Clinical

Laboratory

Improvement

Advisory

Committee

Draft Summary Report

<u>September 7-8, 2005</u>
Doubletree Atlanta/Buckhead Hotel
Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

Clinical Laboratory Improvement Advisory Committee
September 7-8, 2005, Summary Report
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IX. Adjourn

Record of Attendance

Committee Members Present

Dr. Lou Turner, Chair
Dr. Kimberle Chapin
Ms. Joeline Davidson
Ms. Merilyn Frances
Ms. Paula Garrott
Dr. Carol Greene
Dr. Lee Hilborne
Dr. Anthony Hui
Mr. Kevin Kandalaft
Dr. Michael Laposata
Dr. Dina Mody
Dr. Valerie Ng
Dr. Barbara Robinson-Dunn
Dr. Jared Schwartz
Dr. David Smalley
Dr. Thomas Williams
Dr. Jean Amos-Wilson

Committee Member(s) Absent

Dr. Kathy Foucar
Dr. Peter Gomatos
Dr. Patrick Keenan

Executive Secretary (Absent)

Dr. Robert Martin

Ex Officio Members

Dr. Thomas Hearn, CDC
Ms. Judith Yost, CMS
Dr. Steven Gutman, FDA

Liaison Representative - AdvaMed

Ms. Luann Ochs, Roche Diagnostics Corporation

Record of Attendance, continued

Centers for Disease Control and Prevention

Ms. Nancy Anderson
Dr. Rex Astles
Ms. Pam Ayers
Ms. Carol Bigelow
Dr. D. Joe Boone
Ms. Diane Bosse
Ms. Carol Cook
Ms. Joanne Eissler
Mr. David Elswick
Ms. Christine Ford
Ms. Maribeth Gagnon
Ms. Sharon Granade
Dr. Devery Howerton
Dr. Lisa Kalman
Dr. John Krolak
Dr. Ira Lubin
Dr. Laurina Williams
Mr. Kevin Malone
Dr. Adam Manasterski
Ms. Leslie McDonald
Ms. Anne Pollock
Ms. Andrea Scott
Dr. Shahram Shahangian
Ms. Colleen Shaw
Mr. Darshan Singh
Ms. Monica Swann
Dr. Julie Taylor
Mr. Howard Thompson
Ms. Pam Thompson
Ms. Glennis Westbrook
Ms. Rhonda Whalen
Ms. Darlyne Wright

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

Ms. Carol Benson (FDA)
Ms. Valerie Coppola (CMS)
Dr. Elliot Cowan (FDA)
Ms. Cecilia Hinkel (CMS)
Mr. Scott McFarland (FDA)
Mr. Donald St. Pierre (FDA)
Ms. Roxanne Shively (FDA)
Ms. Harriett Walsh (CMS)
Ms. Cheryl Wiseman (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.

CALL TO ORDER – INTRODUCTIONS/FINANCIAL DISCLOSURES

Addendum A

Dr. Lou Turner, CLIAC Chair, welcomed the Committee members and called the meeting to order. She introduced Mr. Kevin Malone, CDC attorney advisor, who provided an instruction sheet and explained the requirements and process for public disclosures, including those for conflict of interest. Mr. Malone advised the Committee that two members would need to recuse themselves from participating in the cytology proficiency testing (PT) discussion portion of the meeting because of their respective roles within the College of American Pathologists (CAP), a professional organization recently approved as a cytology PT provider and involved in lobbying Congress regarding the CLIA cytology PT provisions. Mr. Malone also requested other members holding comparable positions to recuse themselves. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Food and Drug Administration (FDA) ***Addenda B,C***

Dr. Steven Gutman, Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA, provided an update on the draft waiver guidance, "Draft Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications." The document was announced in the *Federal Register* on September 7, 2005, and is available on the CDRH website http://www.fda.gov/cdrh/oivd/guidance/1171.pdf. It is a proposed, non-binding document soliciting public comment in the process of moving toward final guidance and regulation. Based on CLIAC recommendations, the guidance is scientifically detailed without precluding flexibility and addresses the elements of simplicity, insignificant risk of error, fail-safe design, and clear labeling. The objective of the document is to encourage innovation while assuring quality and patient safety.

Dr. Gutman reviewed the recent concept paper on the co-development of drugs and diagnostic devices, and provided an update on new regulatory tools and products, work on informed consent, and regulation of analyte specific reagents. He concluded his presentation by discussing OIVD's work structure, emphasizing the total product life cycle and combining regulatory functions (premarket, compliance, and surveillance) from a common technical basis.

Committee Discussion

- A Committee member asked what impact the Patient Safety and Quality Improvement Act of 2005 had on FDA operations, specifically regarding issues related to laboratory medicine. Dr. Gutman responded the agency is putting numerous traditional and innovative programs in place. Ms. Yost added the CLIA program now places more emphasis on patient safety. The survey process focuses on the impact of survey findings as well as meeting regulatory requirements.

- One member asked when the recommendations in the draft waiver guidance would become binding. Dr. Gutman explained the process will move from a non-binding draft guidance to final more definitive guidance, then to a proposed regulation, and ultimately to a final binding regulation. Public comments will be solicited and evaluated throughout the process.

Centers for Medicare & Medicaid Services (CMS) ***Addendum D***

Ms. Judy Yost, Director, Division of Laboratory Services (DLS), Survey and Certification Group (SCG), CMS, updated the Committee on CLIA statistics. She enumerated laboratories by self-selected type and by certificate type, pointing out approximately 60% hold certificates of waiver (CWs). She noted 88% of laboratories are relatively small, performing less than 25,000 tests/year; only 0.3% perform greater than one million tests/year; and there are now 3,874 pharmacies enrolled. The most frequently cited deficiencies were in the areas of test method verification, calibration and calibration verification, and quality control (QC) procedures, where the most significant changes were made in the final regulation. Commenting on CW surveys, Ms. Yost stated CMS will continue to conduct visits in 2006. Data continues to demonstrate quality issues are ongoing but follow-up visits reflect improvement.

