

Devices and Radiological Health

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table Devices

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	\$378,215	\$378,509	\$375,989	\$386,766	\$10,777
Center	\$282,116	\$285,977	\$280,655	\$285,168	\$4,513
FTE	1,319	1,406	1,374	1,413	39
Field	\$96,099	\$92,532	\$95,334	\$101,598	\$6,264
FTE	473	496	492	531	39
Program Level FTE	1,792	1,902	1,865	1,944	78
Budget Authority	\$322,370	\$322,182	\$322,672	\$319,127	-\$3,545
Center	\$240,486	\$240,695	\$241,475	\$239,072	-\$2,403
Field	\$81,884	\$81,487	\$81,197	\$80,055	-\$1,142
Budget Authority FTE	1,519	1,603	1,611	1,606	(5)
Center	1,066	1,127	1,139	1,134	(5)
Field	453	476	472	472	0
User Fees	\$55,845	\$56,327	\$53,317	\$67,639	\$11,312
Center MDUFMA	\$35,627	\$40,370	\$33,177	\$40,093	\$6,916
FTE	230	248	209	248	39
Field MDUFMA	\$1,138	\$1,586	\$1,060	\$1,281	\$221
FTE	12	12	12	12	0
Center MQSA	\$6,003	\$4,912	\$6,003	\$6,003	\$0
FTE	23	31	26	31	5
Field MQSA	\$13,077	\$9,459	\$13,077	\$13,077	\$0
FTE	8	8	8	8	0
Field Reinspection ¹				\$3,579	\$3,579
FTE				24	24
International Courier User Fee ¹				\$3,606	\$3,606
FTE				15	15
User Fees FTE	273	299	255	338	39

¹ Proposed User fee; the amount includes associated rent activity

The FDA Devices and Radiological Health Program operates under the following legal authorities:

- Federal Food, Drug, and Cosmetic Act¹ (21 U.S.C. 321-399)
- Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss)
- Medical Device Amendments of 1976¹
- Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
- Safe Medical Devices Act of 1990¹
- Mammography Quality Standards Act of 1992 (42 U.S.C. 263b)
- Medical Device Amendments of 1992¹
- Food and Drug Administration Modernization Act¹
- Medical Device User Fee and Modernization Act of 2002¹

Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005¹
Food and Drug Administration Amendments Act of 2007 (FDAAA)¹
Patient Protection and Affordable Care Act, 2010

Allocation Method: 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 to the Food, Drug, and Cosmetic Act (the Act). Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness.

- Class I, General Controls, is the lowest risk category of devices and includes items such as adhesive bandages. These devices are subject to the general controls of the Act, which include establishment registration and device listing and compliance with current Good Manufacturing Practice (cGMP), labeling, record-keeping, and reporting requirements.
- Class II, Special Controls, is a medium-risk category of devices and includes devices such as intravenous catheters and powered wheelchairs. Class II devices typically require that FDA review a premarket notification (510(k))² prior to marketing. These devices are subject to the general controls of the Act as well as Special Controls, which may include special labeling requirements, mandatory performance standards, and postmarket surveillance, in order to ensure device safety and effectiveness.
- Class III is the highest risk category of devices and includes devices such as heart valves and coronary stents. These devices are subject to the general controls of the Act, plus require approval of a premarket approval application (PMA) prior to marketing. PMAs are the most rigorous premarket submission type, and contain substantial scientific evidence to support the device's safety and effectiveness.

Under the Devices Program, the Center for Devices and Radiological Health (CDRH) and the Office of Regulatory Affairs (ORA) protect and promote public health by ensuring the safety, effectiveness and quality of all medical devices. The Devices Program also protects the public from unnecessary exposure to radiation from radiation-emitting products, such as microwave ovens, x-ray equipment, medical ultrasound and MRI machines, and many other consumer, industrial, and medical products. In addition, the Program monitors mammography facilities to make sure their equipment is safe and properly run.

¹ Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified in scattered sections of 21 U.S.C.

² A 510(k) is a premarket submission to demonstrate that the device to be marketed is "substantially equivalent" to another legally marketed (predicate) device.

ORA Field offices support Devices Program activities by assessing industry compliance with applicable regulations. To provide this support ORA:

- conducts premarket and postmarket inspections of domestic and foreign manufacturers
- investigates medical device reports (MDR) and consumer complaints
- monitors and evaluates compliance with recalls of violative products
- performs laboratory analysis to support inspections
- reviews and evaluates imports of medical devices and radiological products to ensure products meet FDA quality standards
- conducts enforcement activities.

A combination of appropriations and user fee programs funds the regulatory process to assure product safety and effectiveness. The Program's user fees are authorized under the Mammography Quality Standards Act (MQSA), enacted in 1992, and the Medical Device User Fee and Modernization Act (MDUFMA), enacted in FY 2002, and reauthorized in FY 2007 as the Medical Device User Fee Act (MDUFA). The current legislative authority for MDUFA expires in September 2012 and FDA anticipates new legislation to reauthorize user fee collections for the medical device program for FY 2013 to FY 2017. The Centers for Medicare and Medicaid Services (CMS) user fee program, authorized by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), also provides support for the Devices Program.

The Devices Program executes its regulatory responsibilities in five areas:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA).

Premarket Device Review – Center Activities

FY 2012 Enacted Amount: \$133,382,559 (BA: \$110,820,346 / UF: \$22,562,213)

CDRH's Premarket Device Review activities focus on ensuring the safety and effectiveness of new devices and radiological products before they can be marketed in the United States. By increasing the predictability, consistency, and transparency of its premarket review programs, CDRH works to provide new treatments and diagnostic tests to patients more quickly and to stimulate investment in and development of promising new technologies to meet critical public health needs.

Through Premarket Device Review activities, CDRH is able to achieve important FDA, HHS, and Administration priorities including:

- applying the least burdensome principle
- proactively facilitating innovation and addressing unmet public health needs

- improving health care quality and patient safety
- reducing health care costs
- protecting Americans in public health emergencies
- accelerating scientific advances in lifesaving cures and quality health outcomes.

Public Health Outcome

CDRH evaluates the safety and effectiveness of new devices and approves or clears thousands of products annually, many of which are critical to the delivery of health care in the United States. Recent examples of device approvals include:

- A device that uses an innovative technique to correct a heart arrhythmia condition that cannot be treated with medication. The process freezes and destroys abnormal heart tissue responsible for producing irregular beats and restores normal electrical activity.
- A novel device to treat adults with the most common form of primary brain cancer, glioblastoma multiforme (GBM). This device is at least as effective as chemotherapy and provides end-stage patients with a better quality of life.
- A pacemaker system designed to deliver standard pacing therapy in patients who have slow heart rates (bradycardia). This system was the first specifically designed and tested to permit patients implanted with the device to receive magnetic resonance imaging (MRI) scans in certain circumstances where the imaging may be critical to diagnosis and treatment.

Nearly two years ago, CDRH recognized that, given the growing complexities of medical product development, the Center needed to re-evaluate and modernize its regulatory review processes in order to ensure that patients had timely access to safe and effective medical devices. At that time, CDRH began to undertake a new systematic approach to device regulation, moving away from the traditional misperception that safety and effectiveness and innovation are incompatible. Rather than focus on *more* regulation or *less* regulation, CDRH began to focus on smart regulation.

