DEVICES AND RADIOLOGICAL HEALTH

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Devices and Radiological Health	**440,010**	**442,689**	**450,304**	**463,402**	**13,098**
Budget Authority	***320,825***	***320,793***	***323,253***	***325,764***	***2,511***
User Fees	***119,185***	***121,896***	***127,051***	***137,638***	***10,587***
Center	344,278	350,180	352,048	360,836	8,788
Budget Authority	240,345	240,318	240,808	243,319	2,511
User Fees	103,933	109,862	111,240	117,517	6,277
Medical Device (MDUFA)	*97,810*	*104,569*	*104,991*	*111,140*	6,149
Mammography Quality Standards Act (MQSA)	*6,123*	*5,293*	*6,249*	*6,377*	128
Field	95,732	92,509	98,256	102,566	4,310
Budget Authority	80,480	80,475	82,445	82,445	---
User Fees	15,252	12,034	15,811	20,121	4,310
Medical Device (MDUFA)	*1,913*	*1,949*	*2,199*	*2,328*	129
Mammography Quality Standards Act (MQSA)	*13,339*	*10,085*	*13,612*	*13,892*	280
International Courier	---	---	---	*3,901*	3,901
FTE	**2,087**	**2,190**	**2,117**	**2,166**	**49**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss); Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Mammography Quality Standards Act of 1992 (42 U.S.C. 263b); Medical Device Amendments of 1992; Food and Drug Administration Modernization Act; Medical Device User Fee and Modernization Act of 2002; Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3); Medical Device User Fee Stabilization Act of 2005; Food and Drug Administration Amendments Act of 2007 (FDAAA); Patient Protection and Affordable Care Act, 2010; FDA Safety and Innovation Act (FDASIA), 2012

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Devices and Radiological Health Program (the Devices Program) began in 1976 with the passage of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act. The Devices Program operates with appropriations and user fees and is comprised of the Center for Devices and Radiological Health and the Office of Regulatory Affairs.

The Devices Program is responsible for the national regulation of all medical devices, from simple articles such as tongue depressors to complex robotic equipment for surgery and cutting-edge diagnostic products such as implantable defibrillators. To protect the public from unnecessary exposure to radiation, the Devices Program also regulates radiation-emitting products that include microwave ovens, X-ray equipment, and medical ultrasound and MRI machines. In addition, the Devices Program monitors mammography facilities to make sure the equipment is safe and properly run.

The mission of the Devices Program is to protect and promote the public health. FDA assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. FDA provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products it oversees. FDA facilitates medical device innovation by advancing regulatory

science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and by assuring consumer confidence in devices marketed in the United States.

The vision of the Devices Program is to ensure that patients in the United States have access to high-quality, safe, and effective medical devices of public health importance – first in the world. The United States is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. postmarket surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the United States and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

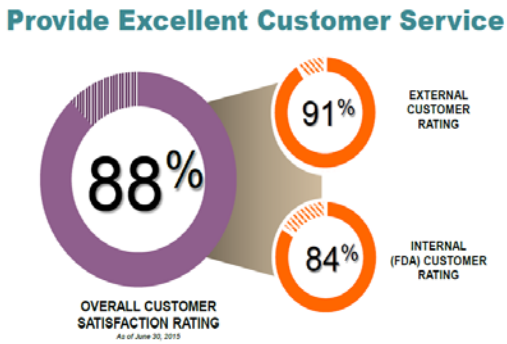
The following strategic priorities describe the most important areas that the Devices Program will focus on to reach this vision. These priorities are to:

- establish a National Evaluation System for Medical Devices
- partner with Patients
- promote a Culture of Quality and Organizational Excellence.

By addressing these priorities, the Devices Program aims to help medical device developers choose the United States as the country of first choice for their innovative new technologies – a key contributor to early patient access to high quality, safe and effective devices. Providing excellent customer service will also improve interactions with stakeholders and colleagues, both internal and external, support better regulatory outcomes, and improve patient health.

Recent accomplishments of the Devices Program include the following:

- reduced the number of Investigation Device Exemptions (IDEs) requiring more than two cycles to full approval by 53 percent from FY 2013 to FY 2015
- decreased review times for investigational device exemption (IDE) submissions, from a median time of 101 days in FY 2014 to 30 days in FY 2015
- increased the number of Early Feasibility Studies (EFS) approved by over 100 percent from FY 2014 to FY 2015
- achieved an 88 percent Customer Satisfaction Rating by June 30, 2015.



The following selected accomplishments demonstrate the Devices Program's delivery of its regulatory and public health responsibilities within the context of current FDA strategic goals and priorities.[52]

Improve and Safeguard Access

The Devices Program is committed to flexible, smart regulation, and to working with industry and the clinical community to ensure that innovative new medical devices that demonstrate a reasonable assurance of safety and effectiveness are available for U.S. patients. Each year, the Devices Program evaluates the safety and effectiveness of new devices and approves or clears thousands of products for market. As a result, millions of U.S. patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

This is a time of remarkable advances in medical device technology, advances that can extend lives, and minimize suffering for American patients. New technologies hold out promise for empowering patients in their own health care decision-making and for delivering precision treatments that are truly targeted to individuals. At the same time, the promise of advances in medical technology will only be realized if the patients and providers who use them are confident that they are safe and can do what they are intended to do.

The Devices Program has evolved alongside changes in medical technology and in the global marketplace. The Devices Program has implemented several new policies and programmatic improvements to ensure American patients have timely access to devices without compromising standards of safety and effectiveness. Devices are coming to market more quickly, and more products that go through The Devices Program's premarket process are being approved and cleared for marketing. In addition, FDA has made its review of investigational devices more efficient and expeditious, streamlining the pathway to conducting clinical investigations in the United States.

Among the FDA strategic goals and priorities, the Devices Program supports FDA's Smart Regulation, Regulatory Science, and Safety and Quality priorities through efforts including the Clinical Trial Enterprise, Early Feasibility Studies, and the Medical Device Innovation Consortium.

Guidances

Below are selected guidances issued by the Devices Program during calendar year 2015. These guidances help address various issues.[53]

Date	#	Title	Description
Jul 2015	FDA-2015-D-2148	Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices	This draft guidance provides a description of the information that should be included in a premarket notification (510(k)) submission for a magnetic resonance diagnostic device.