Ms. Yost reviewed the activities surrounding QC for the future. CMS introduced Equivalent Quality Control (EQC) in the 2003 regulations to offer laboratories flexibility in performing external QC under certain conditions by using Interpretive Guidelines instead of regulations. At the request of CMS, the Clinical and Laboratory Standards Institute (CLSI) convened a meeting of laboratory and professional organizations to discuss development of QC alternatives under the consensus process. Ms. Yost added CLSI is developing EP22, a project assigned to the Subcommittee on Validation of Risk Mitigation for development of guidance ("Principles of Manufacturer's Validation of Risk Mitigation Using Quality Controls") for manufacturers to follow in making user QC recommendations. She indicated an additional CLSI document has been proposed to provide guidance to laboratories in developing QC protocols based on the manufacturer's risk management information and environmental factors unique to the laboratory. If both CLSI documents are developed and followed, CMS would accept this as meeting CLIA QC requirements. Ms. Yost concluded her presentation with an update of the Partners in Laboratory Oversight and of the ongoing Government Accountability Office (GAO) audit focusing on CMS oversight and performance of accrediting organizations and state agencies under CLIA.

Committee Discussion

- Several Committee members inquired about the continuation of CMS surveys of CW facilities, since in the past the surveys have not been supported by funding and CMS has no authority by law to perform them. Ms. Yost said currently surveys are performed in approximately 2% of CW facilities per year and funding comes from revenues over expenses. DLS is seeking funding from CMS administration to continue the surveys indefinitely.
- One member asked how CMS decides which CW facilities to visit. Ms. Yost stated a complaint puts a facility first on the list, and each state has the discretion to select the laboratories to be visited. All laboratory types are visited, including physician office laboratories, nursing facilities, rural health centers, and ambulatory surgical centers.

- Another member inquired about efforts to consider flexible quality standards when there are no commercial test systems available, such as when performing non-commercial methods in testing for rare diseases. Ms. Yost commented CLIA applies to all clinical laboratory testing, whether or not test systems are FDA approved. Dr. Hearn suggested that specialized testing may benefit from specific guidance provided by CLSI or other professional organizations.
- Committee members questioned whether CMS had considered laboratory patient safety issues, such as correct test ordering and interpretation, especially in genetic testing. Ms. Yost responded CLIA contains little specificity pertaining to clinical consultant responsibilities, although this is the individual responsible for pre-testing (test ordering) and post-testing (test interpretation) issues. She commented DLS is attempting to collaborate with others at CMS who are involved with issues of patient safety. She added CMS and CDC are working on a proposed rule for genetic testing and encouraged comments when the proposed regulation is published.
- A member asked if the CLSI QC documents would address the fact that unsatisfactory PT data may reflect the state of the art of various assays and encourage manufacturers to improve assay performance. Ms. Ochs replied the manufacturers' guidance document will apply to traditional as well as equivalent QC, and if a manufacturer is making a QC recommendation, it will need to be supported by data.
- The same member inquired whether there is a role in post-market surveillance for the Partners for Laboratory Oversight. Ms. Yost replied there is a proposal to include post-market surveillance in the CLSI laboratory QC document. Ms. Ochs commented on the manufacturer and the laboratory documents in development by CLSI, expressing concern the CLSI committees do not currently view a corresponding laboratory document as substantial enough to warrant separate publication and requested Committee feedback on this matter. The Committee had further discussion on the laboratory document, which is included under the EQC Option 4 Update.
- A member commented that many facilities performing testing are not traditional laboratories and therefore need valid QC procedures and information on interpreting test results. Valid QC needs to be built into the test system.
- Another member stated the CLSI document must emphasize the importance of laboratory directors understanding their responsibilities. A third member noted a lack of clinical expertise in the field of pathology and suggested ways of encouraging the development of better training programs to produce experts in clinical as well as anatomic pathology.

Centers for Disease Control and Prevention (CDC) Update

Data Exchange between Public Health and Clinical Laboratories: Why Standards and Interoperability are a Critical Part of Quality ***Addendum E***

Dr. Claire Broome, Acting Director, Integrated Health Information Systems, Coordinating Center for Health Information and Service (CoCHIS), CDC, spoke of the importance of using information technology (IT) standards in electronic laboratory reporting, focusing on communications between public health and clinical laboratories. She challenged medical laboratories to play a leading role in national health data exchange by adopting and using the Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant Logical

Observation Identifier Names and Codes (LOINC), Systematized Nomenclature of Medicine (SNOMED), and Health Level Seven (HL7) coding and messaging standards for communicating laboratory results and other patient data. She emphasized reliable coding of a complete set of laboratory results requires use of all three standards.

Dr. Broome advised the Committee that wide adoption of these IT standards within the U.S. would expedite the flow of critical information among federal, state, local, and private sector laboratories during emergencies. She gave the example of Nebraska, where laboratory report delays dropped from 26 to 2 days after adopting these standards. Dr. Broome said CDC is working to implement these standards among the nation's public health laboratories, noting only 26 states could now handle an HL7 message including laboratory results. She described the utility of such standards in the Laboratory Response Network, which requires efficient communications among the FDA, Federal Bureau of Investigation, and Environmental Protection Agency. In addition, the Public Health Information Network (PHIN) requires secure communications to carry out early event detection, outbreak management, and countermeasure efforts. Using a map, Dr. Broome illustrated those states making progress in developing messaging and content standards. She mentioned CDC's role in developing the PHIN-MS software tool enabling HIPAA-compliant bi-directional data transport. She expressed hope that laboratory information management system (LIMS) vendors would integrate coding and message formatting tasks into newer systems, thereby reducing the burden of coding, formatting, and reporting. She concluded by saying clinical laboratories have an opportunity to take a leading role enhancing the quality of our national health data exchange.

Committee Discussion:

- The Chair commented that states can be slow to adopt standards. Dr. Broome acknowledged this, pointing out that the states shown on her map as not using standards are working toward that goal.
- A member described a situation where the county health and the hospital epidemiology departments reported data to the state electronically, but their data mining and entry were still performed manually without benefit of statewide standards. Dr. Broom responded online data entry is as slow as manual documentation, however, it expedites data sharing to near real time. It does not address data exchange interoperability. She reemphasized the utility of automatic data entry into LIM systems. CDC promotes these standards to laboratories and LIMS vendors, emphasizing they will be compliant with HIPAA requirements for billing and payment.
- Another member pointed out standardization would lessen misunderstanding but worried that in complicated diagnostic and patient counseling situations it might constrain the practice of medicine. Dr. Broome acknowledged the challenge of balancing structure and interoperability with flexibility.
- Another member found it easier to use the HL7 overlay of a medical record after it had passed through the institution's electronic medical records system rather than use various laboratory information formats. Dr. Broome agreed an institution using HL7 as a tool could efficiently bring patient data in from various sources, making the clinician's work easier. She encouraged laboratories to take an interest in these standards and provide leadership in laboratory data integration within their institutions.