In August 2010, following extensive public input, CDRH released two reports that identified problems with our premarket programs and potential actions to address their root causes. After considering extensive public input, CDRH announced 25 specific actions that the Center would take to improve the predictability, consistency, and transparency of our premarket programs. Since then, CDRH announced additional efforts to improve premarket review, including actions to improve clinical trials and the Investigational Device Exemption (IDE) program. Collectively, these actions can be grouped into three main areas of emphasis that seek to:

- create a culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks
- ensure more predictable and consistent recommendations, decision-making, and application of the least-burdensome principle

- implement more efficient processes and use of resources.

On October 19, 2011, CDRH released a detailed report that supports FDA's Transparency Initiative and informs constituents of the many actions and activities CDRH is undertaking to improve its premarket device review programs.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276272.htm>).

The improvements CDRH is undertaking include developing a range of updated and new guidance documents to clarify FDA requirements for timely and consistent product review. These efforts include:

- On August 15, 2011, CDRH issued draft guidance clarifying the criteria used to make benefit-risk determinations a part of device premarket decisions. With these criteria, CDRH will provide greater predictability and consistency and apply a more patient-centric approach by considering patients' tolerance for risk in appropriate cases.
- On October 3, 2011, CDRH issued draft guidance streamlining the de novo review process, the pathway by which novel, lower-risk devices without a predicate can come to market. The guidance makes clear which devices are eligible for the de novo process and what data are necessary to support de novo classification of suitable devices.
- On November 10, 2011, CDRH issued guidance streamlining the clinical trial – investigational device exemption (IDE) processes by providing industry with guidance to clarify the criteria for approving clinical trials, and the criteria for when a first-in-human study can be conducted earlier during device development.

These actions help balance patient safety with innovation by providing manufacturers and developers with clear and predictable outlines of CDRH expectations while at the same time creating incentives to bring new technologies to the United States.

Other improvements include launching a Reviewer Certification Program in September 2011 – a combination of required courses and auditing of work product – which all new reviewers must complete. The purpose of the program is to give reviewers the type of training that can help accelerate their learning curve and help them develop the skills and experience necessary to perform high-quality reviews.

In FY 2011, CDRH also announced its Innovation Initiative, which includes several proposals to help maintain the position of the U.S. as the world's leader in medical device innovation. The initiative includes the creation of a new approach for important, new technologies called the Innovation Pathway. In FY 2012, CDRH is expanding the Innovation Pathway and broadening its mandate. The effort is designed to take a fresh look at how we assess risks in the context of probable benefits, how we engage early on with innovators, and how we create a program that is adaptable, sustainable, and value-adding. To achieve this goal, CDRH assembled a team of entrepreneurs in residence – made up of external experts in medical device development, business

process improvement, and information technology – who will work day-to-day with FDA staff and leadership to use innovative approaches that can rapidly build an improved Innovation Pathway.

CDRH is also in the process of completing the classification of the remaining Class III medical device types that were in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law. In FY 2011, CDRH published five proposed rules and four final rules pertaining to the Class III pre-amendment devices. CDRH is completing the final classification process for the remaining Class III pre-amendment devices.. This resource intensive effort requires a risk-based evaluation of each of the remaining Class III pre-amendment devices and a rule-making process, as required by statute.

To accelerate the development of medical products to treat Americans in the event of a chemical, biological, radiological or nuclear (CBRN) attack or an infectious disease outbreak, CDRH is engaged actively in the Department-wide Medical Countermeasures Initiative (MCMi). CDRH evaluates the safety and effectiveness of diagnostic and detection devices, personal protective equipment, and emergency devices such as ventilators – and addresses gaps in these critical areas. The CDRH MCM Program is working on dozens of projects designed to enhance MCM regulatory science innovation and infrastructure capacity. Some of these projects look at emergency usage of existing medical devices to identify and overcome challenges, while others seek to understand what types of devices may be needed in the future.

CDRH works to provide scientific and regulatory guidance to sponsors of MCM devices during the product development phase, and CDRH conducts interactive premarket reviews of these products. An essential component of these efforts includes accelerating regulatory pathways for emerging technologies critical to speeding diagnosis and treatment in response to a CBRN threat. In FY 2011 and the first quarter of FY 2012, CDRH held public workshops on whole genome sequencing and multiplex diagnostic devices to obtain important input from stakeholders on the evaluation of these vital, new technologies.

Through the Bioresearch Monitoring Program (BIMO), CDRH continues to prevent unnecessary harm to human research subjects and to assure the integrity of data collected. In FY 2011, CDRH issued over 370 clinical and non-clinical inspections of medical device research, and provided outreach programs to foster understanding of clinical-study data integrity and human research subject protections. As a result of these BIMO inspections, CDRH issued 13 warning letters in FY 2011 for clinical investigators, Institutional Review Boards, nonclinical laboratories, and sponsors who revealed human subject protection violations and premarket data integrity issues.

Promoting Efficiency

CDRH continually works to stretch its limited Premarket Device Review Program resources to keep U.S.-based companies leading the roughly \$350 billion global

medical device industry while ensuring the highest return of service to American patients and consumers.

On December 1, 2011, CDRH issued draft guidance to facilitate the development and marketing of Artificial Pancreas Device Systems (APDS) and to provide maximum flexibility to manufacturers seeking to bring this device to U.S. patients. The draft guidance provides for flexibility in the choice of study endpoints, number of patients to be studied and the length of the clinical trial. The approach outlined in the draft guidance allows sponsors to take the least burdensome approach to showing safety and efficacy of APDS.

Other key efforts include CDRH's streamlining of the path to market for full field digital mammography systems to permit less costly and more rapid review and clearance of submissions. This effort included issuing guidance for industry and FDA staff that down regulated full field digital mammography systems from class III devices to class II devices. As a result, the number of commercially available, FDA cleared, full field digital mammography systems increased in FY 2011 by 120 percent. Down regulating well-validated and understood devices promotes U.S. economic and job growth by reducing unnecessary regulatory burdens on device makers without compromising patient safety. CDRH also took steps to effectively down regulate 30 other medical devices in FY 2011.

Premarket Device Review – Field Activities

FY 2012 Enacted Amount: \$8,465,000 (BA: \$7,457,000 / UF: \$1,008,000)

Public Health Focus

The ORA Field force supports the Devices Program in the initial phases of the total product life cycle by conducting preapproval inspections of domestic and foreign establishments to determine if the facility is able to manufacture products according to the specifications stated in their application. ORA also conducts bioresearch monitoring inspections of clinical research studies—including the clinical investigators, sponsors and monitors, and Institutional Review Boards—to safeguard patients and to validate laboratory methods for device premarket application decisions.

Public Health Outcome

ORA conducts inspections to ensure that medical device establishments are able to manufacture products according to the specifications outlined in an application and that concerns or issues raised during review of the application are accounted for. ORA efforts help to assure that medical products are cleared or approved based on reliable data and evidence of manufacturing capability, and once manufactured, become a viable supply of safe commodities for U.S. consumers.

