material is on the website and many calls are received. Callers are also referred to existing programs, like COLA's LabUniversity and the University of Washington's Medical School, which is developing a 20-CME in-house training for physicians on laboratory medicine.
- A member stated that with the emphasis on pre- and post-analytical error rate improvement, laboratories have a difficult time appropriately addressing those improvements in the current environment of productivity targets and efficiency. The member asked if there were any thoughts on supporting staffing levels for those activities and supporting advanced education for clinical laboratory scientists.
 - Ms. Duncan responded staffing was not something that COLA usually addresses because it is difficult to make the assessment of appropriate staffing or to tell a laboratory that their staffing may not be adequate.
 - Ms. Rapp stated the AABB requires that facilities have adequate staff to perform the work that needs to be done. If the staffing is not adequate, nonconformance or deficiency will be noted and the laboratory will have to submit corrective action/plans. The CLIAC

- member then commented the problem is often in defining “adequate.”
- Ms. Duncan agreed that the number of personnel could not be dictated. It is a matter of judgment as to how many people are needed to do the work. However, if the work is not being accomplished in a timely manner or there are many errors, it should be easy to tell there is something wrong.
 - Dr. Williams explained that the CAP may post signage that says if anything affecting the health or safety of the patients or laboratory personnel is observed, CAP should be notified. Although the CAP inspection may identify staffing issues, a call from someone working in the laboratory is another way of bringing complaints to CAP’s attention.
 - Ms. Peck added that the JC does not prescribe any suggested staffing ratios per number of tests, but they do evaluate turnaround time, staff overtime, and errors. The JC’s leadership policy makes the laboratory director responsible, which in turn motivates laboratory directors to evaluate their needs in a particular discipline.
 - Dr. Jenny commented that in New York the regulations for supervisory-level personnel require that a supervisor be onsite during all hours of testing. A citation can assist laboratories in finding the resources and acquiring supervisory level personnel. He agreed with statements made by the panel that a laboratory needs to define itself and its processes and measure those processes. If a laboratory finds that the quality indicators are identifying problems attributable to lack of staff, either in number or in qualifications, then the expectation is that the laboratory addresses what has been identified as a source of those defects in the testing process.
- A member congratulated all of the accreditation organizations for the small changes made in the focus of inspections over the past several years that have assisted laboratorians and laboratory directors in correcting known pre-analytic problems, e.g., patient identification issues and patient safety goals. The accreditation organizations, by focusing on small changes to the inspection checklist, can go a long way in helping CLIA and laboratory directors correct some of these known pre-analytic problems.
 - In thinking about ways of producing better or normative behavior, members suggested creating some metrics for specific actions that could be tracked via a central database. This would identify non-conforming areas and allow feedback to physicians and teaching opportunities to bring sub par areas back to the norm, recognizing that at the same time, the norm may vary for very good reasons as previously mentioned.
 - Dr. Williams commented, and a CLIAC member agreed, that increasingly patients are better-educated, well-informed consumers, and in the continuum of care, if they identify discrepancies in a treatment regimen based on results they ask for the laboratory results and often they are the first to bring discrepancies to the provider's attention. He added that the complaint database is not a controlled system where valid statements of whether there are problems in the use of waived devices can be made.
 - Dr. Turner thanked the panelists for doing a wonderful job and acknowledged the very thoughtful discussion. She suggested it might be helpful if there was a way to grade healthcare facilities similar to restaurants, with specific reasons provided for the grade. She added as technology changes and new diseases, new benchmarks, and new measures emerge, there will be changes that need to be addressed and working together will make a big difference. Communication and marketing are critical, among laboratorians, to physicians, to patients and to everyone.