PRESENTATIONS AND COMMITTEE DISCUSSION

National Cytology Proficiency Testing (PT) Update ***Addendum F***

Ms. Cheryl Wiseman, Health Insurance Specialist, DLS, SCG, CMS, gave preliminary midpoint data from the first year of national cytology PT. She noted the CLIA statute was the foundation for the PT regulations, and it specifies "...periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytologic preparations...." The annual PT event described in the CLIA regulation is a 10-slide challenge examined in a maximum of two hours, with retesting scheduled in the event of failure. The State of Maryland program, approved in 1995, and Midwest Institute for Medical Education (MIME), a national program approved in 2004 and in its first year of operation, are the only cytology PT programs currently approved under CLIA.

Ms. Wiseman presented preliminary national cytology PT results through August 26, 2005. The national data from MIME and the State of Maryland showed 91% overall pass rates for cytotechnologists, 87% for pathologists working with cytotechnologists, and 59% for pathologists working alone. Data also showed MIME PT pass rates for this initial year of testing were similar to initial year testing in Maryland for the above categories. For 2006, Ms. Wiseman announced the State of Maryland and MIME cytology PT programs have been reapproved and the College of American Pathologists' cytology PT program has been initially approved by CMS.

Committee Discussion

- A Committee member asked if the glass slides represented only conventional Pap slides and if PT pass rates had improved over the first 6 months. Ms. Wiseman said Maryland used only conventional Pap slides, while MIME offered both conventional and liquid-based preparations. She said overall pass rates had remained steady (86% to 89%), but future improvement is expected.
- A member referenced an article documenting inconsistency among experts interpreting certain Pap test abnormalities and remarked that the regulations may need to be revised to address new technology. Another member emphasized this point, describing the use of molecular testing for human papillomavirus (HPV) to resolve discrepancies in interpreting Pap tests. Ms. Yost and Ms. Wiseman acknowledged this, but noted HPV testing is a virology test.
- Another member remarked, because cytopathology has advanced and improved considerably since 1988, the best solution to cytology PT problems might be to change the statute to allow laboratories to be tested rather than individuals. In response to several members' questions, Ms. Wiseman explained a pathologist must be tested as a primary screener if performing any primary screening during the year.
- One member remarked cytology PT has a single correct result, while PT in some clinical laboratory specialties may have a range of acceptable results, adding it appears cytology is held to a higher standard. Another member added the Pap test is a screening test, often not correlating with biopsy, and suggested it would be reasonable if one degree of discordance was allowed as in clinical testing.

- One member suggested using biopsy results and patient outcomes data to determine work quality, adding that PT might be more effective if it simply focused on problematic, high-risk diagnoses. Another member countered this would work only for abnormal results and not for the large majority of Pap tests signed out as negative.
- Two members suggested a different interpretation of the statutory phrase "individual testing" for cytology PT, indicating it might be viewed separately from "individual scoring." Such an approach would allow laboratory directors to track individual performance within the laboratory's normal Pap testing routine, with only the final diagnosis being subject to a CLIA-graded score. One member thought this format more likely to promote continuing education than job dismissal, and another member noted CLIA has no requirement for continuing education except after PT failure.
- Several members discussed the impact of cytology PT lowering the number of pathologists continuing to perform examinations of Pap smears.
- A member raised the issue of competency assessment, asking why it was not also open for regulatory revision. Ms. Whalen replied competency is addressed separately from PT in CLIA. She said there are laboratory-wide requirements for competency assessment that apply to cytology as well as cytology-specific competency assessments, such as the 10% rescreen of negative slides.
- One member asked if there had been any problems with the slides used in cytology PT challenges. Ms. Wiseman replied the PT providers had dealt with several appeals and complaints.
- Two members believed cytology PT was unfair because it lacked field-validated slides. Ms. Wiseman acknowledged that all slides used in 2005 had not been field-validated, but they would be by 2006. She said CMS plans to publish the cytology PT data after the first year of testing. In response to a couple of members' request to review the consequences of failing the test in the first year, Ms.Yost said the PT process allows individuals to continue testing until they pass, but requires documented education beginning with the second retest. She added that all individuals who have stopped evaluating Pap smears have done so by choice, not because of test failure, and noted individual failures in cytology PT would not be counted the first year. She stated CMS welcomed constructive feedback, especially scientific, technical, data-driven, or evidence-based information that could be used to revise the PT regulations.
- The Chair reminded the Committee of its request from the previous CLIAC meeting that CMS consider revising the cytology PT regulations to reflect current laboratory technology and clinical practice. She suggested forming a workgroup to assess the matter and report to CLIAC. A motion was made to form a cytology PT workgroup, seconded, and unanimously approved by Committee vote with three Committee members immediately volunteering to serve on the workgroup.
- A member requested information on the plan for the cytology workgroup. Ms. Whalen explained that CDC and CMS would assemble a construct for the types of information to be solicited from the cytology organizations and proficiency testing programs and would clarify regulatory versus statutory authority. She noted the agencies have authority to update regulations, but not to change statutory requirements, such as testing of individuals. Comments and recommendations are needed from the professional organizations on provisions for both PT programs and laboratories. In addition, the organizations will need to provide data supporting the impact of such revisions on

laboratory operations and workforce in order for the agencies to prepare the required cost/benefit analysis. Ms. Whalen reminded the Committee that a workgroup format allows inclusion of outside experts, such as cytotechnologists and cytopathologists, and explained that comments from the cytology community would be presented to the workgroup for its consideration and evaluation. The workgroup would report to CLIAC and the full Committee would have the opportunity to review the workgroup findings and make recommendations to HHS concerning changes to the cytology PT regulations.

- Ms. Yost thanked the Committee for its willingness to assist CMS in revising the CLIA regulations. She reminded the Committee that CLIA was enacted as a result of Congressional concerns with Pap testing quality. She mentioned an often-overlooked cytology laboratory quality check, the continuing CMS contract with the American Society for Cytotechnology to perform selected on-site cytology laboratory CLIA inspections. These inspection findings corroborate preliminary PT data demonstrating physicians who screen Pap tests without cytotechnologists' assistance have more problems.