Promoting Efficiency

ORA collaborates with CDRH to ensure that ORA field staff conduct the most efficient bioresearch monitoring inspections possible. This collaboration provides ORA investigators with information on the use of the device being studied, previous clinical trials, and concerns raised during review of preapproval inspections. These Field activities allow FDA to efficiently focus its available inspection resources on significant issues related to data integrity and human subject protection. By doing so, FDA helps ensure that sponsors collect data that can support a device application rather than conducting clinical trials that yield data that cannot support device approval.

In 2011, ORA worked with CDRH to develop a pilot program designed to increase the review efficiency of inspectional findings related to pre-clearance 510(k) violations. This pilot encourages early collaboration between the field and center to more quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and more efficient and quicker issuance of Warning Letters, if appropriate. This will result in more rapid decision-making and communication with manufacturers, which should result in industry taking swifter action to comply, and improved public health protection.

Performance Measures

The Premarket Device Review program is supported by the MDUFA user fee program. Under MDUFMA and MDUFA, FDA agreed to pursue a comprehensive set of device review performance goals.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. <i>(Outcome)</i>	FY 2009 ^{1/} : 77% of 37 in 180 days and 85% of 37 in 295 days Target: 60% in 180 days and 90% in 295 days (Target Not Met)	50% in 180 days and 60% in 295 days	50% in 180 days and 60% in 295 days	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
<u>253204</u> : Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. <i>(Outcome)</i>	FY 2009 ^{1/} : 85% of 162 in 180 days and 91% of 162 in 210 days Target: 85% in 180 days and 95% in 210 days (Target Not Met)	75% in 180 days and 85% in 210 days	75% in 180 days and 85% in 210 days	Maintain
<u>253205</u> : Percentage of 510(k)s (Pre-market Notifications) reviewed and decided upon within 90 and 150 days. <i>(Outcome)</i>	FY 2009 ^{1/} : 90% in 90 days and 98% in 150 days Target: 90% in 90 days and 98% in 150 days (Target Met)	75% in 90 days and 80% in 150 days	75% in 90 days and 80% in 150 days	Maintain
<u>253201</u> : Number of Medical Device Bioresearch Monitoring (BIMO) inspections. <i>(Output)</i>	FY 2011: 322 Target: 300 (Target Exceeded)	300	300	Maintain

^{1/} FY 2009 Pre-market performance data are accurate as of October 21, 2011, Industry Stakeholder meeting. FY 2009 cohort remains open.

Postmarket Safety – Center Activities

FY 2012 Enacted Amount: \$50,032,538 (BA: \$44,307,671 / UF: \$5,724,867)

Public Health Focus

CDRH Postmarket Safety activities focus on monitoring medical device and radiological product performance, including adverse events, once the products reach the market. CDRH analyzes safety signals with potential clinical impact and – when an issue surfaces – strives to respond quickly to identify and limit potential public health problems. These efforts are critical to ensuring that devices and radiological products remain safe and effective for patients and consumers.

Through Postmarket Safety activities, CDRH is able to achieve important FDA, HHS, and Administration priorities including:

- improving health care quality and patient safety
- promoting the adoption and meaningful use of health information technology
- fully implementing a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device’s cycle.

Public Health Outcome

CDRH uses two principle systems to capture device-related adverse event and product problem reports: the Medical Device Reporting regulation (MDR) and the Medical Product Safety Network (MedSun).

MDR is the mechanism by which FDA receives over 300,000 significant medical device adverse events from manufacturers, importers, and user facilities annually. Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to CDRH under the MDR program. CDRH carefully evaluates the reports received to identify safety concerns of public health importance.

MedSun is an “active” adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. Over 350 health care facilities, primarily hospitals, participate in the MedSun Network. In FY 2011, improved MedSun reporting and analysis resulted in over 40 MedSun-based recalls and 115 manufacturers’ actions, which is an increase of over 60 percent and 20 percent respectively from FY 2010 levels. MedSun provides better understanding of how certain devices are used in the clinical environment, how regulatory actions against manufacturers will affect the patient care in hospitals, and if manufacturer recalls and other actions successfully solved the reported device problems.

CDRH utilizes postmarket surveillance data to detect and respond to device-related public health issues as they arise. and to provide the public with important information about the risk-benefit profiles of medical devices. CDRH addressed issues with transvaginal placement of surgical mesh devices for pelvic organ prolapse (POP). This condition occurs when tissues that hold the pelvic organs in place become weak or stretched. Based on an updated analysis of adverse events, CDRH identified that serious complications associated with this form of POP treatment are not rare and are a serious public safety concern. As a result, CDRH provided updated safety recommendations and warned the public, clinical community and manufacturers of the risks associated with the transvaginal placement of mesh to repair POP.

CDRH proactively works with multiple stakeholders to advance the development of device registries. In FY 2011, CDRH worked with Cornell University and Kaiser Permanente to develop a strategic plan for establishing a large-scale scientific infrastructure, in the form of a distributed consortium, of U.S. and internationally-based orthopedic registries. In May 2011, CDRH held the first meeting of the International Consortium of Orthopedic Registries (ICOR) with 29 registries, which collectively represented 14 nations and 3.5 million hip/knee replacement patients. This ground-breaking consortium enables harmonized collaborations and approaches to answer key research questions and fill important gaps in knowledge concerning safety and effectiveness of devices.

CDRH is also leading an effort to develop and implement a national strategy for the best public health use of health-related electronic data that incorporates a Unique Device

Identification (UDI) system and leverages existing device and procedure registries. The purpose of UDI is to allow all stakeholders to unambiguously and consistently identify medical devices throughout the supply chain up to the point of patient use and throughout the device's life cycle. In September 2011, CDRH held a public workshop to discuss the adoption, implementation, and use of UDIs in electronic healthcare data sources and its incorporation into a National Medical Device Registry. During FY 2011, CDRH completed the proposed rule to require medical device manufacturers to place a UDI on a label or the device itself. The proposed rule is currently under OMB review. Investments in UDI will provide significant benefits to industry by supporting more efficient and effective recalls, creating supply chain efficiencies, and reducing costs to distribute products internationally by using a single device identification framework.

Consistent with FDA's transparency initiative, CDRH is enhancing its efforts to disseminate valuable postmarket device information to the public and industry. In calendar year (CY) 2011, CDRH had over 220 post-approval studies (PAS) publicly available on FDA's website, an increase of more than 15 percent from CY 2010. Information is now available on products' study designs, including the size, population, data collection methods and follow-up visits. Completed studies include final results, safety and effectiveness findings, strengths and weaknesses of the study, and any recommended labeling changes. Greater access to information about the scope, progress and results of PAS studies will provide healthcare professionals, patients and the public with an improved understanding of the performance of high risk devices after they have been marketed.

Promoting Efficiency

CDRH strategically invests in cost-saving, postmarket safety activities to enhance FDA's capability to efficiently monitor the safety and effectiveness of medical devices. These efforts include converting from a paper-based, adverse event reporting system to electronic reporting. Electronic medical device reporting (eMDR) provides significant cost savings to taxpayers and industry by replacing a far less efficient paper-based reporting system that requires manual database entry. It also encourages more rapid reporting of vital postmarket information from industry. As a result of CDRH's active industry engagement and outreach, the percentage of electronic submissions in FY 2011 doubled (56%) compared to electronic submissions in FY 2010 (28%). Electronic reporting reduces document control costs for FDA and industry and enables quicker analysis and identification of emerging public health issues.

