the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National HIV Prevention Program Monitoring and Evaluation (NHM&E) (OMB 0920–0696, Expiration 03/31/2016)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a three-year approval for revision to the previously approved project.

The purpose of this revision is to continue collecting standardized HIV prevention program evaluation data from health departments and community-based organizations (CBOs) who receive federal funds for HIV prevention activities. Grantees have the option of key-entering or uploading data to a CDC-provided web-based software application (EvaluationWeb®).

This revision includes changes to the data variables to adjust to the different monitoring and evaluation needs of new funding announcements without a change in burden. CDC is adjusting the variables by deleting some of the client-level variables related to determining risk factors during the HIV Testing process and replacing these variables with aggregate testing variables that have previously been reported by grantees as part of their progress reports. This will streamline and simplify data submission for the grantees.

The other significant change is to add budget allocation data variables for CBOs but offset that addition with reductions in client-level variables and conversion of some variables to aggregate-level reporting. There are other minor changes in variables and values to adjust to new technologies and interventions and to improve reporting related to linkage to care and retention in care for HIV positive persons. However, the number of variables deleted approximately equals the number of variables added, so the net result is no change in the grantee reporting burden.

The evaluation and reporting process is necessary to ensure that CDC receives standardized, accurate, thorough evaluation data from both health department and CBO grantees. For these reasons, CDC developed standardized NHM&E variables through extensive consultation with representatives from health departments, CBOs, and national partners (*e.g.,* The National Alliance of State and Territorial AIDS Directors, Urban Coalition of HIV/AIDS Prevention Services, and National Minority AIDS Council).

CDC requires CBOs and health departments who receive federal funds for HIV prevention to report non-identifying, client-level and aggregate-level, standardized evaluation data to: (1) Accurately determine the extent to which HIV prevention efforts are carried out, what types of agencies are providing services, what resources are allocated to those services, to whom services are being provided, and how these efforts have contributed to a reduction in HIV transmission; (2) improve ease of reporting to better meet these data needs; and (3) be accountable to stakeholders by informing them of HIV prevention activities and use of funds in HIV prevention nationwide.

CDC HIV prevention program grantees will collect, enter or upload, and report agency-identifying information, budget data, intervention information, and client demographics and behavioral risk characteristics. Data collection will include searching existing data sources, gathering and maintaining data, document compilation, grantee training, review of data, and data entry or upload into the web-based system.

There are no additional costs to respondents other than their time. As noted above, the number of added variables is approximately equal to the number of deleted variables, so there is no change in burden hours from the previously approved information collection. The total estimated annual burden hours are 206,226.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Health jurisdiction	Health Department Reporting	69	2	1377
Community-based organization	Community-based organization Reporting	200	2	40.5

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–20478 Filed 8–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2781]

Obstetrics and Gynecology Device Panel of the Medical Device Advisory Committee; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 9, 2014 (79 FR 32964). Due to some recent confusion with the 2014 docket, this 2014 notice and all materials associated with it are being moved to a new docket. This document announces the new docket number.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning,

Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014–13290, appearing on page 32964, in the **Federal Register** of Monday, June 9, 2014, the following correction is made:

On page 32964, in the second column, in the headings section of the document, [Docket No. FDA–2014–N–0736]'' is corrected to read ''FDA–2015–N–2781''.

Please be aware that this new docket is no longer open for comment.

Dated: August 12, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–20397 Filed 8–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2458]

Center for Devices and Radiological Health Participation in International Medical Device Regulators Forum, Regulated Product Submission, Table of Contents Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), Offices of Device Evaluation (ODE) and In Vitro Diagnostics and Radiation (OIR) are announcing their participation in the International Medical Device Regulators Forum's (IMDRF) Regulated Product Submission Table of Contents Pilot Program. Participation in the Pilot is voluntary and open to applicants who submit premarket approval (PMA) applications or premarket notification (510(k)) to either ODE or OIR. The Pilot project is intended to provide industry, IMDRF, and CDRH staff the opportunity to evaluate the Table of Contents structure and to receive input from industry participants. Participants will be asked to submit their submissions electronically using IMDRF's Table of Contents (ToC) format.

DATES: The IMDRF is seeking interest for participation in the voluntary IMDRF Regulated Product Submission, Table of Contents Pilot Program. See section II.A. for instructions on how to submit a request to participate. The Pilot project will accept submissions with the ToC structure starting September 2015 through September 2016.

FOR FURTHER INFORMATION CONTACT: Jodi Hope N. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1520, Silver Spring, MD 20993, 301–796–9299, *Jodi.Anderson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The IMDRF was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force. The Forum aims to accelerate international medical device regulatory harmonization and convergence.

The Regulated Product Submission (RPS) proposal was endorsed as a new work item by IMDRF at its 2012 inaugural meeting in Singapore. The Work Group, consisting of regulatory authorities from the United States, European Union (EU), Australia, Brazil, Japan, China, and Canada, created a comprehensive Table of Contents for Non-In Vitro Diagnostics (nIVD) and also for IVD Marketing Authorizations, which were formalized in August 2014.

The ToC provides a comprehensive submission structure that can be used as a harmonized international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is intended to provide guidance regarding the location of submission elements. These documents can be found on IMDRF's Web site (Refs. 1 and 2).

This document is intended to work together with a regional classification matrix, a separate document created for each participating jurisdiction. The classification matrix defines whether a heading is required, not required, optional, conditionally required, etc., for the given submission type. FDA's Classification Matrices can be found on FDA's Web site (Ref. 3).

The ToC Work Group has previously conducted Pilots for both of the ToC structures, using historical submissions. These Pilots provided valuable feedback regarding the ToC structure and completeness; however, there were limitations to using historical submissions and also a limited number of samples involving submission to more than one jurisdiction. Furthermore, there were no specific guidelines regarding the means of building a submission in a non-standard implementation. Additional IMDRF testing is considered necessary to both evaluate the ToC structures using real regulatory submissions and also evaluate the ToC structure from an industry perspective.

II. CDRH Participation in IMDRF Regulated Product Submission Table of Contents (ToC) Implementation Pilot

FDA's participation in the IMDRF RPS ToC Implementation Pilot will provide both local and international benefits for FDA, as it will provide FDA feedback into decisions regarding the ToC's suitability.

CDRH is participating in the Pilot. In doing so, CDRH will receive premarket submissions from the medical device regulated industry using the IMDRF ToC and FDA Regional Classification Matrices. Applications are to be real regulatory submissions—either PMAs or 510(k) applications—that will result in regulatory decisions by CDRH. PMAs exclude combination products and bundled submissions. The 510(k)s exclude special, abbreviated, and third-party submissions, as well as combination products, bundled submissions, and amendments after a final decision. Pilot participation requires that an application submitted to FDA also be submitted sequentially or simultaneously to at least one additional participating IMDRF region. Currently the participating regulating authorities are Australia (Therapeutic Goods Administration), Brazil (ANVISA), Canada (Health Canada), China (China Food and Drug Administration), and the European Union (Notified Bodies).

The Pilot is described in greater detail in the IMDRF/RPS WG/N26 Informational Document ''IMDRF Table of Contents (ToC) Pilot Plan'' (Ref. 4).

The Regulators participating in this Pilot intend to use submissions only for the requested regulatory activity and objectives of this Pilot. Any submissions generated in relation to this testing will not be distributed to other manufacturers or other regulators. Industry participants should share any submission content directly with the appropriate regulators through the official regulatory processes in place—*i.e.*, submission content will be shared across regulators directly by regulated industry.

Feedback provided on the ToC structure, experience developing regulatory submissions, or suggestions