health of American women by advancing and coordinating a comprehensive women's health agenda throughout HHS. The office fulfills its mission by advancing policy and issuing competitive contracts to an array of community, academic, and other organizations at the national and community levels. In addition, OWH's national educational campaigns provide information about the important steps women can take to improve and maintain their health, such as NWHW.

NWHW is a week-long health observance that kicks off on Mother's Day, Sunday, May 12 and ends Saturday, May 18, 2013. NWHW seeks to educate women about improving their physical and mental health and preventing disease. More than 2,200 events were held nationwide in 2012. Week-long, daily messages encourage women to make their health a top priority and take simple steps for a longer, healthier, and happier life. For more information about NWHW, please visit *http://womenshealth.gov/nwhw/.*

Dated: March 27, 2013.

Nancy C. Lee,

Deputy Assistant Secretary for Health—Women's Health.

[FR Doc. 2013–07617 Filed 4–1–13; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 5812, dated January 28, 2013) is amended to reflect the reorganization of the Office for State, Tribal, Local, and Territorial Support.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and function statements for the Knowledge Management Office (CQA5), Office of the Director (CQA).

Revise the functional statement for the Public Health Law Office (CQA2), Office of the Director (CQA) as follows:

After item (8), insert the following: (9) establish collaboration and coordination between clinical medicine and public health to better coordinate and partner for healthier communities.

Dated: March 22, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–07582 Filed 4–1–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 5812, dated January 28, 2013) is amended to reflect the reorganization of the Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and function statements for the Public Health Prevention Service Branch (CPLCC), Division of Leadership and Practice (CPLP).

Dated: March 22, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–07545 Filed 4–1–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0338]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing an invitation for participation in its Experiential Learning Program (ELP). The ELP provides a formal training mechanism for regulatory review staff to visit research, clinical, manufacturing, and health care facilities to observe firsthand how medical devices are designed, developed, and utilized. This training is intended to provide CDRH staff with an opportunity to observe the device development life cycle and provide a better understanding of the medical devices they review, and the challenges faced throughout development, testing, manufacturing, and clinical use. The purpose of this document is to invite medical device and health care facilities to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the program.

DATES: Submit either an electronic or written request for participation in this program by May 2, 2013. The request should include a description of your facility relative to product areas CDRH regulates. Please include the Area of Interest/Medical Device or Technology (identified in table 1or 2) that the visit will demonstrate to CDRH staff.

ADDRESSES: Submit either electronic requests to *http://www.regulations.gov* or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4448, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH launched the ELP Pilot in 2012 and will fully implement the program in 2013. The Center is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to safe, effective, high-quality medical devices and safe radiation-emitting products. In support of this mission, the Center launched various training and development initiatives to enhance performance of its regulatory review staff and other staff involved in the premarket review process. CDRH is driven to advance regulatory science; provide industry with predictable, consistent, transparent, and efficient regulatory pathways; and assure consumer

confidence in medical devices marketed in the United States and throughout the world. This program is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, and regulatory impacts and needs.

These formal training visits are not a mechanism for FDA to inspect, assess, judge, or perform a regulatory function (i.e., compliance inspection), but rather, are an opportunity to provide the CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities. This request includes those that have previously participated in the ELP or other FDA Site Visit programs, as well as new interested parties.

II. ELP

A. Experiential Learning Program

In this program, groups of CDRH staff will observe operations of medical device establishments, including, research, manufacturing, academia, and health care facilities. The areas of focus and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST—MEDICAL DEVICES/TECHNOLOGY