AGENCY AND OTHER UPDATES AND COMMITTEE DISCUSSION

Centers for Medicare & Medicaid Services (CMS)

Addenda M, M1-M3

Judith Yost, M.A., MT (ASCP)
Director, Division of Laboratory Services
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

Ms. Yost updated the Committee on a variety of issues pertaining to the CLIA regulations and administration of the CLIA program. She began her presentation with a review of current laboratory statistics categorized by CLIA certificate type. She gave an overview of the cytology PT proposed regulation, explaining that it reflects 17 CLIA recommendations as well as comments from the public and PT providers. She stressed that the proposed regulation will contain questions for and solicit comments from the public. Ms. Yost reviewed the improvement in the cytology PT pass rate since 2005, noting similar PT findings over time in other areas of the laboratory. In discussing oversight of genetic testing, she explained that in lieu of a genetic testing specialty CMS is recommending the use of professional standards to address good laboratory practices. Also with respect to genetic testing, CMS is pursuing enrollment of more laboratories into the CLIA program, monitoring direct-to-consumer testing, expanding information on the CLIA web site, and collaborating with CDC and FDA on appropriate oversight of genetic testing. Next, Ms. Yost gave a brief review of the changes to the requirements for QC in the 2003 final CLIA rule, clarifying the requirements for calibration verification and the use of external QC materials. As part of the QC discussion, she also updated the Committee on the status of alternative QC. Other helpful information provided by Ms. Yost included formats for complaint filing, reminders pertaining to PT referral, and hints for avoiding the top 10 deficiencies cited by CMS. Ms. Yost concluded her presentation by reviewing the status of CMS responses to the recommendations issued by the Government Accountability Office 2006 survey, highlighting changes that had been made to the CLIA program as a result of this survey.

Committee Discussion

- One member requested clarification of whether specimens may be collected offsite and transported to a laboratory. Ms Yost replied that this is permitted, and explained that although CLIA covers sites where testing is performed and not sites of specimen collection only, CLIA does require the testing laboratory assure proper handling and specimen integrity.
- Another member voiced continuing concern with the current requirements for cytology PT and then asked how to handle unintentional PT referrals in facilities where there are satellite laboratories. Ms. Yost answered that sites with multiple laboratories under one CLIA certificate should have systems in place that identify the process for handling PT samples.

- A member asked if PT performance was evaluated statistically from year to year and a second member asked if CMS compares PT organizations to be sure that all programs are equally robust. Ms. Yost replied that CMS monitors laboratory performance on PT for all regulated analytes on an ongoing basis and takes action when successive failures occur; national statistics are also monitored. She added that CMS needs to collaborate with CDC, PT providers, and experts in the field on issues pertaining to PT.
- In conclusion, Dr. Turner suggested providing a CLIA booth at professional meetings to improve communication and provide information relevant to the program. Ms. Yost noted that CMS has participated in several professional meetings to share CLIA information.

Food and Drug Administration (FDA)

Addendum N

Steven Gutman, M.D., M.B.A.

Director, Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)

Center for Devices and Radiological Health (CDRH)

Food and Drug Administration

Dr. Gutman began his update by indicating changes in key FDA personnel along with new mandates for user fee submission deadlines and In Vitro Diagnostics (IVD) specific agreements. He discussed a variety of IVD user fee goals, some of which are directed toward creation of very specific guidance, while others involve development of more general “migration” guidance. He explained the term “migration” describes how an analyte is moved from one platform to an essentially equivalent platform without necessarily repeating clinical studies. Dr. Gutman briefly discussed two controversial guidances: one concerning Analyte Specific Reagents (ASRs) which he said was a clarifying guidance finalized last fall and secondly a guidance on In Vitro Diagnostic Multivariate Index Assays (IVDMIA) which is under review and is a new application of an existing guidance. He said three alternative regulatory proposals for the IVDMIA guidance have been received from 21st Century Medicine Alliance, ACLA, and AdvaMed. Dr. Gutman then briefly described the tasks of the current Secretary’s Advisory Committee on Genomics, Health, and Society. He concluded his presentation by providing an outline of the goals and accomplishments of OIVD including new products, new guidances, outreach, critical path initiatives, leveraging activities and compliance actions.

Committee Discussion

- A member asked about the type of feedback the FDA is receiving on the ASRs. Dr. Gutman explained that since companies are marketing multiple ASRs in a single vial they are no longer viable if they are broken up. He stated that the only feedback they are receiving is on multiple-moiety issues.