Postmarket Safety – Field Activities

FY 2012 Enacted Amount: \$791,000 (BA: \$739,000 / UF: \$52,000)

Public Health Focus

The ORA Field force supports the Devices Program in postmarket safety by conducting follow-up investigations of MDRs. These inspections of reporting medical facilities or manufacturers identify significant problems by analyzing recurring problems and

performing trend analysis. ORA also collects data on complaints, significant problems and potential hazards so corrective actions can be initiated. ORA conducts bioresearch monitoring inspections of post-approval studies, which monitor the postmarket safety of products already available for public use.

Public Health Outcome

ORA conducts inspections of both domestic and foreign medical device firms where issues or concerns have been identified. These inspections ensure the marketplace is safe from defective or hazardous products.

Promoting Efficiency

In 2011, FDA issued press releases, guidance to industry and alerts providing industry, health care professionals and consumers with FDA recommendations, guidance or warnings on specific medical devices. Examples include infusion pumps, infusion set needles, and counterfeit surgical mesh. These notices provided industry with guidance on the FDA’s current initiatives and provided up-to-date information to consumers and medical professionals about device safety concerns. These FDA communications raised industry and consumer awareness, ensured efficient and timely public health response, and minimized negative public health outcomes and the financial and personal costs associated with them.

ORA worked with CDRH to develop a pilot program designed to increase the efficiency of the review of inspectional findings related to MDR violations. This pilot encourages early collaboration between the field and center to more quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and more efficient and quicker issuance of Warning Letters, if appropriate. This will result in more rapid decision making and communication with the manufacturer, which should result in industry taking swifter action to comply and improved public health protection.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
<u>252202</u> : Enroll the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. (Outcome)	FY 2011: 80% Target: 67% (Target Exceeded)	87%	93%	+6%

Compliance, Enforcement, and Radiation Safety – Center Activities

FY 2012 Enacted Amount: \$37,212,387 (BA: \$37,212,387 / UF: \$0)

Public Health Focus

CDRH's Compliance, Enforcement, and Radiation Safety activities focus on protecting patient safety by assuring that manufacturers comply with laws and regulations. These efforts enable CDRH to achieve important FDA, HHS, and Administration priorities of:

- improving health care quality and patient safety
- protecting patients by strengthening the safety and integrity of the global supply chain
- strengthening compliance and enforcement activities to improve patient safety and support public health.

Public Health Outcome

Compliance, Enforcement, and Radiation Safety activities are designed to quickly identify major violations and take prompt, clear, and appropriate actions to resolve issues. Examples of recent enforcement efforts include:

- obtaining a consent decree in early 2011 to protect patients from unsafe cardiac and vascular surgical devices marketed by Terumo Cardiovascular Systems (Terumo CVS). This action was the result of a finding of systemic and procedural deficiencies identified during FDA inspections.
- seizing Rite-Dent, Inc.'s adulterated and misbranded dental devices in January 2011. The devices were seized because the company failed to comply with quality system regulations. These violations included using expired raw materials to manufacture devices.
- identifying serious health risks associated with the King International Shoulderflex Massager, which led to the recall of 11,934 devices on August 30, 2011. CDRH informed the public that use of the device could result in strangulation and death, and advised patients and consumers to immediately stop using the device.

In FY 2011, CDRH began its Recall Process Improvement project to advance the clarity and timeliness of regulatory actions against medical device firms in which violations of the Food, Drug and Cosmetic (FD&C) Act are found. As a result of the process improvements, CDRH classified 45 percent more recalls in FY 2011, while simultaneously increasing the number of recalls classified within current timeframe goals by 9 percent. By streamlining the recall classification process and improving recall notice timeframes, CDRH is able to more rapidly resolve public health risks and better protect patients from devices that are defective, could be a risk to public health, or both.

Obstacles to business-wide integration of best quality practices exist within the industry that FDA regulates, and they have grown dramatically over the past decade. To better define high-impact quality manufacturing practices and engage industry, CDRH initiated

the Business Case for Quality Initiative and released the “Understanding Barriers to Medical Device Quality” report on October 31, 2011.

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf> The report describes many of the barriers that device manufacturers face in integrating best-quality manufacturing practices across their organizations, details several reasons for the barriers, and recommends steps to overcome them. By closely collaborating with industry to identify and better define high-impact quality practices, CDRH is working to enhance quality manufacturing and better protect American patients and consumers.

CDRH’s strategic and targeted compliance efforts are essential to maximizing the value of limited resources. CDRH recently conducted an in-depth examination of three device categories that historically have been responsible for a disproportionate share of adverse events and recalls. The evaluation of external infusion pumps, external defibrillators, and ventilators included analysis of adverse events and recalls along with data from manufacturers, users and patients. Systemic deficiencies were identified in the design, manufacture, and review of these products. As a result, nearly one million unsafe devices were removed from the market and seven firms were requested to improve manufacturing processes of these products to ensure the safety of American patients.

To address current public health needs related to electronic product radiation, CDRH administers— through its Radiological Health Program—the Electronic Product Radiation Control provisions of the FD&C Act. CDRH monitors industry for compliance with required performance standards, monitors radiation dose to the public, and balances public health safety benefits and risks. These activities identify and correct unnecessary and hazardous radiation exposure and reduce the incidence and severity of acute and chronic radiation injury. In FY 2011, CDRH reduced its average timeframe for review of field establishment inspection reports to less than 30 days, an improvement of over 50 percent from the 64 day average timeframe in FY 2010 and over 75 percent from previous years. This accomplishment permitted more timely communication and rapid correction of deficiencies in radiation emitting electronic products and devices.

Through the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, CDRH collaborates with partners in the Federal government and the healthcare professional community to promote safe use of medical imaging devices, support informed clinical decision making, and increase patient awareness. Examples of recent CDRH activities include:

- developing, in collaboration with manufacturers and the National Electrical Manufacturers Association, a new device safety standard that safeguards computed tomography (CT) scanners from delivering excessive radiation
- producing, in collaboration with Image Wisely, a medical imaging professional group, a Patient Medical Imaging Record for tracking the date, type, and location of radiology exams

- developing, in collaboration with the National Council on Radiation Protection and Measurements, Diagnostic Reference Levels for common CT procedures.

The goal of the initiative is to support the benefits associated with medical imaging while minimizing the risks. Through a balanced public health approach, CDRH seeks to ensure each patient will receive the right imaging exam at the right time with the right radiation dose. CDRH's actions are based on the principles of optimizing the dose of radiation administered and performing medical imaging that uses ionizing radiation only when justified.

Promoting Efficiency

The U.S. medical device industry is one of the few sectors, in these challenging economic times, with a positive trade balance. In 2000, the U.S. medical device industry ranked 13th in venture capital investment – a decade later, it is our country's fourth largest sector for venture capital investment. In fact, in the third quarter of 2011, more than 62 percent of the \$631.4 million that venture capital invested in the life sciences went to medical device companies. CDRH compliance activities protect capital investments in the device sector and the jobs they create by:

- ensuring manufacturers comply with laws and regulations that maintain or enhance public confidence in their product by minimizing public safety concerns
- helping to rapidly remove defective products from the market before they have wide spread impacts on consumer confidence.