Institute for Quality in Laboratory Medicine (IQLM) Update ***Addendum G****

Dr. Joe Boone, Acting Associate Director for Science, National Center for Health Marketing (NCHM), CoCHIS, CDC, provided CLIAC with an update on the progress and future directions of the IQLM. A CDC supported independent institute, IQLM focuses on integrating laboratory services across the continuum of healthcare, including patients, clinicians, laboratory professionals, manufacturers, bio- and information technologists, government agencies, employees, payers, members of accrediting bodies, and health systems personnel. He described the 2005 IQLM inaugural conference as a landmark summit bringing together a diverse group of stakeholders and partners to focus on improving quality in laboratory tests and services and patient safety. He went on to discuss IQLM workgroups' accomplishments, which include a first draft report on the evaluation of proposed quality indicators that laboratories could track to determine their performance across the total testing process, the results of a pilot survey of quality practices in laboratories, and an outline of a National Report on the Quality of Laboratory Services.

Dr. Boone provided an overview of future IQLM initiatives: collaboration with the National Quality Forum (NQF) to define laboratory service issues and potential solutions, continued research into laboratory performance indicators, creation of networks to gather data on collective laboratory practices and timely information, development of a National Report, and expansion of the website, http://www.IQLM.org. He described the latter as a source of information, a point of coordination, and a site for the exchange of ideas and practices in laboratory medicine.
Dr. Boone concluded his presentation with a discussion of how laboratory medicine can support current and future healthcare system issues. He invited individuals and organizations to join IQLM in promoting and improving the practice of laboratory medicine and patient safety. To assist all meeting attendees interested in volunteering for relief work in the aftermath of Hurricane Katrina, Dr. Boone concluded his remarks by providing an HHS website and telephone number for deployment of healthcare professionals, https://volunteer.hhs.gov, 1-866-kat-medi.

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

Committee Discussion

- Committee members commended the accomplishments and future directions of IQLM in improving the quality of laboratory medicine and focused their discussion on IQLM's goal to address test utilization and interpretation.
- Several members voiced concern over the management of test ordering, inappropriate use of tests, and incorrect interpretation of test results. They stressed the importance of laboratory directors using consultants with expertise in specific areas of laboratory medicine to provide the medical community with information on test utilization and interpretive support.
- Other members felt medical school curricula should place more emphasis on laboratory medicine, guidelines for test ordering should be developed, and information system algorithms should be less heavily relied upon for test ordering.
- Dr. Boone agreed with CLIAC comments and clarified the IQLM role as not focused on dictating processes but rather on engaging stakeholders and professional organizations in collaborations that will lead to more effective and efficient processes in the practice of laboratory medicine including test utilization.

Proficiency Testing for Infectious Disease Agents ***Addendum H****

Distribution of a Non-Circulating Human Influenza Virus (H2N2) for Proficiency Testing
Root Cause Analysis: H2N2 Causal Factor Chart ***Addendum I***

Dr. Thomas Hearn, Associate Director for Laboratory Systems, Division of Public Health Partnerships (DPHP), NCHM, CoCHIS, CDC, summarized the events and collaborative response of CDC and other stakeholders to the distribution of a non-circulating, human influenza A virus (H2N2) for proficiency testing (PT) purposes. He described the triggering events and ensuing media coverage that followed the revelation that H2N2 had been inadvertently distributed as a PT sample. He went on to discuss the stages of the response, which included identifying and notifying laboratories that had received PT samples containing H2N2 to ensure safe handling and compliance with local, state, and federal disposal regulations. Dr. Hearn referred to a chart, devised by Dr. Dan Jernigan, Acting Associate Director for Epidemiologic Science, Division of Healthcare Quality Promotion, National Center for Infectious Diseases (NCID), Coordinating Center for Infectious Diseases (CCID), CDC, illustrating the sequence of events and causal relationships leading to the distribution of H2N2. He then provided the agenda and outcomes summary from a meeting of PT program representatives and stakeholders convened earlier this year to study the causal factors, review PT requirements, and provide input on how to increase safety and reliability of PT samples. He concluded with a discussion of the significant issues identified and the final recommendations developed to prevent reoccurrence of this or similar PT events in the future. After completing the presentation, Dr Hearn recognized the efforts of two members of the CDC lead team, Dr. Dan Jernigan and Dr. Janet Nicholson, Associate Director for Laboratory Science, Office of the Director, NCID, CCID, CDC.

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

Committee Discussion

- CLIAC members gave accolades to the CDC response and the recommendations. Several members recounted events involving significant communication lapses and inaccurate reporting of the facts by the media. Other members shared their experiences as the H2N2 incident unfolded and their involvement in the meeting of stakeholders and experts that later convened to look at the issues uncovered in the CDC investigation of the event.

- CLIAC members agreed that educating the media and the public on healthcare issues and improving their trust of the scientific community are critical to achieving the level of communications needed to address similar events effectively in the future.

Update: Good Laboratory Practices for Waived Testing Sites ***Addendum J***

Dr. Devery Howerton, Chief, Laboratory Practice Evaluation and Genomics Branch, DPHP, NCHM, CoCHIS, CDC, provided a summary of activities culminating in the development of recommendations for good laboratory practices for waived testing sites. She outlined the rationale for publication of the recommendations as follows:

- The use of waived testing is increasing
- Results from CMS surveys and CDC studies consistently demonstrate quality issues and a lack of knowledge about basic good laboratory practices
- CMS on-site visits included a well-received educational component
- *Morbidity and Mortality Weekly Report* (*MMWR*) is regarded as a reliable source for information

She reviewed data from the last 10 years showing significant increases in waived testing and the top 10 types of Certificate of Waiver (CW) facilities. Dr. Howerton discussed an overview of a 2002-2004 CMS survey of CW laboratories, reviewed the contents of the report "Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing," and described the recommended good laboratory practices. In conclusion, Dr. Howerton explained the next steps include completion of the *MMWR* publication process, promotion of the *MMWR* recommendations as a comprehensive source document, and development of other adaptations of this document to reach targeted audiences.

Committee Discussion

- A member asked if there were data correlating incorrectly performed waived tests with a negative impact on patient care and if improvement has been noted in previously surveyed CW sites. Ms. Yost responded that potential risk of harm is the most that can be inferred using current data, and CMS preliminary data shows almost 86% of previously surveyed CW sites have made improvements.