[52] Please visit FDA.gov for additional program information and detailed news items.
[53] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

Date	#	Title	Description
Apr 2015	FDA-2014-D-0090	Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval	This final guidance clarifies FDA's current policy on balancing premarket and postmarket data collection during the Agency's review of premarket approval (PMA) applications
Apr 2015	FDA-2014-D-0363	Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions	This final guidance outlines the new, voluntary Expedited Access for Premarket Approval and De Novo Medical Devices (Expedited Access Pathway or EAP) program
May 2015	FDA-2015-D-1439	Adaptive Design for Medical Device Studies	The purpose of this draft guidance is to provide information on how to plan adaptive designs for clinical studies for medical device development programs

Product Approvals

Below are examples of selected Devices Program product approvals that occurred during calendar year 2015. This list does not represent any degree of importance or priority ranking of products.[54]

Date	Product Name	Description
Jul 2015	Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA)	The device is the first prosthesis for rehabilitation of above-the-knee amputations for adults who have rehabilitation problems with, or cannot use, a conventional leg prosthesis.
Jun 2015	Brio Deep Brain Stimulation System	An implantable, rechargeable device designed to deliver low-intensity electrical pulses to specific targets within the brain in various combinations of amplitude, pulse width, and frequency
May 2015	Nevro Senza Spinal Cord Stimulation System	A SCS System indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain
Apr 2015	Gastric Emptying Breath Test	Non-invasive breath test diagnoses delayed gastric emptying – dgastroparesis – disorder that slows or stops the movement of food from the stomach to small intestine
Mar 2015	Abiomed Impella 2.5 System	A medical device that helps the heart pump blood during a high risk percutaneous coronary intervention procedure to restore blood flow to the heart

[54] For more information on product approvals and designations visit http://www.fda.gov/NewsEvents/ProductsApprovals/.

Clinical Trial Enterprise

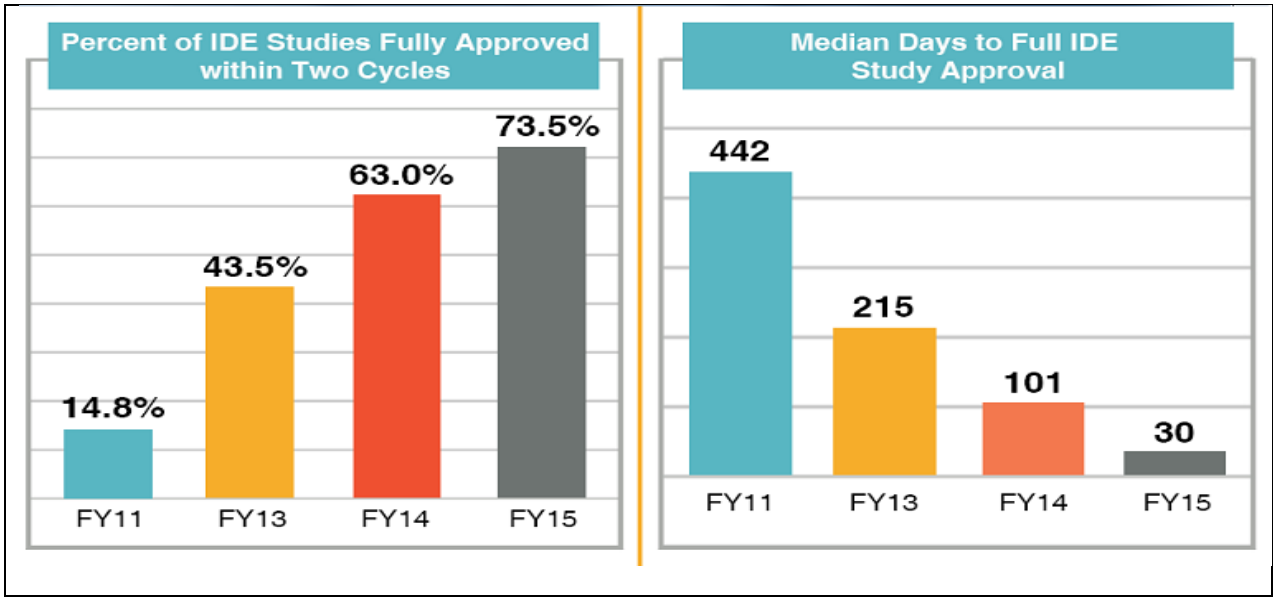
The Devices Program is committed to improving U.S. patient access to new devices by strengthening and streamlining the clinical trial enterprise. As part of our 2014-2015 Strategic Priorities, CDRH committed to reducing the time and cost of regulatory and non-regulatory aspects of the U.S. clinical trial enterprise, while assuring the protection of human subjects and the generation of robust data.

In 2015, CDRH continued to advance our clinical trials program with publication of a new draft guidance document related to how we consider benefits and risks for Investigational Device Exemptions (IDEs) decisions as well as issued a draft guidance that, when final, will encourage the use of adaptive designs for clinical trials and we are considering additional process improvements. CDRH also trained our review staff on the practical challenges related to conducting a successful trial, which included more than 100 review staff visits to sponsors of clinical trials to better understand the context and challenges of initiating and conducting clinical trials in the United States.

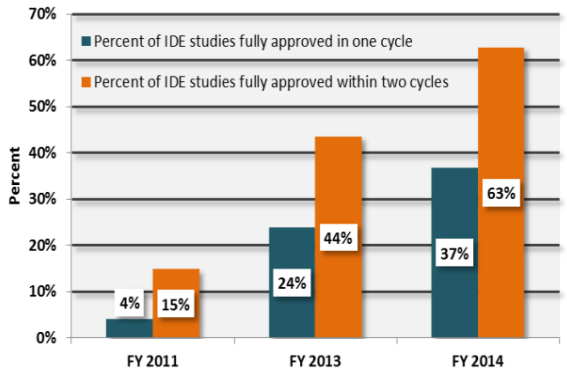
These program improvements have greatly shortened the time for an IDE to reach full FDA approval, allowing medical device clinical trials to begin sooner in the United States. As a result of these efforts:

- from FY 2011 to FY 2014, the median number of days to full IDE approval decreased from 442 days to 101 days
- during FY 2015, the median number of days to full IDE approval decreased to approximately 30 days.

