DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Times and Dates:
8:30 a.m.–5:00 p.m., EDT, April 12, 2017
8:30 a.m.–12:00 p.m., EDT, April 13, 2017

Place: CDC, 1600 Clifton Road NE., Tom Harkin Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. This meeting will also be webcast, please see information below.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters for Discussion: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will focus on the implementation of next generation sequencing in clinical laboratories; laboratory testing in the era of telemedicine; and a report from the Institute of Medicine (IOM) CLIA workgroup.

Agenda items are subject to change as priorities dictate.

Webcast: The meeting will also be webcast. Persons interested in viewing the webcast can access information at: http://cdclabtraining.adobeconnect.com/aprilcliac/

Online Registration Required: All people attending the CLIA meeting in-person are required to register for the meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for international registrants. Register at: http://www.cdc.gov/cliac/Meetings/MeetingDetails.aspx. Register by scrolling down and clicking the “Register for this Meeting” button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than April 5, 2017 for U.S. registrants and March 29, 2017 for international registrants.

Providing Oral or Written Comments: It is the policy of CLIA to accept written public comments and provide a brief period for oral public comments on agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item.

Oral Comments: In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting’s Summary Report. To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least one week prior to the meeting date.

Written Comments: For individuals or groups unable to attend the meeting, CLIA accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person at the mailing or email address below, and will be included in the meeting’s Summary Report.

Availability of Meeting Materials: To support the green initiatives of the federal government, the CLIA meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIA Web site on the day of the meeting for materials: http://www.cdc.gov/cliac/Meetings/MeetingDetails.aspx. Note: If using a mobile device to access the materials, please verify that the device’s browser is able to download the files from the CDC’s Web site before the meeting.

Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An internet connection, power source, and limited hard copies may be available at the meeting location, but cannot be guaranteed.

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, CDC, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors,
National Institute for Occupational Safety and Health (BSN, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 8:30 a.m.–12:45 p.m., EDT, April 12, 2017.
Place: 1095 Willowdale Road, Morgantown, WV 26505. The meeting is also available via webcast.

Status: This meeting is open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. The public is welcome to participate during the public comment period, 9:20 a.m.–9:30 a.m. EDT, April 12, 2017. Please note that the public comment period ends at the time indicated above or following the last call for comments, whichever is earlier. Members of the public who wish to comment must sign up by providing their name by mail, email, or telephone, at the addresses provided below by April 7, 2017. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come-first served basis. Written comments will also be accepted from those unable to attend the public session via an on-line form at the following Web site: http://www.cdc.gov/niosh/bsc/contact.html. The meeting is also open to the public via webcast. If you wish to attend in person or by webcast, please see the NIOSH Web site to register (http://www.cdc.gov/niosh/bsc/) or call (404–498–2539) at least five business days in advance of the meeting. Teleconference is available toll-free: please dial (888) 397–9578, Participant Pass Code 63257516. Adobe Connect webcast will be available at https://odniosh.adobeconnect.com/nioshbsc/ for participants wanting to connect remotely.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors provides guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board provides guidance on the Institute’s research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board evaluates the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters for Discussion: NIOSH
Director's update; occupational motor vehicle safety, the nanotoxicology program, flu-related research, and mold investigations.

Agenda items are subject to change as priorities dictate.

An agenda is also posted on the NIOSH Web site (http://www.cdc.gov/niosh/bsc/). Members of the public who wish to address the NIOSH BSC are requested to contact the Executive Secretary for scheduling purposes (see contact information below). Alternatively, written comments to the BSC may be submitted via an on-line form at the following Web site: http://www.cdc.gov/niosh/bsc/contact.html.

Contact Person for More Information:
Paul J. Middendorf, Ph.D., Executive Secretary, BSC, NIOSH, CDC, 1600 Clifton Road NE., MS–E20, Atlanta, GA 30329–4018, telephone (404) 498–2500, fax (404) 498–2526.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) proposes to clarify the definitions for ‘sufficient’, ‘limited’, and ‘insufficient’ levels of evidence for the designation of NIOSH skin notations. In NIOSH Current Intelligence Bulletin (CIB) 61—A Strategy for Assigning New NIOSH Skin Notation Profiles; Request for Comment

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2017–0017, NIOSH 153–D]

Proposed Revised Definitions for the Levels of Evidence for NIOSH Skin Notation Profiles; Request for Comment

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comments.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) proposes to clarify the definitions for ‘sufficient’, ‘limited’, and ‘insufficient’ levels of evidence for the designation of NIOSH skin notations. In NIOSH Current Intelligence Bulletin (CIB) 61—A Strategy for Assigning New NIOSH Skin Notation Profiles; Request for Comment

Notation Profiles; Request for Comment

Data sets classified as sufficient are those that include human and/or animal toxicity studies conducted according to standardized protocols and that provide in-depth descriptions of the exposure conditions and study findings. Data sets classified as insufficient include studies that primarily either did not apply standard protocols or did not provide an in-depth description of the exposure conditions or study findings. Data sets that receive the insufficient ranking will not be used as the basis for the NIOSH skin notation.”

NIOSH proposes to clarify the definitions for the sufficient, limited,