Marketing the Good Laboratory Practices for Waived Testing Sites ***Addendum K***

Ms. Sharon Granade, Health Scientist, Laboratory Practice Standards Branch (LPSB), DPHP, NCHM, CoCHIS, CDC, summarized brainstorming discussions within DPHP related to marketing the recommended good laboratory practices for waived testing sites. She stated DPHP has considered ways to market the recommendations using social marketing concepts, a customer-driven rather than expert-driven process basing decisions at every phase on input from the target audience. Discussions have focused on identifying the initial target audience, potential partners, and possibilities for promotional channels. CMS data shows that physician office laboratories (POL) comprise the majority of waived testing facilities (46%). Because of this, nurses and physicians performing and directing testing in these facilities could be considered as primary and secondary target audience segments. DPHP is working with NCHM's Division of Health Communication (DHC) to consider additional factors and develop a strategy to effectively market the recommended good laboratory practices for waived testing sites.

Committee Discussion

- One member stressed the need for understanding the importance of correct testing practices, while another pointed out how difficult it is to reach the appropriate audiences.
- Several members offered suggestions for target audiences that should be included and/or involved in the good laboratory practice marketing process: nurses, nursing homes, lawyers and risk managers, malpractice carriers, managed care organizations, manufacturers, and distributors.
- Committee members suggested promoting compliance with good laboratory practices by publicly displaying some type of prestigious document. A separate certificate or an addition to the Certificate of Waiver were proposed by several Committee members.
- One member suggested that CMS inspectors ask laboratories if they are familiar with the good laboratory practices document when surveying laboratories. Ms.Yost responded CMS could distribute the document, albeit to a small number of laboratories. Additionally, she indicated CMS was considering whether to add additional recognition to the Certificate of Waiver. She reminded CLIAC that CMS, as a government agency, cannot solicit but can only provide information using existing mechanisms.
- Members proposed information dissemination and promotion through health plans, POL initiatives, IQLM, NQF, Institute for Health Care Improvement, National Committee for Quality Assurance, and hospitals doing testing for POLs.
- One member suggested using consumer groups to educate patients on questions to ask during a physician visit. Ms. Yost responded that consumer groups have thus far been more interested in advocating for more highly visible medical service areas such as nursing homes.
- Members suggested simplifying the good laboratory practices on a "Top Ten" or even a "Top 3" poster.
- Ms. Ochs said industry representatives would be happy to hand out educational materials, especially if the company name is printed on the materials promoting their company and good practices.
- One member asked if the number of laboratories doing testing without a CW could be determined. Ms. Yost responded while there is no formal method, there are mechanisms that work well. For example, CLIA waived tests have specific Medicare/Medicaid billing codes.

When a facility without a CW attempts to bill the government, the payment will be denied. An informal mechanism is the "neighbor method" in which uncertified facilities are pointed out by a nearby certified facility. In response, several CLIAC members countered that many institutions do not bill for waived tests, which could result in a gross underestimation of facilities performing waived testing without a CW.

- Ms. Whalen stated DPHP will continue to work with DHC to develop a social marketing plan for recommended good laboratory practice for waived testing sites and that CLIAC will be given further opportunity to provide comments and suggestions.

Appropriate Quality Control (QC) for Diverse and Evolving Test Systems ***Addendum L***

Ms. Rhonda Whalen, Chief, LPSB, DPHP, NCHM, CoCHIS, CDC, introduced the topic of appropriate quality control (QC) requirements under CLIA. In doing so, she reviewed the CLIA law, the 1992 CLIA regulations, and the changes made in the 2003 revised CLIA regulations to incorporate a quality system concept throughout the testing process. She discussed the regulations and illustrated how guidance could provide flexibility for certain requirements. She then summarized the requirements for verifying performance specifications, calibration, calibration verification, and control testing and noted where clarification or guidance is needed, especially for alternative control procedures.

Ms. Whalen acknowledged the QC dilemmas facing laboratorians because of the considerable variations in test systems, laboratories, and personnel. Because of this, there is a need for a uniform approach and process to determine the applicability of QC requirements and assist laboratories in complying with CLIA. An overall QC system needs to incorporate flexibility where possible, while at the same time ensure that laboratories meet minimal quality standards. She emphasized traditional and alternative quality control schemes will need to co-exist. Ms. Whalen concluded by posing a series of questions for CLIAC consideration as to how to accommodate existing, diverse, and evolving technologies under CLIA.

Quality Control Procedures: One Lab Director's Perspective ***Addendum M***

Dr. Greg Miller, Professor of Pathology, Virginia Commonwealth University, presented his approach to statistical process control and ways to monitor the process. He emphasized problems can arise during manufacturing, transportation, and storage; due to user errors; and within the measurement process itself. He explained the laboratory director needs to have confidence in the correctness of the test result. This can be achieved through understanding what can go wrong, by monitoring the measurement process, and through data supporting the probability the result is correct. He said one can verify a system is performing as expected by determining that calibration has not changed and imprecision is within the expected variability. Dr. Miller used data point charts to demonstrate variability must include all sources of error over longer periods of time to detect changes. He explained the limitations of QC and calibration materials as additional sources of variability because they are not always commutable with clinical samples, therefore, when changing reagent lots, patient samples should be run with new and old lots for comparison. Additionally, when comparing QC materials and different reagent lots, matrix interactions may cause changes in target values and require "accommodation" (adjustments).

Dr. Miller then addressed point of care/near patient testing system issues, stating the physician expects the same reliability from these systems as the main laboratory systems; however, these methods are typically less precise, may have different ranges and specificity, and need sophisticated internal controls. Dr. Miller identified key information needed from manufacturers to define QC monitoring procedures. He addressed the subject of QC sampling frequency, which focuses on method stability and the clinical impact on patients, noting that cost considerations associated with QC materials and reagents should be balanced by the cost of erroneous medical procedures, repeat patient testing, and the cost of recollecting samples.