To more effectively leverage limited compliance resources and lower costs to industry and taxpayers, CDRH is working with Health Canada to establish the Single Audit Program (SAP). As part of this effort CDRH will access and review reports of inspections conducted by trusted foreign authorities that use U.S.-recognized inspection standards. SAP can provide significant cost savings to American taxpayers and industry by eliminating duplicate inspections by trusted regulatory counterparts and enabling a single, shared audit under one uniform regulatory standard.

In FY 2011, CDRH expanded its efforts to educate and empower foreign and domestic regulatory partners and help industry become more efficient. These efforts include CDRH Learn, a comprehensive, interactive, and easily accessible online training resource available in multiple languages. In FY 2011, CDRH Learn training modules were utilized over half a million times, a 400% increase from FY 2010 levels. In FY 2011, CDRH also responded to over 36,000 inquiries from industry via phone, email, and fax. CDRH proactively assists the medical device sector to more efficiently deploy resources by providing interactive, high quality responses to thousands of industry questions concerning device and radiological health regulatory issues.

Compliance, Enforcement, & Radiation Safety – Field Activities

FY 2012 Enacted Amount: \$68,474,000 (BA: \$68,474,000/ UF: \$0)

Public Health Focus

The ORA Field force supports the Devices Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its nationwide field offices, ORA supports Compliance, Enforcement and Radiation Safety activities by conducting risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. The work includes conducting inspections of reproprocessors of single-use devices and manufacturers of radiological health products. ORA's radiological health activities include inspecting radiation emitting products such as lasers, sunlamps and x-ray equipment to ensure that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated products.

ORA works with state contractors through the inspection contract program to support the mission of assuring the safety, quality, and effectiveness of medical devices. Inspections ensure that Class I (low risk) and Class II medical device manufacturers are in compliance with the Quality Systems Inspection Technique (QSIT)/Good Manufacturing Practices (GMP) regulations.

ORA conducts import entry reviews, import field exams, and import sample collections to determine if import entries comply with the medical device registration and listing requirements and other general controls. These reviews assure that import entries declared as import for export are CDRH approved. ORA detains all import entries that do not comply with applicable regulations.

As part of the recall program, CDRH determines the level or classification of public health risk a product presents and makes appropriate public notification of a recall. ORA monitors recalls of medical devices that have been found to present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce.

ORA field offices investigate and build enforcement cases, which are initiated by CDRH or ORA. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serves to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

Public Health Outcome

In FY 2010, ORA established a dedicated foreign device cadre consisting of ten experienced medical device investigators to augment the existing foreign inspection program. The cadre performs foreign device firm inspections, which provide greater assurance that products manufactured abroad are safe for use in the United States. In FY 2011, the dedicated foreign device cadre conducted approximately 170 inspections. In follow-up to objectionable conditions noted during these inspections, FDA has issued twenty-five Warning Letters, nine of which included placing the firm on Import Alert with automatic detention. In addition, in FY 2011 FDA established a new import alert for foreign medical device firms that refuse ORA surveillance inspection, and ORA added one firm to that Import Alert.

In FY 2011, ORA continued to staff the Commercial Trade Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once risks are identified, the appropriate agencies work together to minimize the risk. ORA is working closely with other government agencies on several ongoing cases including Devices Program products such as lasers. In FY 2011, ORA, in conjunction with CDRH, U.S. Customs and Border Protection Service (CBP), and other government agencies, worked to stop importations of "Wicked Lasers," which are dangerously high powered laser products marketed to US consumers via the internet. Although marketed as FDA compliant laser pointers, these products are considered a significant public health hazard because of the risk they pose to the public in causing severe eye damage or blinding, skins burns, and flash blinding. Some of the products have power levels at 250 times the regulatory power. FDA subjected the product to detention without physical examination and also issued a warning to consumers not to use the product.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections. Also available is a searchable database of inspected facilities with FDA inspection classifications. The website premiered May 2011 and includes inspection data for FY 2009, FY 2010, and the first six months of FY 2011. The Agency is committed to updating the data periodically, but at least twice per year. This action provides the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

In FY 2011, FDA classified and issued recalls for 427 Class I; 2,665 Class II; and 119 Class III recalls of medical device products to protect consumers from violative or unsafe products. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death. As part of the recall program, CDRH determines the level or classification of public health risk a product presents and makes appropriate public notification of a recall. ORA monitors recalls of medical devices that

present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce.

ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure that FDA posts firm recall notices on the intranet within 24 hours of receipt.

ORA continues to provide FDA with greater assurance that imported commodities comply with FDA requirements by:

- conducting import entry reviews and import field examinations to ensure imported medical devices and their components are in compliance with FDA requirements
- collecting surveillance samples of imported medical devices and their components to assure industry conformance with FDA regulations and standards
- collecting "for cause" sample collections when concerns or issues arise that indicate possible non-conformances with FDA regulations.

When it is determined, either through review, examination or sampling that an imported commodity does not comply with applicable regulations, ORA works to detain those products to ensure they do not reach U.S. consumers.

In FY 2011, ORA issued 91 notices for numerous medical device products and medical device firms that were found to be manufacturing or shipping violative medical device products. These actions were a result of ORA import surveillance collections and testing of regulated products at the time they were offered for import into the U.S., as well as "for cause" sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These actions serve to provide ORA with a mechanism for automatic detention of violative products, and the notices provide increased communication of those actions, resulting in increased coverage at the border to assure that these products are not available to the U.S. consumer.

In FY 2011, ORA issued 175 warning letters to prevent the continued distribution of adulterated medical device products in U.S. commerce. In addition, there was one seizure for medical device products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

ORA field offices investigate and build enforcement cases, which are initiated by CDRH or ORA. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serve to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

In May, 2011 ORA implemented a new streamlined enforcement process for seizures and injunctions. The new process

- increases collaboration at an early state in the process of case development
- reduces paperwork by removing redundant and unnecessary documentation
- removes a bias toward inaction by making the process less daunting and more collaborative
- provides a mechanism for continuous improvement in case development
- shortens approval times.

ORA drafted a new Compliance Policy Guide (CPG) (currently in final clearance status with the Department) describing the policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection. This CPG will facilitate the Agency's ability to prevent the introduction of medical devices in U.S. commerce from facilities that have delayed, denied, or moved to avoid an FDA inspection.