Centers for Disease Control and Prevention (CDC)

Addenda O & O-1

D. Joe Boone, Ph.D.

Acting Director, Division of Laboratory Systems
National Center for Preparedness, Detection, and Control of Infectious Diseases
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention

Dr. Boone reviewed CLIA-related projects currently underway in DLS. He began with the guidance for genetic testing, sharing an outline of the proposed *MMWR R&R* document: Good Laboratory Practices for Ensuring the Quality of Genetic Testing. He then provided a summary of follow-up work for the 2007 Institute “Managing for Better Health,” and requested input from CLIAC. Next, he provided an update on the status of three 2007 laboratory medicine reports developed through a contract with Battelle and the *2008 Status Report* to be drafted by the Lewin Group under subcontract to Battelle. Dr. Boone concluded his presentation with a brief timeline and update on the status of “CLSI M50: Quality Control for Commercial Microbial ID Systems,” which is being developed based on recommendations made by CLIAC.

Committee Discussion

The Committee discussion focused on the proposed *MMWR R&R* document, and the importance of providing clear guidance, especially on aspects of the pre- and post-analytic phases of genetic testing.

- A member suggested the topic of confidentiality should be addressed in the document.
- Another member commented that a discussion of genetic counseling might be needed. Dr. Boone replied that since ethical/legal issues pertaining to patient communication are outside the general purview of the laboratory a decision must be made on which of these issues should be included in the document.

Board of Scientific Counselors Report to the Clinical Laboratory Improvement Advisory Committee: NCPDCID Investments for Assuring Public Health *Addendum P*

Lou Turner, Dr.P.H., HCLD, CPM
Chair, Clinical Laboratory Improvement Advisory Committee
Deputy Section Chief, Epidemiology
North Carolina Division of Public Health

Dr. Lou Turner summarized for the CLIAC a presentation reported to CDC’s Coordinating Center for Infectious Diseases Board of Scientific Counselors on NCPDCID investments for assuring public health laboratory system capacity. The report provided examples of NCPDCID investments, described current strengths and directions of several NCPDCID programs, and outlined strategies for improving CDC and state public health reference testing. The report concluded with a look to the future and what will be most needed and helpful in sustaining funding streams and infrastructure, especially in addressing the workforce crisis currently facing public health laboratories.

Committee Discussion

- None

CCCLW, Coordinating Council on the Clinical Laboratory Workforce

Addendum Q

Joeline Dillard Davidson, MBA, CLS, MT

Liaison, Coordinating Council on the Clinical Laboratory Workforce
Administrative Director, Laboratory Services
West Georgia Health System (Retired)

Ms. Davidson presented highlights of the Council's *2008–2011 Strategic Plan Draft*. She provided a list of participants involved in the strategic planning process and briefly discussed their input in developing key vision elements for 2008-2011 and the underlying contradictions to the vision's elements. Ms. Davidson closed by outlining for CLIAC the proposed CCCLW strategic goals and suggested action plan strategies for attaining these goals.

Committee Discussion

- CLIAC members hailed the CCCLW proposed strategic goals as on target and much needed in terms of addressing current clinical and public health laboratory workforce laboratory issues but felt the goals were overly ambitious. There was general consensus among the members that CCCLW should prioritize their goals, look at what is most easily accomplished in the short term, and implement activities to accomplish short-term goals immediately.
- One member acknowledged the role of the American Society of Clinical Laboratory Science (ASCLS) in the creation of the CCCLW, complimenting the CCCLW on successfully bringing all of the various laboratory groups together to form a single unified voice championing significant major laboratory issues.
- Another member encouraged inclusion of organizations in CCCLW that could provide information to the public about the importance of laboratory testing and workforce shortages, suggesting the AARP, consumer unions, and senior health organizations as possible contacts.
- Many members felt CCCLW should increase its efforts to address workforce shortages of cytotechnologists.
- Several members requested additional information on the activities of CCCLW. Elissa Passiment, CLIAC member, and Executive Director for ASCLS, offered to provide past quarterly reports via email to interested members and extended an invitation to all CLIAC members to attend the next CCCLW meeting.
- Several members questioned whether all professional laboratory organizations were represented on CCCLW. It was clarified the list of organizations in the CCCLW presentation was incomplete and reflected only those present at the strategic planning meeting. CLIAC was informed the complete CCCLW member roster could be found at www.ascls.org/ssclp/index.asp.