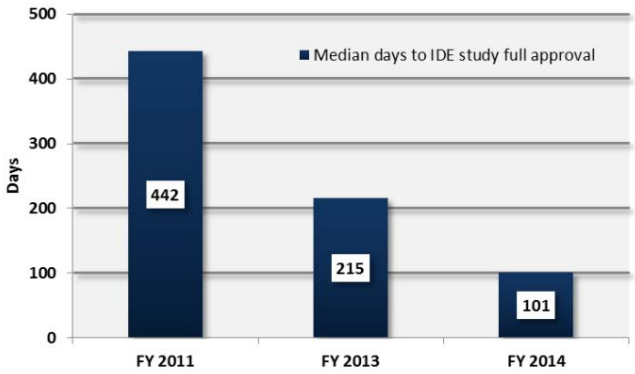
In addition, full approval now entails fewer review cycles. In FY 2011, only 15% of IDEs were approved within two review cycles. By FY 2015, approximately 74% of IDEs were approved in two review cycles. This performance meets FDA's strategic goals and, more importantly, means that important technologies have the potential to reach US patients sooner. Making it easier to start clinical studies in the United States, while assuring patient protections, can result in device makers choosing to bring their innovate technologies and treatments to U.S. patients first in the world.



Percentage of IDE studies fully approved.



Median number of days to full IDE approval.



Early Feasibility Studies

Early Feasibility Studies (EFS) are small clinical studies designed to gain early insights into an innovative technology during the development process before starting a larger clinical trial. EFS often are a critical step in device innovation, but they are frequently conducted in other countries rather than in the U.S. Device developers tend to conduct subsequent feasibility and pivotal clinical studies and then bring their products to market earlier in those countries, where they conducted an EFS to leverage clinicians who have gained experience with their technologies.

As part of our 2014-2015 Strategic Priority to Strengthen the Clinical Trials Enterprise, CDRH established a goal of increasing the number of EFS IDEs submitted to each review division in the Center. Interest in our EFS program has grown substantially, with a 50% increase in the number of EFS submissions during the first nine months of 2015, compared with the same period in 2013. In addition, six of our seven Office of Device Evaluation (ODE) review divisions reported an increase in the number of EFS submissions for 2015 compared with 2013. The Devices Program believe these results are clear evidence that we are moving the right direction, helping to ensure that robust and efficient clinical trials that provide appropriate human subject protections take place here in the United States. [55]

Expedited Access Program

On April 15, 2015, the Devices Program launched the Expedited Access Program (EAP) to speed qualifying devices to patients. Specifically, EAP is a voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to PMA or are eligible for *de novo* requests.

Under this pathway program, FDA provides earlier and more interactive engagement with sponsors of devices. This engagement includes the involvement of senior management and the development of a collaborative plan for collecting the scientific and clinical data to support approval – features that, taken together, will provide patients with earlier access to safe and effective medical devices. The program targets devices with potentially high impact on patient health because, for example, they fulfill an unmet need by offering an important advantage over existing devices. To promote earlier patient access, some data collection for devices marketed

[55] Available at http://www.fda.gov/downloads/medicaldevices/deviceregulationand%20guidance/guidancedocuments/ucm279103.pdf

under this pathway might be moved from premarket to postmarket, provided there is still a reasonable assurance of safety and effectiveness concerning the device.

FDA believes the EAP program will reduce the time it takes to develop important new medical devices for U.S. patients with unmet medical needs, without lowering standards of safety and effectiveness.[56]

Patient Preference Initiative

The Devices Program recognizes patients are uniquely positioned to inform medical product development with firsthand experience gained from living with a disease, including their use of available therapies to treat their conditions. To strengthen patient preferences in regulatory decisions, the Devices Program established the Patient Preferences Initiative. With this initiative, the Devices Program expanded upon the current approach for capturing patient-centered perspectives in its structured benefit-risk framework, to outline a way of incorporating patients' views on benefits and risks together with those of FDA's health care professionals, scientists, and engineers during regulatory decision-making about certain medical devices.

This approach incorporates scientific, empirical evidence from different patients who, as a group, may have a range of views about the degree and types of risks associated with a medical device and how risks should be weighed against the anticipated benefits. CDRH believes that by better understanding patients' experiences, needs, and views, FDA will be able to improve the development of medical products and enhance the safe and effective use of those products.[57]

Patient Engagement Advisory Committee (PEAC)

On September 18, 2015, the Devices Program announce FDA's first-ever Patient Engagement Advisory Committee (PEAC). This body will provide advice to the FDA Commissioner on a range of complex issues relating to medical devices, the regulation of devices, and their use by patients. It will give FDA the opportunity to obtain expertise on various patient-related topics, with the goal of improving communication of benefits and risks and increasing integration of patient perspectives into the regulatory process. These data can be used in several major ways to:

- help identify the most important benefits and risks of a technology from a patient's perspective
- assess the relative importance to patients of different attributes of benefit and risk, and clarify how patients think about the tradeoffs of these benefits and risks for a given technology
- help understand how patient preferences vary across a population.

These efforts are helping to drive a more patient-centered medical product development and assessment process.[58]

Medical Device Innovation Consortium (MDIC)

Through the Medical Device Innovation Consortium (MDIC), FDA collaborates with industry, nonprofit organizations, patient organizations and other Federal agencies to find solutions for common medical device challenges. It's collaborations focus on advancing regulatory science to

[56] Available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf
[57] Available at http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhpatientengagement/ucm462830.htm
[58] Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHPatientEngagement/ucm462829.htm

propel device development through the regulatory process and to market, resulting in smarter regulation and earlier patient access to safe, effective, and high-quality devices. This includes providing a venue for leveraging resources, people, and intellectual capital to support the development of non-clinical device development tools that can reduce the need for or size of clinical studies to support market approval as well as steps to reduce the time and cost of clinical trials.