The ORA Office of Criminal Investigation (OCI) is responsible for criminal investigation activities in cases involving significant FDA violations. During FY 2011, ORA's OCI made 20 arrests and secured 18 convictions with fines, restitutions and other monetary penalties in excess of \$278 million. The successful investigative efforts of OCI resulted in several actions during FY 2011, including these examples:

- In January 2011, sentencing was handed down on Guidant LLC for failure to report defibrillator problems. OCI initiated an investigation based on a New York Times article alleging that Guidant made unreported changes to the Prizm 2 Implantable Cardioverter Defibrillator (ICD), which led to the death of a patient in March 2005. The investigation revealed that Guidant made numerous changes to the Prizm to mitigate an arcing problem, but did not properly report the changes to FDA. The investigation also determined that Guidant experienced a similar arcing problem in the Renewal Cardiac Resynchronization Therapy Device (CRT-D) in 2004. The device failures resulted in the display of a warning screen which did not properly identify the problem. Guidant disguised the purpose of a communication of this information to the physicians and did not correct the device labeling to instruct for proper analysis when the screen was encountered. In 2011, Guidant LLC was sentenced and ordered to pay a fine of \$253,962,251, and was also sentenced to a term of 36 months probation and ordered to forfeit \$42,079,675 in assets.
- In September 2011, Lake County Indiana Sheriff's Department (LCSD) personnel were charged with conspiring to defraud the FDA by knowingly submitting fictitious police department purchase orders and related forms and knowingly selling lasers to the general public via the Internet, circumventing the authority of the FDA. This OCI investigation case was initiated upon a request

by the United States Attorney's office in the Northern District of Indiana who sought OCI assistance in a joint investigation with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Defense Criminal Investigative Service (DCIS). Federal Agents identified one of the laser sights (Class IIIb) for sale on eBay and conducted a test purchase. The laser was traced back to equipment received by LCSD personnel and signed for by a LCSD Deputy Chief. LCSD personnel submitted fictitious police department purchase orders and signed product disclosure agreements, indicating these items were being purchased for police department use, but were subsequently being sold via the internet. Final sentencing remains pending.

- In April 2011, a clinic owner and others associated with the clinic were federally indicted for twenty-five (25) counts of Health Care Fraud, one (1) count of Conspiracy, and one (1) count of Forfeiture for \$8,100,000. This OCI investigation case originated from a request for assistance by the Nevada State Health Department regarding the Endoscopy Center of Southern Nevada, Las Vegas, NV. The investigation revealed several individuals infected with Hepatitis C were patients of the Endoscopy Center. A state inspection documented the unsafe medical practice of reusing single use vials and syringes resulting in the adulteration of an anesthetic. The State sent letters to more than 39,000 former and current patients of the Center, informing them that they should immediately be tested for Hepatitis C, Hepatitis B, and HIV. Final sentencing remains pending.
- In May 2011, the president and sole shareholder of two corporations in Florida was charged with engaging in a scheme to sell approximately 6,000 boxes of counterfeit LifeScan One Touch diabetic test strips. The owner purchased the test strips from China and England and sold them to wholesale customers in the U.S. and Canada, who in turn, sold the counterfeit products for purchase in pharmacies and other stores throughout the U.S. The indictment charged the individual with mail fraud, trafficking in counterfeit goods, entry of goods into the U.S. through a false statement on a customs form, and making a false statement to a federal agency. If convicted, the defendant faces a maximum possible sentence of 57 years' imprisonment and fines up to \$3,000,000.
- During FY 2011, OCI continued the coordination and communication between criminal investigators, regulatory components of FDA, and the United States Attorney's Offices investigating health care fraud-related investigations. As a result of the investigative efforts during FY 2011, OCI secured two indictments against a physician and clinical research coordinator for falsifying study data in a clinical trial. The indictment alleges the defendants falsely stated physical examinations had been conducted on two unqualified test subjects, signed false statements to FDA indicating the clinical study was being conducted in accordance with proper protocol, and arranged for the unqualified subjects to have office visits while the executive director was at lunch to conceal the fact

the test subjects were ineligible as they were employees of the research institute and under the required age to participate.

OCI regularly conducts criminal investigations involving the internet, where some of the most egregious examples of the threats to the public health can be found. OCI investigates a wide variety of alleged violations, including illegal Internet pharmacies and any other websites engaged in the illegal marketing or sale of any FDA-regulated products. These products include prescription drugs, supplements, biologics, medical devices, and tobacco products.

The investigations are often complex and resource-intensive, as they have become increasingly global in nature. Criminals are regularly based in foreign countries and attempt to masquerade behind the anonymity of the Internet while offering counterfeit, stolen, and unapproved FDA-regulated products to U.S. consumers. These criminals manufacture, sell and distribute substandard (and potentially deadly) products solely for monetary profit, with total disregard for consumer health and safety.

OCI has been identified by our domestic and foreign law enforcement peers as an expert and global leader in Internet investigations. Violative websites are proactively identified, researched, and investigated by OCI. Field offices receive criminal investigative assignments, which often include undercover test purchases and other resource-intensive activities, such as: subpoena and search warrant service; reviews of thousands of emails; the identification of subjects, witnesses, and victims; and the analysis of voluminous financial data associated with the illicit profits.

. In FY 2011, OCI provided multiple Internet investigation training courses (both domestic and foreign) to our regulatory counterparts from many countries, including Canada, Italy, United Kingdom, Ireland, Israel, Romania, Estonia, Poland, Czech Republic, and others. OCI continues to build and foster strong working relationships with other law enforcement agencies in the U.S. as well as in countries throughout the world to identify and prosecute violators who use the Internet to sell FDA-regulated products that threaten the health and safety of the American public.

In FY 2011, OCI received special funding from the Department of Justice to apply toward completion of the recently established OCI National Document Center. The support provided by the center helps OCI criminal investigations obtain substantive data relating to fraudulent activity which maximizes monetary recoveries related to illicit proceeds. Many OCI investigations are complex and very document intensive, requiring a scanning and optical character resolution (OCR) solution in order to search, identify, extract and analyze key information. This information is often required by the U.S. Attorney's Offices who are accepting the cases for federal prosecution. The OCI Document Center is being used for, but not limited to, OCI criminal investigations including the off-label promotion of FDA approved drugs and medical devices, application fraud, clinical investigator fraud, healthcare fraud involving FDA regulated

products, import investigations involving any criminal investigations national in scope, and document-intensive cases involving FDA regulated products.

Promoting Efficiency

ORA and CDRH recently developed a set of automated database lookup procedures for the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system. FDA is using these automated PREDICT procedures to determine the admissibility of imports of medical devices and radiological health products. With appropriate data submitted by import entry filers, the system can electronically determine the marketing status of a product during import review. This enhancement to PREDICT allows FDA to expedite the clearance of firms' low risk products, while allowing ORA to focus resources on higher risk device products. PREDICT provides both Industry benefits and greater assurance that imported products are safe and effective for use by U.S. consumers. As of December 2011, PREDICT is fully implemented and in use within all import districts within ORA.

The universe of FDA regulated medical devices and radiation-emitting products is diverse. Many of these devices and products have unique regulatory and performance requirements. ORA and CDRH continue to implement a joint initiative to create and issue a series of field advisories to assist ORA investigators. This effort to establish and implement nationwide guidance resulted in uniform national procedures that increase the efficiency of admissibility decisions while minimizing delays in processing import shipments. These efforts allow ORA to efficiently allow medical devices to enter U.S. commerce in a timely manner, ensuring that safe and effective products are available to U.S. consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
<u>254202</u> : Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. <i>(Output)</i>	FY 2011: 54% Target: 75% (Target Not Met)	60%	60%	Maintain
<u>254201</u> : Number of domestic and foreign Class II and Class III device inspections. <i>(Output)</i>	FY 2011: 1,799 Target: 1,445 (Target Exceeded)	1,515	1,600	+85

Device Innovation and Regulatory Science – Center Activities

FY 2012 Enacted Amount: \$50,896,397 (BA: \$46,006,476 / UF: \$4,889,921)

Public Health Focus

CDRH's Device Innovation and Regulatory Science investments focus on strengthening the U.S. research infrastructure and promoting high-quality regulatory science, facilitating the development and evaluation of transformative innovative technologies and scientific breakthroughs, and developing and sharing scientific information and tools to assess the safety and effectiveness of medical devices for American patients.