Committee Discussion

- A member commented that the absence of temperature verification of transported specimens received in the laboratory, especially for certain analytes, could cause testing errors. He inquired about the frequency of reagent lot failures when comparing old and new lots using repeat patient samples and requested a further explanation of Dr. Miller's term "accommodation." Dr. Miller described his acceptance criteria process using repeat patient sample studies when changing reagent lots. While lot-to-lot failures with comparison patient samples are seldom seen, QC results do change; therefore, we "accommodate" by adjusting the QC target values while retaining the same intervals and standard deviations reflecting method imprecision so that the QC rules continue to work correctly. The discussion continued on the use of patient samples as controls to detect QC material degradation or the need for instrument recalibration. Dr. Miller agreed those problems could be more reliably detected using repeat patient samples because the commutability of QC material is variable.
- A member requested a comment on the use of the X-bar method looking at the mean of patient values over time and trends and shifts. Dr Miller agreed it was a very useful tool for indicating a significant shift in calibration especially with big changes that would have a greater clinical impact.
- Dr. Miller was asked how he determines the lower limit of the reportable range and a coefficient of variation (CV) cut point. He responded the most reliable method, in his opinion, is to dilute a patient specimen to the lowest clinically significant value, determine the imprecision of the procedure at that level, and decide if that imprecision meets the requirements for clinical care. The CV would vary with each analyte and how it is used clinically but generally speaking a 20% CV cut point is used.
- A member inquired if Dr. Miller could gauge the challenge for average laboratories to customize their quality control design to meet the needs for analytic quality. Dr. Miller responded that laboratories have a difficult time understanding appropriate QC acceptance criteria and inherent method variability. He favors the following pragmatic approach: What do you need to know? You need to know the method is stable. How do you know that? You know that if your values are recovering what you think they recover within the expected variability. Dr. Miller agreed this entails detail and subtlety and setting up effective and appropriate QC presents a challenge for the average laboratory.

Clinical and Laboratory Standards Institute (CLSI) – Voluntary Consensus Standards in Clinical and Laboratory Quality Control ***Addendum N***

Dr. Robert Habig, President Elect, CLSI, and Vice President, Regulatory Affairs/Compliance/Audits, Diagnostic Division, Abbott Laboratories, presented an explanation and review of CLSI functions and services. He described CLSI as an

American National Standards Institute accredited consensus standards development organization and a not-for-profit, educational, volunteer, global association of organizations with industry, government, and professional constituencies. After listing CLSI principles and values, Dr. Habig described the processes for project selection and document development, including drafting and circulating a document for reviews, comments, and revisions, with publication usually completed in twenty-two months. An evaluation of the utility and use of the published document is conducted. One example is the use of CLSI documents by industry scientists since they are recognized by FDA for product submissions. He provided information regarding many CLSI publications relating to laboratory quality covering a wide range of disciplines. The objectives, scope, function, and intended audience were presented for EQC Option 4 – EP22: Principles of Manufacturer's Validation of Risk Mitigation Using Quality Controls. Dr. Habig concluded with a status report of EQC activities including a project proposal for a companion publication of EP22 for laboratorians, a summary of the QC for the Future Workshop (X6-R) now available from CLSI, and presentations from that workshop published in *Laboratory Medicine* in October 2005.

Committee Discussion

- A Committee member asked if the *MMWR* guidance document on good laboratory practices for waived testing was consistent with and referenced CLSI standards, and was assured by Dr. Howerton there were numerous references to CLSI standards in the *MMWR* guidance document. Ms.Yost added that CMS collaborated with CLSI regarding CMS's best laboratory practices document; consequently, the document CMS currently provides to waived laboratories was compared to and is consistent with the CLSI point-of-care document. Dr. Hearn recounted that when CLIAC first considered preparing information for users of waived test devices the option of asking CLSI to take on the project was discussed. It was determined that the intended audience would benefit from the wisdom of CLIAC and existing waiver guidance should be considered and referenced. A member pointed out a particularly useful CLSI document was not included in the presentation, that being GP29-A: Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline.

<u>CLIA EQC Option 4 Update</u> ***Addendum O***

Ms. Luann Ochs, Chairholder, CLSI Area Committee on Evaluation Protocols, presented a report on the status of the proposed CLSI document (EP22) for manufacturer's validation of risk mitigation using alternative QC. She explained the intent of the proposed CLSI document by stating manufacturers may validate a QC recommendation with objective evidence which, if FDA agrees is equivalent to traditional QC, laboratories may use instead of the CLIA–mandated QC. However, laboratory directors retain the responsibility to ensure this QC is appropriate for their facility. This process started with an AdvaMed proposal for EQC option 4 in May 2004, followed by establishment of a CLSI committee in May 2005. A document for manufacturers is expected in March 2007 with a companion document for laboratories proposed for early October 2007. Ms. Ochs described the manufacturers' document as platform and QC recommendation neutral, leaving decisions for recommendations to individual manufacturers while recognizing the need for objective evidence. The document is planned to include points to consider for designing quality into a device. Sections of the document related to QC validation and risk mitigation are currently under development. Ms. Ochs concluded with the next steps for completion of a preliminary draft to be reviewed by November 2006. The proposed title is "Establishment of Manufacturers' Recommendations for User Quality Controls for In Vitro Diagnostic Devices".

Committee Discussion

- Dr. Gutman stated creating a document like this clarifies the kinds of information manufacturers could provide to laboratories, increases transparency, and enables more informed decision making. He expressed concern that there is little published information relating QC to the kind of risk management and risk mitigation design features that are driving the document. Another issue is a desire to allow relatively sophisticated, heterogeneous laboratories to make decisions based on their unique circumstances and clinical needs. Dr. Gutman believes that without science-based decisions, FDA could not support this document and in his view a companion document is necessary. Another member agreed a companion document for laboratories is critical, stating laboratorians and manufacturers use different approaches to QC. A motion was made and passed unanimously that the Committee request or encourage development of a companion document specifically for laboratorians to accompany the new CLSI document for manufacturers.
- A member referred to Dr. Gutman's comment on transparency of QC and expressed frustration when requesting information from manufacturers regarding QC recommendations. As a followup to this comment, several Committee members expressed frustration over a lack of accurate, current information provided in product literature or when requested directly from manufacturers about different aspects of quality control.
- Another member highlighted the urgency to clarify QC in multiplex molecular genetic testing since some tests do not have publicly available genomic or synthetic controls. The member pointed out the potential for these tests to be performed by increasing numbers of non-geneticists in the future, adding the scarcity of FDA-cleared products could cause serious problems if not addressed proactively.
- One member asked Ms. Ochs about the term QC recommendation neutral. Ms. Ochs clarified that any manufacturer's recommendation must be backed by objective evidence or data. Conversely, today's practice of running two levels of controls a day is not backed by objective evidence. Current labeling requires adherence to local, regional, and national requirements. She explained the CLSI committee is proposing that if manufacturers deviate from what is currently required, they must have objective evidence to substantiate the alternative approach.
- Another member complimented Ms. Whalen on her presentation and asked how the Committee could help address the questions she presented. Ms. Whalen responded that all issues presented at CLIAC are open for comment and feedback. She stated AdvaMed's recommendation, EQC Option 4, proposed the manufacturer would provide information in the labeling and if FDA concurred with the QC proposal and supporting data it would be acceptable. She went on to say that QC procedures are not the only issue where advice is needed from the Committee. Other issues need input such as performance verification and, for quantitative procedures, verification of calibration and reportable ranges. She noted the need for manufacturers to provide clarification that will allow laboratory directors some flexibility. She acknowledged the challenges of new technology and stated that, in addition to the unique approaches of industry, the Committee's perspective is needed. Ms. Whalen continued if the proposed CLSI document provides information on what the manufacturer will provide to FDA for review and labeling, there is still a need to address the laboratory component. Ms. Ochs responded explaining the intention to expand EP15 (a laboratory