Focus area	Specific areas of interest
Performance validation and reliability testing of intensive care unit ventilator and anesthesia gas machines.	Ventilators, continuous positive airway pressure devices, anesthesia gas machines, and closed-loop ventilators.
Implantation techniques for spinal devices	Implantation training and assessment using cadavers and direct observation of surgical procedures for spinal implants including, but not limited to, lateral intervertebral body fusion devices, minimally invasive pedicle screw systems, and spinous process plates.
Manufacturing of ultra-high molecular weight polyethylene device components.	All joint replacement devices.
Clinical use of orthopedic bone void filler devices	Observation of surgical procedures (posterolateral spine fusion, foot, ankle) utilizing bone void fillers.
Reprocessing methods and techniques in the clinical environment.	Cleaning and sterilization methods and techniques for endoscopes (including colonoscopes, duodenoscopes, cystoscopes, etc.) and accessories; automatic endoscope reprocessors.
Bariatric surgery	Observation of bariatric surgical techniques, with and without bariatric devices.
Manufacturing and assessment of hemodialyzers and filters	Hemodialyzers, hemofilters, hemoconcentrators, ultrafilters, and plasma filters.
Sourcing and manufacturing of animal-derived collagen	Surgical meshes, wound dressings.
Traumatic wound care, management, and treatment	Observation of clinical uses of wound management/treatment devices and hemostatic products for use on traumatic injuries.
Clinical use of plastic and reconstructive devices	Observation of surgical procedures utilizing surgical meshes, dermal fillers, hemostatic agents, and bone waxes.
Treatment of acute ischemic stroke	Clot retrieval procedures, clot retrieval devices and ancillary products (medications, angiograms), stroke centers, and acute stroke care programs.
Clinical use of neurosurgical monitoring devices	Neuro-evoked response devices that are used for real-time monitoring of patients undergoing a back procedure.
Clinical use of rehabilitation devices	Clinical use of physical medicine devices (prostheses, pressure-relieving seat cushions, tilt-in-space wheelchairs, and devices for pain relief) in a rehabilitation center setting for treatment of various conditions (e.g., spinal cord injuries, traumatic brain injuries, and amputations).
Clinical use of cardiovascular devices	Endovascular stent grafts and associated delivery systems; Stents and associated delivery systems.
Manufacturing of cardiovascular devices	Drug coated devices (e.g., stents and balloons), endovascular stent grafts and associated delivery systems, stents and associated delivery systems, percutaneous heart valves.
Animal testing for chronic care cardiovascular devices	Observation of surgical procedures and chronic care maintenance in animal models using chronic care cardiovascular devices, such as heart valves and ventricular assist devices.
Manufacturing of contact lenses and care products	All contact lenses and care products.
Treatment of severe hearing loss	Surgical implantation of cochlear implants, electro-acoustic stimulation using hybrid cochlear implants, preservation of residual hearing, postoperative evaluation of residual hearing and implant performance.
Auditory brainstem implants (ABIs)	Observation of ABI surgical procedures.
Management of clinical trials for medical devices	Understanding clinical trial infrastructure, roles/responsibilities of your organization, and relationships with other organizations involved in the management and conduct of clinical trials; institutional review boards; clinical research organizations.

TABLE 2—AREAS OF INTEREST—IN VITRO DIAGNOSTIC DEVICES/TECHNOLOGY

Focus area	Specific areas of interest
Manufacturing and development of molecular/immunology devices.	Molecular diagnostics devices, and companion diagnostics devices.
Manufacturing, development, and assessment of cytology/pathology devices.	Semiautomated cytology screening devices; cytology collection devices use in human papillomavirus tests; immunohistochemistry tests development in clinical trials.
Manufacturing of microbiology devices	Antimicrobial susceptibility devices.

TABLE 2—AREAS OF INTEREST—IN VITRO DIAGNOSTIC DEVICES/TECHNOLOGY—Continued

Focus area	Specific areas of interest
Manufacturing of chemistry devices	Clinical Laboratory Improvement Amendments (CLIA) waived devices, blood collection tubes, fecal occult blood devices.
Manufacturing and development of hematology devices	Hematology analyzers (specific interest in new technology).
Manufacturing and development of coagulation devices	Coagulation assays and controls, platelet aggregatometers devices, prothrombin time/international normalized ratio meters and assays, D-Dimer analyzers and assays.
Observation of clinical testing in a CLIA high complexity laboratory.	Observation of testing in a clinical testing environment.

B. Site Selection

CDRH will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CDRH's priorities for staff training and the resources available for this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract to the applicant, that firm must agree to participate in the program and must also have a satisfactory compliance history.

III. Request for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07593 Filed 4–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0305]

Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket for interested parties to submit to FDA comments on the Institute of Medicine's (IOM) recommendation regarding third-party governance of industry-sponsored tobacco product research.

DATES: Submit electronic or written comments by September 30, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0305, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Electronic Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0305. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laila Noory, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), FAX: 240–276–3761, email: *CTP.3PGovernance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act). The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding chapter IX (21 U.S.C. 387 *et seq.*) and grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA expects that tobacco product manufacturers will undertake tobacco product research as part of activities regulated under the Tobacco Control Act, including submission of applications for marketing orders under sections 910 and 911 of the FD&C Act. Section 911 of the FD&C Act requires FDA to issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products (MRTPs). Section 911(*l*)(2) requires that such regulations or guidance be developed in consultation with the Institute of Medicine (IOM), among others, on the design and conduct of such studies and surveillance. Pursuant to this requirement, the IOM convened a multidisciplinary committee and published a report in December 2011. In the report, entitled ''Scientific Standards for Studies on Modified Risk Tobacco Products'' (*http://www.iom.edu/Reports/2011/Scientific-Standards-for-Studies-on-Modified-Risk-Tobacco-Products.aspx*), the IOM notes that ''governance of research is critical to the production of credible and reliable evidence.''

Specifically, the IOM report states ''[t]here is profound distrust of the tobacco industry and of research supported by the tobacco industry. This distrust is the direct result of the tobacco industry's history of improperly influencing or manipulating scientific findings and messaging about the health