Through Device Innovation and Regulatory Science activities, CDRH is able to achieve important FDA, HHS, and Administration priorities:

- transforming health care by improving health care quality and patient safety
- proactively facilitating innovation and addressing unmet public health needs
- accelerating the process of scientific discovery to improve patient care.

Public Health Outcome

CDRH's Device Innovation and Regulatory Science activities are essential to assure that advances in science and technology translate into improvements in human health. These activities include researching how new devices interact with the body, developing test methods for new technologies, testing products to identify root causes of failure, and developing epidemiological methods to help conduct postmarket studies of devices.

As a medical device is developed and evaluated, regulatory science plays an important role in evaluating its benefit-risk profile. It provides a vehicle through which CDRH collaborates with other stakeholders in developing tools that help manufacturers develop innovative products, and it helps manufacturers and FDA assess those products. The result is a more effective, efficient, and timely approach to device development, assessment, and manufacturing.

In the premarket design stage, new regulatory science advances mirror the emergence of new types of products, such as those used in modern minimally-invasive diagnosis and therapy. For example, one important category of minimally-invasive medicine is optical diagnosis — a suite of techniques that shine light onto tissue to make diagnoses rather than taking invasive surgical tissue biopsies. CDRH scientists designed new test methods for evaluating and comparing benefit-risk profiles of optical technologies such as optical coherence tomography (OCT). These methods help industry evaluate new devices and provide CDRH reviewers a better foundation to assess safety and effectiveness for new device technologies.

CDRH regulatory science investments also help manufactures redesign and evaluate existing devices with systematic safety problems. For instance, when device failures cause injuries, CDRH scientists conduct and share scientific investigations that provide in-depth analyses of the underlying causes. In one recent case, blindness-inducing infections occurred in two independent outbreaks in association with contact lens solutions. These incidents led to substantial product recalls. CDRH lab investigations

revealed the cause to be a previously unrecognized incompatibility between some contact lenses and contact lens solutions. CDRH scientists then developed new, more effective tests to identify potentially problematic combinations of lens materials and solutions. This method was provided to industry and academia to aid in their testing of new lens and cleaning solution products.

As technology advances, medical devices are becoming increasingly complex. CDRH must be able to anticipate these advances, creating the scientific tools that will assist the industry in developing new products and assessing their safety, effectiveness, quality, and performance. In FY 2011, CDRH enhanced its personalized medicine (PM) staff to prepare for and address the new generation of medical products that provide patients with targeted medical treatment based on individual patient genetic attributes. The PM staff is tracking inter-center reviews for personalized medicine products, assuring consistent regulatory and policy advice to sponsors, and taking the lead on developing validation requirements for novel in vitro diagnostic (IVD) products, such as devices that employ whole genome testing. Additionally, in July 2011, CDRH released draft guidance intended to increase predictability for industry on the requirements for companion diagnostics – tests used to help health care professionals determine whether a patient with a particular disease or condition should receive a particular drug therapy or how much of the drug to give.

CDRH is working to provide regulatory clarity on FDA's approach to nanotechnology, an emerging technology that has the potential to revolutionize medical devices and the delivery of medical care. To help understand possible toxicity of nanoparticles and how to measure their size, CDRH is investigating ways to determine the biological effects of nanoparticles and whether current methods can predict these properties effectively. These investigations have already yielded development of accurate methods of measuring nanoparticle size and uniformity. CDRH's nanotechnology efforts are strengthening FDA's scientific capacity to evaluate potential safety problems of this emerging technology and supporting the responsible development of nanotechnology devices for American patients.

In FY 2011, CDRH established a Center Science Council (the Council) to help assure consistency and predictability in our scientific decision making and to monitor the quality and performance of the scientific programs. Important scientific issues that warrant senior level review are now brought to the Council for consideration. The Council now reviews device review team recommendations for an increase in clinical data requirements for all manufacturers of a type of device. Implementation of this process improvement helps ensure decisions are made consistently and efficiently, at the appropriate level, and apply the least-burdensome principle. Consistent with the transparency initiative, the Council's draft charter is available on FDA's website: (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm249248.htm>).

Promoting Efficiency

CDRH's Device Innovation and Regulatory Science activities help foster a robust medical device industry by reducing the time and resources needed to develop and assess new products. CDRH scientists identify the underlying mechanisms of device actions on the body and develop the science-based questions, test methods, and tools necessary to assess the safety and effectiveness of medical products. These tests and tools are then designed, validated, and provided to consensus standards organizations and industry.

Magnetic Resonance Imaging (MRI) is an important and widely-used diagnostic tool. However, MRI machines can significantly heat or move certain types of implantable devices and can disrupt implant function. Implanted devices may also distort the MRI images. For these reasons, patients with some types of implanted devices (e.g., implanted defibrillators and brain stimulators) have not been able to undergo MRI testing, which puts their physicians at a diagnostic disadvantage. To facilitate the development of innovative MRI-compatible implanted devices, CDRH scientists, in collaboration with academia and industry, performed electromagnetic testing of novel device designs, developed physical and computer models to evaluate them, and established standards for new MRI-compatible devices. This has helped open a scientifically sound pathway for the development of new products, and in FY 2011 led to approval of the first MRI-compatible implantable device—a pacemaker.

CDRH's development of well-validated and reliable tests, methods, and tools are essential to maintain the growth of the U.S. medical device industry and the jobs it creates. These investments can reduce the cost of device development, assessment, and review for U.S. device manufacturers, reduce ambiguity as industry develops and submits data for review, and provide FDA the means to assess the safety and effectiveness of transformative innovative technologies and scientific breakthroughs. In CY 2011, CDRH signed a Memorandum of Understanding with Minnesota's LifeScience Alley to advance the development of critical test methods.

Device Innovation and Regulatory Science –Field Activities

FY 2012 Enacted Amount: \$1,784,000 (BA: \$1,784,000 / UF: \$0)

Public Health Focus

ORA's Winchester Engineering and Analytical Center (WEAC) conducts analyses and develops new analytical test methods for medical devices and radiation emitting electronic products in support of regulatory actions to ensure safe and effective medical devices.

Public Health Outcome

ORA continues to make advancements in device safety for consumers by leveraging internal and external stakeholders, by conducting postmarket analytical methods

development activities on pressing public health risks, and by developing a proactive FDA approach for post-market device testing. WEAC continues to:

- develop new and improved methodology to support regulatory analysis
- validate analytical methods to support enforcement activities
- conduct product evaluation study projections to provide comprehensive postmarket surveillance information about devices.

The focused efforts of ORA's laboratories, in collaboration with academia, federal and state partners, continue to ensure that suspect medical devices are removed from U.S. commerce. In FY 2011, new methods, analyses and expert scientific testimony in federal court by ORA supported criminal convictions by US Attorneys in New York and California.