QUALITY MANAGEMENT SYSTEMS PRESENTATIONS AND

PANEL/COMMITTEE DISCUSSION

Progress and Process in International Laboratory Quality

Addendum R

Michael A. Noble, M.D., FRCPC
Professor and Chair, Clinical Microbiology Proficiency Testing Program and,
Program Office for Laboratory Quality Management
Department of Pathology and Laboratory Medicine
University of British Columbia

Dr. Noble began with a historical review of the earliest evidence of QC and standards of measurement, beginning with ancient civilizations and leading up to modern times and the coordinated activities of ISO to develop internationally accepted standards. Although the use of quality systems is not new to human activities, it is relatively new to medical laboratories. The laboratory community is gradually moving toward adopting QMS using guidance documents, in particular those developed by CLSI and ISO. Dr. Noble concluded with a summary of the benefits laboratories could realize through the process of ISO certification.

A Quality Management System in a Public Health Laboratory – Why and How?

Addendum S

Ms. Johanne Lefebvre
Responsable qualité
Laboratoire de santé publique du Québec

Ms. Lefebvre presented an overview of the four-year endeavor at the Laboratoire de santé publique du Québec to become the first public health laboratory in Canada to achieve ISO 9001 certification. Incentives that encouraged the laboratory to move to ISO standards included increased visibility, recognition of quality, and the opportunity to serve as a model for other clinical laboratories in Quebec. Internally, the laboratory would realize the benefits of standardized practices operating through process analysis and integrating a continuous quality assurance program. Ms. Lefebvre emphasized the involvement of management and employees were key elements to the gradual implementation of ISO 9001:2000 requirements and eventual certification in 2005.

***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

Describing the Incredible Journey in Less Than 30 Minutes – Implementing A Quality Management System for the Laboratory

Addendum T & T-1

Christine Flaherty, MHA, MT(ASCP) CPHQ
Regional Director, Laboratory Services
Sutter Health
Sacramento, California

Ms. Flaherty conveyed her experience developing and implementing a quality system model for a multi-hospital organization using the CLSI documents as guidance. The six-year process for her organization resulted in decreased costs, a single, standardized approach to quality management, consistent work processes and procedures, medical directors who are engaged, and significant improvements in employee satisfaction and quality of service.

Committee Discussion

Addendum U

In opening the discussion, the Chair requested the members to address first any clarifying questions or comments regarding Ms. Flaherty's presentation in the interest of time to accommodate this speaker's return travel to the West Coast.

- The discussion began with a question for Ms. Flaherty about whether the process of implementing a quality system required any additional resources other than existing staff. Ms. Flaherty responded they used an outside consultant a few times as a content expert, but did not have any extra resources for implementation; that is probably one reason implementation took so long to achieve.
- Another Committee member inquired about the connection between implementation of a quality system and a cultural shift to quality within the laboratory. Ms. Flaherty responded the effort to implement came from leadership (herself), and was gradually followed by a cultural shift at the employee level. Having a good infrastructure for event reporting, appropriate training, and adequate work instructions helps staff understand how their work impacts the patient, which leads to ownership in the quality system.
- In light of the complexity of a multi-facility health system and the fact they were already CAP accredited, one committee member asked Ms. Flaherty how she was able to move administration to a quality system. She responded her position as regional director gave her the autonomy to work directly with the laboratory managers. These efforts helped reduce costs, which caused administration to take notice and led to supporting a quality system. The medical directors appreciated the benefits of achieving a consistent state of readiness for inspections. Because the quality management program made the managers' and directors' jobs easier, they supported her efforts and implementation was transparent to administration.
- Another member asked about criteria for selecting best practices. Ms. Flaherty stated they looked at hard data performance indicators to identify existing practices that had positive outcomes in operational performance as a basis for establishing best practices.
- One Committee member asked Dr. Noble about the Canadian system of socialized medicine; how does it impact quality, is there a shortage of laboratorians, and what can be learned from Canada's experience? Dr. Noble explained Canada has ten provincial jurisdictions, similar to state jurisdictions in the U.S., where each province develops its own system. In the U.S., there is the interaction between Medicare, Medicaid, and CLIA. Canada does not have anything equivalent to those federal level programs. Addressing workforce issues, the provinces vary in the availability of technologists, similar to the U.S. situation. Whether a

system has a single insurer, called socialized medicine, or multiple insurers like the American system, both seem to be imploding and neither system has answers.