For example, in FY 2015, MDIC issued a catalog of available methods that can be used for collecting data on patient preferences, along with a framework for considering how to incorporate patient preferences across the total lifecycle of a device. The ultimate goal is to use these data to guide the development, assessment, and delivery of medical devices that better meet patients' needs. As a result, patients will play a more influential role in determining which treatments and diagnostics are available in the U.S. market.

Next Generation Sequencing (NGS)

Many newly developed genomic diagnostic tests rely on next generation sequencing (NGS), an advanced technology, which is becoming a keystone of precision medicine. NGS tests can rapidly generate an unprecedented amount of genetic data for each patient. Most *in vitro* diagnostic devices are used to detect a single or a defined number of markers to diagnose a limited set of conditions; in contrast, a single NGS test can identify thousands or millions of genetic variants that can be used to diagnose or predict the likelihood of an individual developing a variety of diseases.

As part of the Precision Medicine Initiative (PMI), FDA will develop a new approach for evaluating NGS technologies to facilitate the generation of knowledge about which genetic changes are important to patient care and foster innovation in genetic sequencing technology, while ensuring that the tests are accurate and reliable.

In FY 2015, FDA published a white paper outlining a possible approach to review of this technology that would greatly reduce burden by leveraging data in existing high-quality, curated genetic databases as an alternative to conducting new clinical trials and by reviewing analytical performance for only a subset of variants through the creation and use of reference standards. The Devices Program aims to ensure that NGS tests provide accurate, reproducible, and meaningful results relevant to a person's medical condition while continuing to foster innovation so that people have access to the best available results possible.

Experiential Learning Program

To help reviewers understand the challenges of technology development, manufacturing, and use, and become informed about specific current and emerging technologies, the Devices Program implemented the Experiential Learning Program (ELP). The program provides reviewers with real-world training experiences through visits to manufacturers, research facilities, and health care facilities. Since the start of the program in 2012, nearly 1,000 staff participated in 84 visits at 64 sites to gain real world knowledge of regulated products. In FY 2014 – FY 2015, the ELP General Training component was implemented to enhance staff understanding of the cross-product line issues faced throughout device development, testing, manufacturing, and clinical use.[59]

[59] Available at: http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm

CDRH Learn

CDRH continues to proactively assist the medical device sector to efficiently deploy resources by providing interactive, high-quality responses to thousands of industry questions concerning device and radiological health regulatory issues. These efforts include CDRH Learn, a multimedia catalog of online educational modules intended to provide information about medical device laws, regulations, and policies that is comprehensive, interactive, and easily accessible. With the addition of 26 new modules in FY 2015, the catalog has grown to over 90 educational modules to help educate stakeholders. The new design, updated content and the new mobile ready format allows 24/7 access from all devices. In FY 2015, CDRH responded to over 38,000 inquiries from industry, and the CDRH Learn webpage was visited more than 165,000 times.

Customer Service

A key determinant of early U.S. patient access to high-quality, safe and effective devices is the quality of the customer service we provide to our stakeholders, including patients, industry, and health care professionals. That is why the Devices Program made providing excellent customer service a strategic priority and launched an effort to improve customer service that included staff training, surveys to measure customer satisfaction, and actions to improve the quality of service. On December 31, 2014, CDRH ended the 2014 data collection with an 83 percent Customer Satisfaction Rating. As of June 30, 2015, CDRH exceeded its June 2015 goal of 80 percent with an 88 percent Customer Satisfaction Rating, with the rating for the premarket program even higher at 93 percent. High levels of customer satisfaction can help make the United States a more attractive marketplace for early patient access to safe and effective devices of public health importance.[60]

Enhance Oversight

Ensuring manufacturer compliance with laws and regulations helps assure the safety and efficacy of devices and protects consumer confidence in U.S. medical products worldwide. The Devices Program quickly identifies major violations and takes prompt, clear, and appropriate actions to resolve issues before they have widespread negative impacts on public health. At the same time, the Devices Program monitors postmarket performance including adverse events, responds quickly to identify and limit potential public health problems, and collaborates with industry to improve the quality of medical devices for U.S. patients.

Among FDA strategic goals and priorities, the Devices Program supports Smart Regulation through efforts including the National Medical Device Evaluation System and Unique Device Identification. At the same time, Globalization is supported by The Medical Device Single Audit Program and Safety and Quality by efforts including the Case for Quality Initiative and the Mammography Quality Standards Act Program.

Guidances

Below are selected guidances issued by the FDA during calendar year 2015. These guidances help address various issues.[61]

[60] Available at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm384176.htm
[61] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

Date	#	Title	Description
Jun 2015	FDA-2015-D-2245	Unique Device Identification: Direct Marking of Devices	Draft guidance – assists industry, particularly labelers, in understanding FDA's requirements for direct marking of devices for unique device identification purposes
May 2015	FDA-2015-D-1376	Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices	Draft guidance – explains when to leverage existing clinical data to support pediatric device indications in premarket approval applications (PMAs) and humanitarian device exemptions (HDEs)
Mar 2015	FDA-2015-D-06029	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling	This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices.

Medical Device Reporting

Under the Medical Device Reporting (MDR) program, FDA receives more than 1,100,000 medical device reports annually from manufacturers, importers, distributors, user facilities, and voluntary reporters. Incidents in which a device may have caused or contributed to a death or serious injury, or experienced a malfunction must be reported by manufacturers and importers.

In FY 2015, the Devices Program reviewed 95 percent of all death MDRs within five business days of the submission, enabling rapid identification of device issues and failures that help to minimize widespread consequences on public health.

To expedite the report processing and reduce the burden of data entry on the FDA, manufacturers, and importers, FDA implemented the eMDR final rule on August 14, 2015, requiring all medical device manufacturers and importers to submit their reports electronically, rather than in paper form. On August 6, 2015, FDA retired the Manufacturer and User Facility Device Experience (MAUDE) database and replaced it with the System for Uniform Surveillance (SUS). This new adverse event platform and data repository is able to house the increasing number and complexity of reports – for example, reports with images – and allows for more efficient searches and analyses.

Medical Product Safety Network

The Medical Product Safety Network (MedSun) is an "active" adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand, and solve problems associated with the use of medical devices.