document) to include information on how to verify accuracy and calibration and on how to make the verification statistically robust.

- Another member expressed concerns about the one-size-fits-all approach from the perspective of non-waived laboratories that are not highly sophisticated in their QC evaluations.
- A member raised the issue of verifying the performance of a new assay. Because of the shortage of laboratorians, many laboratories request help from manufacturers; however, manufacturers may not address the laboratory's needs for verifying performance specifications and the reportable range.
- One member commented there are a number of issues worthy of discussion by the Committee requiring time and analysis to determine needs. Dr. Hearn responded work is ongoing, particularly in the CLSI EP15 document, for verification and other important quality control areas. He complimented the Committee members on their interesting and important discussions addressing complicated issues. He suggested taking some time to prioritize and organize a process for engaging the Committee on the basic, critical, and fundamental points, which might require creating a workgroup. Dr. Hearn stated to assist less-experienced laboratories, the Committee must share the right mix of knowledge. A member added it is CLIAC's responsibility to promote understanding of the critical need for continuing education for those who work in laboratories and the importance of assuring quality in testing, even with reduced resources.
- Dr. Hearn concluded by re-emphasizing relevant points from the IQLM meeting: Those who control the resources need proof problems exist, which can be provided by using quality indicators and monitoring and surveillance functions. Laboratorians should work with professional organizations to gather data and identify the most serious quality problems.

PREVIOUS BUSINESS

Update on American Society for Microbiology (ASM) Survey of QC Failures with Microorganism Identification Systems ***Addendum P***

Dr. David Sewell, Pathology and Laboratory Medicine Service, Veterans Affairs Medical Center, and Department of Pathology, Oregon Health Sciences University, provided an update on behalf of the ASM on the status of QC for microorganism identification (ID) systems. He reminded CLIAC that CLIA requires laboratories to test each substrate or reagent in microbial ID panels for positive and negative reactivity with each batch, lot number, and shipment. He stated the ASM was asked to collect data on the number of QC failures that occur in order to assist CLIAC in evaluating the need for a policy change regarding appropriate QC. He said ASM decided to collect data for surveillance purposes and discussed with CLSI the use of its consensus process to determine appropriate QC procedures. He stated the survey was pretested in July and August with members of ASM Public and Scientific Affairs Board Committees on Professional Affairs and Laboratory Practices. He went on to detail the content of the survey instrument to include general questions (laboratory type and size, accreditation/certification, educational degree of personnel who oversee microbiology testing) and QC-related questions (ID system, lot numbers, numbers of QC organisms for each ID system, lot replacements due to

QC failure and biochemical tests that failed QC). In his review of the pretest group results, no QC failures were reported among the 668 lots used. Dr. Sewell concluded with the next steps: to work with CMS to obtain a list of microbiology laboratories and with CDC to determine appropriate sample size. He listed an approximate timeline for activities from September to November. In conclusion, Dr. Sewell informed CLIAC that ASM is considering revising the survey before it is sent to a larger audience and asked CLIAC for suggestions to improve the survey.

Committee Discussion

- One member expressed concern over the number of non-responders to the pre-test (pilot) survey.
- One member posed several questions that ASM may wish to consider including in the survey: Is a control failure due to a problem with the test system or the control organism? Does failure of a single substrate result in a decreased probability of a correct identification? Will an inaccurate identification alter patient care?
- More than one member expressed concern that the current survey does not capture whether laboratories are following the CLIA QC requirement to test each substrate in an ID system for positive and negative reactions. Several members added their concerns that laboratories have a misconception that they are fulfilling CLIA QC requirements by following the manufacturer's instructions, which may not specify testing each substrate. One member went on to suggest it would be important in revising the survey to establish not only the laboratories that have been performing QC on every substrate but if they were able to correlate a specific substrate failure with failure to ID an organism. Several members concurred, adding that being able to identify specific substrates as predictable indicators of a particular test system failure may assist in determining where controls are needed.
- One member asked how to capture procedures manufacturers are recommending laboratories perform for QC and inquired whether manufacturers' instructions are addressed in the CLIA regulations. A Committee member pointed out that a major manufacturer placed a statement in its recent newsletter listing additional QC organisms that should be used if local, state, or federal requirements necessitate QC testing beyond that required by the manufacturer.
- Another member expressed concern regarding the current FDA clearance exemptions for new ID systems entering the market.

Clarification of Issues related to Occupational Safety and Health Administration (OSHA) Requirements

At a previous CLIAC meeting, members asked for information on OSHA requirements. In response to this request, using audioconference technology, CLIAC members were provided clarification of several issues related compliance with OSHA requirements from Mr. Bill Grimes, Assistant Regional Administrator for Cooperative Programs OSHA Region IV (Southeast Region) office and Mr. Ben Roth, Assistant Regional Administrator for Enforcement Programs, OSHA Region IV office.

- A member asked for clarification on why there might be differences in OSHA requirements and CLIA accrediting organizations' general safety laboratory requirements. Mr. Grimes replied that national accrediting organizations defer to federal OSHA laws when defining safety compliance requirements. He clarified that federal OSHA laws set minimum

standards for safety and health and explained that some states (hereafter referred to as "federal states") enforce the federal OSHA laws as written, while other states may enact stricter laws within their Occupational Safety and Health (OSH) plan (hereafter referred to as "plan states"). Thus laboratories in OSH plan states may find OSHA requirements more stringent than accrediting organization requirements.