- A member addressed the issue of harmonizing standards in light of the many different standards organizations that exist such as the JC, CMS, CAP, and others. Another member added that the incentive for manufacturers to seek certification is financial. In order to do business in Europe, they need ISO certification. In the U.S., the FDA and ISO come into play for businesses, although they are not harmonized. Laboratories need motivation to move to quality standards.
 - Ms. Lefebvre commented that as more laboratories achieve QMS certification, which includes being accountable to customers, implementation of quality systems would increase.
 - Dr. Noble added the same financial motivation for manufacturers applies to laboratories because a QMS drives out the cost of poor quality and brings in efficiency - the ability to do more with the same resources and to do it better.
 - Ms. Yost stated that CLIA can be cross-referenced to the CLSI GP-26 document, which has moved laboratories toward QMS for compliance. She also noted that CMS supports ISO 15189. The difference is ISO takes a broad approach, whereas CLIA is more prescriptive in its requirements; the two can work in partnership.
 - Dr. Noble commented the ISO standards for clinical laboratories and CLSI's guidelines are constructed differently but embrace the same principles. The result of QMS implementation is to drive down errors.
 - Dr. Hearn noted that global standardization is on the increase. Last year International Health Regulations were adopted by more than 100 countries, including the U.S., and as a result we will likely see more emphasis on adherence to international laboratory quality standards in public health laboratories.
 - A Committee member noted that process improvement is the greatest need in healthcare today. CLSI has a great tool kit and many quality documents; CAP is bringing quality management into its checklists; more collaboration across organizations is needed.
 - One member added there is recent study data about the barriers to implementing QMS. The barriers tend to be information technology-related, data-related and, in particular, related to resistance from leaders. Even though quality systems exist, each of these barriers has to be addressed because they are the most significant barriers to implementation. Dr. Noble reminded the Committee of Deming's example of success where commitment from top management was the driver.
 - The laboratory community is reaching a point where something must be done because the process is really about risk management. Industry standards can teach us a lot about managing risk.
- Dr. Turner pointed out that all the presentations demonstrate QMS takes a long time for implementation. In the public health setting, challenges arise from changes in political leadership. The Committee discussed other challenges of implementing QMS, which include limited personnel and institutional changes. Several members agreed that gradual change, addressing one issue at a time or integration through accreditation cycles, is the best way to accomplish implementation. The Sutter Health presentation also demonstrated by engaging people, even in multiple systems, there is an opportunity to bring them together by looking for successful practices and building on them.
- A member mentioned the role CLSI could play by helping to define what best practices are

today.

- Dr. Turner thanked the Committee and presenters for the discussion.

BIOSAFETY IN CLINICAL LABORATORIES: PRESENTATION AND COMMITTEE DISCUSSION

Biosafety in Clinical Laboratories

Addendum V

Janet K.A. Nicholson, PH.D.
Senior Advisor for Laboratory Science
Coordinating Center for Infectious Diseases, CDC

Dr. Nicholson recounted an incident that occurred as the result of a surrogate *Brucella* organism sent to participating clinical laboratories as part of an October 2007 CAP Laboratory Preparedness Survey. Although no case of laboratory-acquired brucellosis was reported, there was evidence to suggest that 916 laboratorians in 254 laboratories were exposed with 74% categorized as high-risk exposures and 26% low-risk exposures. This, in addition to earlier incidents, has suggested to CDC that there is a need for greater attention to biosafety in clinical laboratories and that a greater focus should be placed on assessing the adequacy of training of laboratory personnel working with infectious agents, the availability of appropriate safety equipment, and the safety procedures currently in use in clinical laboratories. Dr. Nicholson closed by asking CLIAC to consider the following questions:

- *Do clinical laboratories have appropriate safety procedures in place?*
- *Are workers in clinical laboratories adequately trained in safety procedures?*
- *Are clinical laboratories properly equipped to handle infectious agents safely?*
- *What recommendations do you have for ensuring safe practices are followed in clinical laboratories?*