MedSun provides a better understanding of how certain devices are used in the clinical environment, how regulatory actions against manufacturers will affect patient care in hospitals and if manufacturer recalls and other actions successfully solved the reported device problems. In FY 2015, there have been 40 recalls and 84 manufacturer actions directly influenced by MedSun reports.[62]

[62] Available at http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm

National Medical Device Evaluation System

In September 2012, the FDA published a report, Strengthening Our National System for Medical Device Postmarket Surveillance, which proposed a National Medical Device Surveillance System for improving and addressing the limitations of the agency's current system for monitoring medical device safety and effectiveness. This report recommended establishing a national infrastructure for gathering and analyzing real world data, or data collected as part of routine clinical practice and patient experience. In April 2013, FDA published an update to the report that describes to establish a more integrated National Medical Device Surveillance System. [63]

In February 2015, the multi-stakeholder Planning Board issued a report entitled "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," which outlines recommended steps and strategies toward achieving the national system. To that end, the Planning Board was reconvened to move forward on creation of organizational structure of a national system, development of governance, development of a sustainability plan and an implementation plan. The Device Program also made cooperative agreements to promote development of infrastructure and methodologies to support the national system.

The Device Program envisions a national system that would leverage electronic health information from electronic health records, device registries, and payer claims forms through a coordinating center that establishes strategic alliances between data holders, such as health care systems, to use de-identified information according to pre-specified policies and procedures. This system would have the capability to:

- provide benefit and risk assessments of medical devices throughout their use
- quickly identify potential safety signals in near real-time
- accurately characterize and disseminate information about real-world device performance
- efficiently generate data to facilitate the clearance and approval of new devices, or new uses of existing devices.

In FY 2015, the Devices Program achieved tremendous progress laying the groundwork for the national system, including the following:

- advanced implementation of the unique device identification (UDI) rule for the highest-risk devices, including development of a Global UDI Database (GUDID) as the repository for information that unambiguously identifies devices through their distribution and use
- built registry capabilities both domestically and internationally, including the a domestic registry for inferior vena cava filters and the International Consortium of Vascular Registries
- established a Medical Device Registry Task Force consisting of key registry stakeholders as part of the Medical Device Epidemiology Network (MDEpiNet) Program, a collaborative program to develop new and more efficient methods to study devices.

[63] Available at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

Unique Device Identification
On September 24, 2013, the Devices Program published the Unique Device Identification (UDI) final rule, a landmark step in improving patient safety and modernizing FDA's postmarket surveillance system for medical devices. When fully implemented, the label of most devices will include a unique device identifier in human and machine-readable form. The Devices Program also established the GUDID, an information system that serves as a reference for every device with a unique device identifier, empowering stakeholders with access to non-confidential device information.

The Devices Program is moving full speed ahead with implementing the UDI system while promoting its widespread adoption of UDI in the U.S. health care system. In FY 2015, the Devices Program:

- opened the GUDID portal, making UDI data publicly available through Access GUDID to give patients, health care systems, the device industry, and others access to better and more precise device information
- published draft guidance entitled: "Unique Device Identification: Direct Marking of Devices," helping industry understand the requirements for direct marking of devices for unique device identification purposes

The incorporation of UDI into electronic healthcare data sources, such as Electronic Health Records, will have many benefits for patients, the health care system, and the device industry. The UDI system improves the identification of medical devices by making it possible to rapidly and definitively identify the device, through distribution and use, and some key attributes that affect its safe and effective use. This system will facilitate more accurate reporting and analysis of adverse events, make recalls more efficient and effective, enhance postmarket surveillance, and ultimately facilitate device clearance and approval.[64]

Registry-Based Surveillance
Registries play a unique role in modernizing medical device surveillance because they can provide a cost effective method to gain detailed information about patients, procedures, and devices not routinely collected by electronic health records, administrative or claims data.

In FY 2015, to enhance postmarket surveillance efforts and reduce regulatory burdens on industry, the Devices Program expanded its registry-based surveillance of transcatheter valve therapy (TVT) devices using a multi-stakeholder TVT Registry. The TVT Registry is a benchmark tool developed to track patient safety and real-world outcomes involving transcatheter aortic and mitral valve replacement, a minimally invasive surgical procedure to repair a damaged valve in the heart. Information about second generation devices is now routinely captured.

The Devices Program also expanded its International Consortium of Orthopedic Registries and launched the International Consortium of Vascular Registries.

Signal Management Program
The Devices Program established the Signal Management Program (SMP) to provide processes and procedures to consistently evaluate and advance mitigation strategies for safety signals identified for medical devices on the U.S. market. A safety signal is data that suggests a

[64] Available at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/default.htm

potential association between a medical device and an adverse event or set of events of public health concern.

As part of SMP, the Devices Program implemented Signal Review Teams focused on high priority clinical product areas including General Hospital, Surgery, and Neurology devices. In FY 2015, SMP expanded to include the important clinical product areas of Cardiovascular and Orthopedics. SMP evaluated over 75 safety signals that have resulted in actions including device recalls, device labeling changes, and public communications to help limit and address device safety issues before they have widespread impacts on public health.

Case for Quality Initiative

Through the Case for Quality (CFQ), the FDA is working with stakeholders to foster medical device quality by identifying and promoting practices that result in high-quality devices and adapting regulatory approaches to align with those practices. FDA introduced the CFQ in an effort to help device manufacturers elevate their focus from the baseline requirements of compliance with regulations alone, and instead focus on predictive and proactive measures they can take independently to improve quality. CFQ also provides FDA the opportunity to change our approach to focus more on what matters most in assuring product and manufacturing quality and safety for patients.

As part of the initiative, the Devices Program has identified the specific operations, design considerations, and controls that improve the quality of over ten medical devices of public health importance. One of these device types is implantable devices that use batteries, which quality factors have been integrated into inspectional approaches and manufacturing requirements, allowing the Devices Program and industry to collaborate more closely on device quality during site inspections. The Devices Program aims to reduce the risk of patient harm by helping the medical device manufacturing sector deploy quality-related design and production practices to improve the safety of U.S. manufactured devices. [65]

Voluntary Compliance Improvement Pilot Program

The Devices Program launched the Voluntary Compliance Improvement Pilot (VCIP) program as part of its ongoing commitment to use smart regulation to achieve a higher return in service to American patients. Instead of an FDA inspection and the regulatory consequences that may follow, participating manufacturers are afforded the opportunity to voluntarily correct identified deficiencies if they meet VCIP program criteria.