- Mr. Grimes further discussed the minimum standards for clinical laboratories defined under federal OSHA law. He stated the OSHA laboratory standard, an expansion of the Hazard Communication Standard, requires each laboratory to identify a chemical hygiene officer and to develop a written chemical hygiene plan. Required compliance with other OSHA regulations would vary depending on the presence and or quantity of a specific chemical in a laboratory and the risk assessment findings performed by the laboratory as part of its chemical hygiene plan.
- One member asked if OSHA regulations were limited to chemical safety only. Mr. Grimes replied that OSHA requires all employers to comply with the General Duty Clause of the OSH Act. This requires employers to ensure a safe work place for employees and ensure employees are provided with training and protection supportive of the recognized consensus standard/practice guideline for the processes followed and procedures performed by the employees.
- The next question was directed at interpretation of the regulations by OSHA surveyors and use of interpretive guidelines to enforce OSHA regulations. A CLIAC member recounted an experience with the interpretation of the Bloodborne Pathogens Standard (BBP) requiring the laboratory and all associated clinics to replace glass specimen collection containers with plastic containers. The member encountered rigid enforcement of the regulatory interpretation and a refusal by the state OSH enforcement office to consider unpublished data supporting evidence that plastic tubes, in some instances, would impact patient test results; additionally, the timeframe for compliance was unrealistic. Mr. Roth stated the intent of the interpretation is to provide clarity, not to serve as an enforcement mechanism. He went on to explain that sometimes an interpretation may be used by OSHA when making a final ruling prior to issuance of a citation. He described the OSHA requirement to replace glass with plastic collection containers as an example of a requirement unique to the BBP standard where employers have the responsibility, as new technology becomes available, to better protect employees from potential sharps injury and to implement the new technology into their organization's bloodborne pathogens program. Using the case presented, where the State OSH office was unreceptive to evidence of the impact on patient test results or the burden placed on the facility, Mr. Roth described two alternative avenues to pursue. First, a Petition for Modification of Abatement (PMA) with reasonable supporting evidence could be filed. Further, a letter could be sent to the appropriate regional office detailing the issues and providing evidence to show cause for delay in implementing the complete change to plastic tubes. Mr. Roth then commented that final resolution might require calling the Area Director, Regional Office, or sending a letter to the National Office.
- When a CLIAC member asked how laboratories could keep abreast of OSHA regulation updates, Mr. Grimes responded that the Compliance Assistance Specialist or the consultative service department in the OSHA Area Office of federal states would be the appropriate contact. He clarified that OSH plan states would also have this service as well as the Compliance Assistance Specialist, but the titles may vary. He concluded by describing the function of the consultative service as available to all employers with less than 250

employees and emphasized the service is free and performed without risk of the issuance of a citation or penalties, but also indicated there was an obligation by the employer to correct the non-compliant areas identified by the consultative service. In closing, he reiterated using the consultative service would give an employer the greatest assurance of compliance with all OSHA requirements.

- CLIAC members thanked the OSHA representatives for their participation in the audioconference. Mr. Grimes enthusiastically accepted the invitation to advise CLIAC on future OSHA issues and encouraged CLIAC and all meeting attendees to avail themselves of the assistance offered at any regional OSHA office, nationally by calling 202-693-2300, on the web, www.osha.gov, or by calling1-800-321-OSHA for emergencies 24 hours a day/7 days a week.

COMMITTEE DISCUSSION OF FUTURE AGENDA ITEMS

- A member commented on the Hurricane Katrina emergency as it relates to the status of clinical laboratory disaster preparedness, expressing frustration with an apparent lack of enthusiasm on the part of laboratories and administrators and inquiring if there might be an opportunity for CLIAC to discuss the subject at the next meeting. Ms. Whalen said since public health laboratory issues had already been proposed as an agenda item for the next meeting, it could be broadened to include preparedness issues. Committee members suggested including discussion on Health Resources and Services Administration grant mechanisms for laboratory preparedness, emergency transportation of supplies and specimens, and personnel issues/concerns in critical situations. Additionally, a member noted CLSI has published a new document on laboratory emergency preparedness within the last year and suggested the Committee could provide guidance that is more specific. A motion was made and passed to include laboratory emergency preparedness on the February 2006 meeting agenda.
- A member requested an update on the workforce shortage. A Committee member serving on the Coordinating Council on the Clinical Laboratory Workforce (CCCLW) agreed to prepare a report compiling information from CCCLW, CLSI, and the Bureau of Labor Statistics for a workforce update.
- Another member inquired as to the possibility of a cytology workgroup report being generated in time for the February 2006 meeting. Ms. Whalen replied the process requires considerable preparation including receiving and summarizing comments from the organizations, organizing those comments for the workgroup's consideration, clarifying the workgroup's charge, convening the workgroup, summarizing the workgroup's recommendations, and preparing a report for presentation to CLIAC. She stated a workgroup report to CLIAC would not likely occur before the September 2006 meeting.

PUBLIC COMMENTS

Dr. George Birdsong, American Society of Cytopathology ***Addendum Q***

Dr. Barbara S. Ducatman, College of American Pathologists ***Addendum R***

ADJOURN

Dr. Turner thanked the members and partner agencies for their support and participation. The following reflects the recommendations and outcomes from this meeting:

- CLIAC recommended formation of a workgroup to evaluate updated comments from the professional organizations regarding cytology proficiency testing
- CLIAC recommended that a laboratory companion document be created to accompany the CLSI document currently under development for manufacturers addressing validation of risk mitigation
- Incorporating CLIAC suggestions, ASM will refine and proceed with the survey to gather QC performance data for microbiology ID systems and will present a status report on the survey to CLIAC in February 2006
- The Committee requested that the topic of laboratory preparedness for both natural and man-made mass disasters be considered as an agenda item for the February 2006 meeting
- The Committee requested that a status report on the laboratory workforce shortage be included as an agenda item for the February 2006 meeting

Dr. Turner announced the 2006 CLIAC meetings are scheduled for February 8-9 and September 20-21, and adjourned the Committee meeting.

I certify this summary report of the September 7-8, 2005, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Dated: 11/28/2005

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