Committee Discussion

- Most members agreed the majority of laboratories have appropriate safety procedures in place. However, several members expressed concern about safety procedures for specimen collection and transport. The suggestion was made that CDC focus on the entire specimen path, from the time of collection to final disposal.
- Several members stated that laboratory safety training is more than adequate, emphasizing the most safety education can do is raise the awareness of what the risks are and how to minimize those risks through safe work practices. No safety education program can ensure workers will use safe work practices 100% of the time.
- There was general concurrence from CLIAC that most documented exposures in laboratories are not the result of inadequate procedures or policies but rather the failure of an individual to comply with established policies and/or procedures.
- Another member stated experienced laboratory workers become desensitized, over time, to the possibility that they can become infected. No matter how much education is given

workers, no matter how frequently safety education programs are offered, workers will still have lapses in their safe work practices.

- CLIAC was reminded that, for any hazard, the first operating rule of basic safety requires every attempt be made to eliminate the source of a hazard. If that is impossible, the next step is to reduce the potential for exposure to the source through engineering controls and appropriate design of facilities. The last step should be implementation of personal protective equipment (PPE), laminar flow hoods, and biological safety cabinets. No matter how effective PPE, laminar flow hoods, and safety cabinets are, their effectiveness can be compromised by failure of an individual to use them properly or use them at all. Most members concurred.
- A discussion followed on available guidelines and recommendations for laboratory design with several members indicating that although there are numerous recommendations that address air exchange, negative airflow pressure, lockdown and other design features pertaining to safety, no single resource document that provides all of the necessary information is currently available.
- While most members agreed laboratory design should be the first line of defense in reducing worker exposures they reiterated improved laboratory design would not address the issues of failure to follow safe work practices or exposures occurring prior to receipt of the specimen in the laboratory.
- CLIAC unanimously agreed that the administrative culture in the laboratory was the single greatest influence to ensure safe work practices are followed.
- One member recommended having better assessment systems in place and positive incentives to recognize safe work practices.
- Another member suggested using the Assistant Secretary for Preparedness and Response (ASPR), formerly the Health Resources and Services Administration (HRSA), hospital preparedness ratings and grants program to require more stringent training documentation and include an assessment of worker compliance and exposure incidence reports in the hospital's rating.
- Although most members agreed positive incentives would increase the use of safe work practices, they also felt it unlikely a laboratory could attain 100% compliance, 100% of the time.

SPECIAL PRESENTATIONS

Dr. Rima Khabbaz, and Dr. Tom Hearn recognized the contributions of four retiring members whose terms will end on June 30, 2008:

Ms. Joeline Davison

Dr. Dina Mody

Dr. Lou Turner, Chair

Dr. Thomas Williams

PUBLIC COMMENTS

- **George Birdsong, MD, FCAP, on behalf of the American Society of Cytopathology and other professional organizations** *Addenda W & W-1*

Dr. Birdsong discussed the topic of cytotechnology school closures and the potential for a critical shortage of cytotechnologists in the future.

- **Ms. Janie Roberson, SCT (ASCP), American Society for Cytotechnology** *Addendum X*

Ms. Roberson addressed the topic of cytology proficiency testing, specifically expressing the cytology community's concern with the length of time it is taking to issue the Notice of Proposed Rulemaking.

- **Mr. Matthew Schulze, American Society for Clinical Pathology** *Addenda Y & Y-1*

Mr. Schulze spoke on the topic of the laboratory workforce shortage and the need to reauthorize Title VII allied health programs.

- **Mr. Ray Ozmon**

Mr. Ozmon commented on the topic of waived testing, identifying the need for education and training in order to reduce potential laboratory errors in physician office laboratories, at the point of care, and in other non-traditional settings where waived testing may be performed.

ADJOURN

Dr. Turner acknowledged the CDC staff that assembled the meeting program and thanked the CLIAC members and partner agencies for their support and participation. She reminded the members that a Genetic Testing workgroup would be convened in April to make suggestions for the development of the proposed *MMWR R & R* document addressing good laboratory practices for genetic testing; a report of the proceedings from that meeting will be provided at the next meeting for CLIAC's consideration. Dr. Turner announced the next meeting CLIAC meeting date of September 10-11, and adjourned the Committee meeting.

I certify this summary report of the February 20-21, 2008, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Dated: 05/8/2008

Lou Flippin Turner, Dr.P.H., CLIAC Chair