As of FY 2015, four firms have enrolled in the VCIP program, which plan to demonstrate their ability to define problems, analyze root causes, create corrective actions and verify those actions were effective. Through the VCIP program, the Devices Program aims to improve medical device quality by promoting voluntary compliance of firms that have self-identified compliance deficiencies. [66]

Medical Device Single Audit Program

The FDA and its regulatory counterparts abroad have the weighty responsibility of ensuring the safety of the thousands of regulated medical devices imported in their countries each year. To make this task more manageable, in FY 2014, FDA and regulatory agencies in Australia, Brazil, Canada, and Japan embarked on a pilot called the Medical Device Single Audit Program

[65] Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm
[66] Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378183.htm

(MDSAP). The goal of the MDSAP pilot is to develop a process that allows a single audit, or inspection to ensure the medical device regulatory requirements for all five countries are satisfied, in an efficient yet thorough manner. As of September 2015, 50 device manufacturers have committed to participate in this program, and six third-party auditing organizations have been authorized to conduct independent MDSAP audits across five international jurisdictions.

Under the MDSAP pilot, audits will be conducted by recognized third-party organizations, and medical device regulators in the participating countries will be able to use these inspection reports when making their regulatory decisions. Not only does this program reduce the participating regulators' need to individually perform routine inspections; it allows them all to have the same reliable information about inspectional findings. Manufacturers, too, benefit from the MDSAP pilot by cutting down on the number of regulatory audits they have to host, thereby minimizing manufacturing plant and personnel disruptions.

On January 1, 2014 the MDSAP pilot reached a major milestone – manufacturers around the globe were invited to participate in the MDSAP Pilot Study and certain auditing organizations were invited to apply for MDSAP recognition. The intention of the MDSAP Pilot Study is to provide "proof-of-concept" evidence confirming that a regulatory audit conducted by MDSAP recognized auditing organization can fulfill the needs of multiple regulatory jurisdictions. On September 9, FDA posted the MDSAP Mid-Pilot Status Report to document the mid-pilot status of the objectives and performance goals defined to develop the infrastructure, processes, training, and stakeholder commitment necessary to launch the operational phase of the program – by January 2017.[67]

Digital Health Program

To better protect and promote public health and enhance outreach and education to Digital Health customers, the Devices Program established the CDRH Digital Health Program to foster consistency in existing premarket and postmarket programs. The CDRH Digital Health Program is a focused, collaborative, and responsive effort at CDRH to promote the availability of safe innovative digital heath technologies to patients in the United States. The Program is responsible for developing and implementing consistent regulatory strategies and policies for Digital Health Technologies. The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telemedicine, and personalized medicine.

In FY 2015, the program clarified through various guidances (e.g., mobile medical apps, wireless, premarket cyber security) FDA's approach and policies towards digital health technologies. These policies focuses FDA's oversight to higher risk products so patients and clinicians using these technologies can have access to safe and effective digital health medical devices.[68]

Radiological Health Program

The Devices Program protects public safety by monitoring industry's compliance with regulatory performance standards to reduce the incidence and severity of radiation injury. The Devices Program reviews initial and period reports as well as inspects establishments that manufacture radiation emitting electronic products to determine compliance with the law. The Devices

[67] Available at: http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm
[68] Available at http://inside.fda.gov:9003/CDRH/OfficeoftheDirector/ucm461882.htm

Program has initiated multiple efforts to improve the efficiency and effectiveness of these programs through manufacturer engagement, reliance on international standards, and proposals to reduce or eliminate unnecessary reporting. In FY 2015, this included outreach to educate foreign firms who manufacturer the majority of laser and microwave products imported into the United States.

As a regulatory agency, FDA also shares in the responsibility for strengthening radiation protection of patients and health workers with other national and international agencies, institutions, and organizations. That is why in FY 2015, FDA collaborated with stakeholders, including the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO), to develop a list of priorities for radiation protection in medicine for the next decade called the Bonn Call for Action. The Bonn Call for Action is divided into ten principal actions, each of which is considered essential for strengthening radiation protection over the next decade.[69]

Mammography Quality Standards Act Program

The Mammography Quality Standards Act (MQSA) Program helps to ensure all women in the United States have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. As part of the MQSA Program, FDA and its state contract partners, annually inspect over 8,700 certified mammography facilities in the United States to ensure compliance with national quality standards for mammography. In FY 2015, over 99 percent of mammography facilities had no serious violations of the law, and less than one percent of facilities were cited with the most serious Level I violations. These MQSA certified facilities provide nearly 39 million mammography procedures annually in the United States. [70]

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	$384,427,000	$296,240,000	$88,187,000
FY 2014 Actual	$417,583,000	$320,815,000	$96,768,000
FY 2015 Actual	$442,689,000	$320,793,000	$121,896,000
FY 2016 Enacted	$450,304,000	$323,253,000	$127,051,000
FY 2017 President's Budget	$463,402,000	$325,764,000	$137,638,000

BUDGET REQUEST

The FY 2017 Budget Request is $463,402,000, of which $325,764,000 is budget authority and $137,638,000 is user fees. The budget authority increases by $2,511,000 compared to the

[69] Available at: http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM439602.pdf
[70] Available at: http://www.fda.gov/mammography

FY 2016 Enacted level and user fees increase by $10,587,000. The FY 2017 budget allows the Devices Program to continue to ensure the safety and effectiveness of medical devices that U.S. patients rely on every day, while facilitating scientific innovations that extend and improve lives.

BUDGET AUTHORITY

Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health. The FY 2017 budget enables the Devices Program to continue to meet its core mission to protect and promote public health, including:

- assuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products
- providing consumers, patients, their caregivers, and providers with understandable and accessible science-based information about products
- facilitating medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways
- assuring consumer confidence in devices marketed in the United States.

