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) 
help 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

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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 
otice that appeared in the Federal 
Register of June 9, 2014 (79 FR 32264). 
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:


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.

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