The Devices Program's mission – geared toward a system of smart regulation – results in better, safer, more effective treatments and world-wide confidence in, and adoption of, the devices that U.S. industry produces. This work is essential to the protection and growth of the nation's medical device industry, which is made up of over 80 percent[71] small businesses, including:

- 425,000 American jobs[72]
- Over 10,000 U.S. manufacturing establishments[73]
- $55.3 billion in U.S. exports and growing, positive trade surplus of over $4 billion.[74]

The Devices Program has evolved alongside changes in medical technology and in the global marketplace. The Devices Program has implemented several new policies and programmatic improvements to ensure American patients have timely access to devices without compromising standards of safety and effectiveness.

Devices are coming to market more quickly, and more devices that go through the premarket program are being approved and cleared for marketing. The FY 2017 Budget allows the Devices Program to continue these program improvements and support a smarter, more innovative and efficient government for the American people.

Medical Product Safety and Availability: $325.8 million (+$2.5 million)

Precision Medicine: +$1.8 million
Center: +$1.8 million

With this investment, the Devices Program will establish the National Medical Device Evaluation System (NES) to identify patients who benefit most or do not benefit from specific types of devices thereby advancing Precision Medicine.

[71] Medical device small business defined as having 50 or less employees by the Medical Device Manufacturers Association.
[72] Medical device industry employment estimated using 2013 data from Dunn & Bradstreet (D & B) Inc.
[73] Medical device industry establishments estimated using 2015 data from CDRH Registration and Listing database.
[74] Export estimated using 2014 data from the U.S. International Trade Commission.

One of the biggest problems facing the success of Precision Medicine is the challenge of determining which devices are best suited for which patients because of the high cost of developing evidence. Data that can answer these questions is generated every day as a part of routine clinical practice (evidence from clinical experience or "real world" data). However, device makers, providers, and government cannot make good use of this data because there is no systematic way to gather and analyze it.

The NES would leverage electronic health information from electronic health records, device registries, and payer claims forms through a coordinating center that establishes strategic alliances between data holders, such as health care systems, to use de-identified information according to pre-specified policies and procedures.

While the long-term vision for the NES involves multi-stakeholder participation and investment, in order to garner meaningful financial support from the private sector, the NES needs a core investment from the U.S. government. This funding would support the creation of the coordinating center and initial alliances. The Devices Program would have a governing board populated by representatives of the critical stakeholder communities, including patients, providers, industry, payers, and government.

Without additional funding, the U.S. will continue not to know which patients would or would not benefit from which types of medical technologies As a result, the U.S. would continue to provide less than optimal care and at a higher cost due to the inappropriate treatment or failure to treat appropriate patients.

Supporting Medical Device Review: +$0.7 million
Center: +$0.7 million

The Devices Program strives to increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market. The requested increase supports ongoing review activities in the Devices Program to meet statutory requirements for the review of medical device applications. As a result, the Devices Program can continue to ensure the safety and effectiveness of medical devices that Americans rely on every day, while facilitating scientific innovations that extend and improve lives.

USER FEES

Current Law User Fees: +$10.6 million

Compared to FY 2016 Enacted level, The FY 2017 Budget request includes an increase of $10,587,000 for User Fees which will allow FDA to fulfill its mission of protecting the public health, treating and curing diseases, and accelerating innovation in the industry.

MDUFA: +$6.3 million
The Devices Program is committed to increasing the efficiency and timeliness that medical devices are developed and made available to U.S. patients. MDUFA III is scheduled to expire on October 1, 2017, and FDA is ready to work with industry, patients, and Congress in the statutory process toward reauthorization to ensure adequate funding of the Devices Program over the next five years.

As of FY 2016, the Devices Program is on track to meet all of its MDUFA III performance goals related to device review, and premarket performance measures show marked improvement since the start of the current decade. FY 2017 User Fee increases allows the Devices Program to

sustain and build on its record of accomplishment in bringing down total review times for 510(k) submissions, de novo requests, IDEs, and PMA applications, without compromising assurances that devices marketed to American patients are safe and effective.

MQSA: +$0.4 million
This inflationary increase permits FDA to cover the increasing cost of running the MQSA Program. The MQSA program sets national quality standards for mammography facilities, equipment, personnel, and operating procedures, and has improved the quality of mammography and made mammograms a more reliable tool to detect breast cancer in the United States.

International Courier User Fee: +$3.9 million
Millions of shipments of medical product commodities enter the United States through express courier facilities, and the number continues to grow. These shipments are often destined for individual consumers or for illegal distribution. The user fee resources for this activity will allow increased import surveillance of FDA-regulated products at express courier hubs. With this new user fee, FDA will:

- conduct entry reviews
- perform sample collections and physical exams to determine product admissibility into the United States
- initiate compliance actions to prevent release of unsafe products into U.S. commerce
- establish import controls to prevent future unsafe products from entering U.S. commerce

Current FDA staffing does not match the expected growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

PERFORMANCE

The Devices Program's performance measures focus on premarket device review, postmarket safety, compliance, regulatory science, and Mammography Quality Standards activities assuring the safety and effectiveness of medical devices and radiological products marketed in the United States, as detailed in the following table:

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon. *(Outcome)*	FY 2012: 79% in 180 days and 97% in 295 days Target: 60% in 180 days and 90% in 295 days (Target Exceeded)	90% in 180 days	90% in 180 days	maintain
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. *(Outcome)*	FY 2013: 98% in 180 days Target: 85% in 180 days (Target Exceeded)	95% in 180 days	95% in 180 days	maintain
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. *(Outcome)*	FY 2013: 98% in 90 days Target: 91% in 90 days (Target Exceeded)	95% in 90 days	95% in 90 days	maintain
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2015: 305 Target: 300 (Target Exceeded)	300	300	maintain
252203: Percent of total received Code Blue MDRs reviewed within 72 hours during the year. *(Output)*	FY 2015: 91% Target: 90% (Target Exceeded)	90%	90%	maintain
254202: Percentage of time CDRH meets the targeted deadline of 60 working days to review GMP information and issue Device Warning Letters. *(Output)*	FY 2015: 35% Target: 60% (Target Not Met)	50%	50%	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (*Output)*	FY 2015: 89% (Target Exceeded)	85%	85%	maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2015: 2,080 Target: 1,600 (Target Exceeded)	1,600	1,600	maintain
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2015: 51 Target: 50 (Target Exceeded)	50	50	maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2015: 2,480 Target: 2,000 (Target Exceeded)	2,000	2,000	maintain
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	FY 2015: 99.2% Target: 97% (Target Exceeded)	97%	97%	maintain

The following selected items highlight notable results and trends detailed in the performance table.

Premarket Device Review
FDA is committed to protecting and promoting public health by providing timely access to safe and effective medical devices by providing reasonable assurance of the safety and effectiveness of medical devices. In FY 2012 and FY 2013, FDA exceeded all of its MDUFA III performance goals, and raised the future targets to keep pace with the MDFUA III commitments.

Code Blue Medical Device Reports
Code Blue Medical Device Reports (MDRs) are defined as high priority MDR reports based on criteria including but not limited to pediatric deaths, multiple deaths and serious injuries, device explosions, and electrocutions. Timely review of code blue MDRs can minimize widespread failure of the device, thereby limiting the loss of life due to similar events as the one submitted.

Warning Letters
Warning Letters are issued after inspections reveal there are significant violations of the Federal Food, Drug, and Cosmetic Act at a particular firm. These letters give the individuals or firms an

opportunity to take voluntary and prompt corrective action before FDA initiates an enforcement action. This strategy is effective because most, though not all, individuals and firms will voluntarily comply with the law. In FY 2015, CDRH did not meet the target for this measure, in part because of a significant increase in Foreign Establishment Inspection Report's (EIRs) that led to a surge in the expected workload. CDRH will continue to improve the review process for these letters, however the continued increase in workload and complexity of the issues, requires a recalibration of the future targets of this goal to 50 percent in the next two years, which is still an increase over the last two years of actual data.

PROGRAM ACTIVITY DATA

Devices and Radiological Health Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2015 Actual	FY 2016 Estimate	FY 2017 Estimate
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1]	65	40	40
Total Decisions [2]	50	50	40
Approved [3]	32	45	35
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	4	5	5
Total Decisions [2]	10	5	5
Approved	7	4	4
Modular PMAs			
Workload	102	70	70
Actions [4]	84	75	70
180-day PMA Supplements			
Workload	201	180	180
Total Decisions [5]	182	190	180
Approved	167	175	165
Real Time PMA Supplements			
Workload	335	340	340
Total Decisions [6]	324	320	320
Approved	297	305	305
510(k) Premarket Notifications			
Workload	3,726	4,000	4,000
Total Decisions [7] (SE & NSE)	3,160	3,300	3,300
Cleared [9] (SE)	3,080	3,150	3,150
Humanitarian Device Exemptions (HDE)			
Workload	5	6	6
Total Decisions [2]	11	6	6
Approved	4	3	3
Investigational Device Exemptions (IDE)			
Workload	268	250	250
Total Decisions [8]	266	250	250
Approved	153	150	150
Investigational Device Exemption Supplements			
Workload	1,692	1,800	1,800
Closures [10]	1,701	1,800	1,800
Pre-Submissions			
Workload	2,154	2,100	2,200
Closures [11]	2,070	2,100	2,200
Standards			
Total Standards Recognized for Application Review	1,106	1,250	1300
Medical Device Reports (MDRs) [12]			
Reports Received	1,245,715	2,056,000	2,672,800
Analysis Consults [13]	1,105	1,460	1,678

[1] Workload' includes applications received and filed. (Receipt Cohort)

[2] Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial - regardless of the fiscal year received. (Decision Cohort)

[3] Approved' includes applications approved regardless of the fiscal year received. (Decision Cohort)

[4] Actions' include accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module. (Decision Cohort)

[5] Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable. (Decision Cohort)

[6] Total Decisions' include approval, approvable, and not approvable. (Decision Cohort)

[7] Total Decisions' include substantially equivalent (SE) or not substantially equivalent (NSE). (Decision Cohort)

[8] Total Decisions' include approval, approval with conditions, disapproved, acknowledge, incomplete, withdrawal, or other. (Decision Cohort)

[9] Cleared' includes substantially equivalent decisions (SE). (Decision Cohort)

[10] Closures' include approval, approval with conditions, disapproved, acknowledge, incomplete, no response necessary, withdrawal, or other. (Decision Cohort)

[11] Closures' include a meeting with Industry, deficiency, or other. (Decision Cohort)

[12] MDRs' include individual and summary Medical Device Reports.

[13] Analysis Consults' include analysis of individual and summary Medical Device Reports (analyzing trends and signals in MDR data).

Field Devices and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,587***	***2,864***	***2,864***
Bioresearch Monitoring Program Inspections	296	300	300
Pre-Market Inspections	57	67	67
Post-Market Audit Inspections	34	34	34
GMP Inspections	1,555	1,594	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	625	723	723
Inspections (MQSA) FDA Domestic (VHA)	53	43	43
Domestic Radiological Health Inspections	42	101	101
Domestic Field Exams/Tests	96	139	139
Domestic Laboratory Samples Analyzed	176	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS [1]	***729***	***603***	***603***
Foreign Bioresearch Monitoring Inspections	14	25	25
Foreign Pre-Market Inspections	42	31	31
Foreign Post-Market Audit Inspections	26	19	19
Foreign GMP Inspections	639	521	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	55	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,316***	***3,467***	***3,467***
IMPORTS			
Import Field Exams/Tests	26,654	18,821	18,821
Import Laboratory Samples Analyzed	658	1,123	1,123
Import Physical Exam Subtotal	**27,312**	**19,944**	**19,944**
Import Line Decisions	17,252,283	19,044,228	21,022,297
Percent of Import Lines Physically Examined	0.16%	0.10%	0.09%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,904***	***7,929***	***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS [2]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,809	6,800	6,800
Inspections (MQSA) by State non-Contract	1,075	1,110	1,110
GMP Inspections by State Contract	20	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$287,518	$296,144	$305,028
State Contract Mammography Funding	$9,317,189	$9,596,705	$9,884,606
Total State Funding	**$9,604,707**	**$9,892,849**	**$10,189,634**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,220***	***11,396***	***11,396***

[1] The FY 2015 actual unique count of foreign inspections includes 10 OIP inspections (9 for China and 1 for India).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.