In FY 2011, efforts made by ORA led to several medical device product recalls including billions of Huber-style needles used for chemotherapy delivery, counterfeit surgical mesh distributed to hospitals and surgical centers, and tainted contact eye solution distributed to retail establishments throughout the U.S. In addition, ORA laboratory analyses resulted in numerous refusals of unsafe foreign sourced medical devices as well as facilitating commerce by removing compliant firms from previous Import Alerts.

ORA's laboratories support the Devices Program through analysis and surveillance of samples for the Condoms and Gloves programs to assure they are safe and effective. These analyses help reduce the risk to the public and health care community of unnecessary exposure and transmission of blood-borne pathogens, particularly human immunodeficiency virus (HIV), hepatitis B, and hepatitis C infections by increasing the number of medical gloves analyzed at an expedited rate utilizing a high throughput model previously adopted for food borne outbreaks.

ORA conducted 1,513 medical device laboratory analyses in FY 2011 using a risk-based approach focusing on device categories that historically have been responsible for a disproportionate share of adverse events and recalls. Some of these laboratory analyses led to medical device product recalls including infant and neonatal filter line sets used by emergency medical services and hospitals during ventilation of newborn infant patients; blood tubing sets used during hemodialysis; and automatic external defibrillators (AEDs) distributed to fire departments, EMS, health clubs and schools.

In addition, ORA laboratories developed new and innovative test methods for AEDs, infusion pumps, ventilators, endotracheal tubes, and hemodialysis blood tubing sets to evaluate imports of medical devices ensuring products meet FDA quality standards. Test results of many devices led to the addition of firms/products to Import Alerts calling for automatic detention of potentially unsafe products offered for import into the United States.

In FY 2011, ORA scientists, in conjunction with CDRH partners, revealed the cause of blindness-inducing infections which occurred in two previous independent outbreaks associated with contact lens solutions. These methods were provided to industry to aid in their redesign and testing of new lens and cleaning solution products.

Promoting Efficiency

Increased efficiencies and capacity allow ORA to analyze a higher volume of basic yet essential products, such as medical gloves, in reduced timeframes. These efforts support the timely release of industry products into U.S. commerce and also ensure that reliable medical products are available to the health care community, thus safeguarding medical practitioners and patients from ineffective medical devices.

ORA scientists also foster communication between the public and private sectors to develop solutions that meet both the requirements of business and the broader needs of protecting the public from harmful medical devices. One outcome of these activities is to allow manufacturers to more efficiently conduct product development and manufacturing of billions of syringes, which will lead to savings for manufacturers while ensuring the safety of patients.

ORA scientists leveraged ongoing research with federal partners and academia to develop new analytical methods using advances in technology. One specific scientific collaboration between ORA labs and MIT/Harvard on the fracture of stents was cited by the Science Board to the FDA as a model federal government-academia collaboration.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
<u>252101</u> : Number of technical analyses of postmarket device problems and performance. <i>(Output)</i>	FY 2011: 148 Target: 125 (Target Exceeded)	131	131	Maintain
<u>253207</u> : Number of technical reviews of new applications and data supporting requests for premarket approvals. <i>(Output)</i>	FY 2011: 1,697 Target: 1,175 (Target Exceeded)	1,300	1,300	Maintain

Mammography Quality Standards Act (MQSA) – Center Activities

FY 2012 Enacted Amount: \$9,131,120 (BA: \$3,128,120 / UF: \$6,003,000)

Public Health Focus

CDRH administers the Mammography Quality Standards Act (MQSA) to ensure the quality of mammography services. MQSA provides national quality standards for mammography and assures that mammography facilities meet these standards. These activities, combined with new and improved treatment methods, led to a decline in breast cancer morbidity and mortality in the United States.

Through MQSA activities, CDRH is able to achieve the important FDA, HHS, and Administration priorities of:

- improving health care quality and patient safety
- strengthening compliance and enforcement activities to support public health
- transforming health care by reducing the growth of healthcare costs while promoting high-value, effective care.

Public Health Outcome

MQSA requires FDA-approved accreditation bodies to evaluate and accredit mammography facilities based on quality standards. Once accredited, FDA or an FDA-approved State certifying agency grants the facility a certificate so that it can legally operate. FDA, along with its State contract partners, annually inspects each of the approximately 8,650 certified mammography facilities in the United States. As a result of the MQSA program, over 83 percent of the facilities are free of violations at the time of inspection, and less than half of one percent of facilities are cited with the most serious Level I violations. CDRH works with facilities that are not in compliance to bring them into compliance. If these efforts fail, MQSA allows a variety of sanctions to be imposed, including certificate revocation and suspension.

Promoting Efficiency

CDRH continually strives to improve its MQSA program, streamline its efficiency, and reduce costs. These efforts include stretching resources to develop and publish online training for state inspection partners and regulated industry. In FY 2011, CDRH provided two-thirds of MQSA training online for inspectors, thereby reducing access time and travel expenses for FDA and State partners. In addition, mammography facilities, manufacturers, inspectors, and the general public can easily obtain up-to-date information on MQSA program regulations and guidance at FDA's mammography webpage: (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm>).

Mammography Quality Standards Act – Field Activities

FY 2012 Enacted Amount: \$15,820,000 (BA: \$2,743,000/ UF: \$13,077,000)

Public Health Focus

To protect consumers and advance public health for women, ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the states, which includes an annual audit of state inspections and FDA-provided training for state inspectors.

Public Health Outcome

The ORA Field force supports the MQSA program by managing state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries. The Field:

- inspects certified mammography facilities
- conducts follow-up inspections to determine compliance with terms of corrective action plans based on non-compliances found during prior inspections
- performs on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections.

To ensure high quality facility inspections conducted by the states, ORA coordinated with CDRH to offer annual MQSA training courses to new state inspectors as well as to provide continuing education for certified state inspectors.

Promoting Efficiency

ORA works with the states to maintain MQSA contract program quality standards, which ensure that women receive high quality mammography for early breast cancer detection. Maintaining the contract program through collaboration with qualified state partners maximizes resources dedicated to MQSA and ensures that a greater number of mammography facilities are inspected each year than could be accomplished by an individual program alone.

Performance Measures

The following table lists the performance measure associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. <i>(Outcome)</i>	FY 2010: 97% FY 2010 Target: 97% (Target Met)	97%	97%	Maintain

**Information Technology Investments – Devices and Radiological Health
Program Activities (FY 2012 Enacted Amount displayed as a non-add item:
\$61,052,843)**

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state-of-the-art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities. This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In addition to investments in IT infrastructure and enterprise-wide systems, CDRH-specific IT planning and development efforts support the Center's strategic priorities. CDRH adheres to the concept of managing the total product life cycle of medical and radiological products, including premarket evaluation and review, oversight of production practices, and tracking and evaluation of products in the marketplace. The IT systems that CDRH develops are tailored to enhance or expand the total product life cycle and continue the movement away from a paper environment to an electronic environment. CDRH builds externally facing systems that help the public and regulated industry to address information requirements and interact with the Agency, and inward facing systems that provide the data and information necessary for CDRH to perform its mission efficiently.

To achieve its strategic priorities, CDRH depends heavily on modernized IT, informatics standards, and the continued migration from paper to standardized electronic submissions and communications. In addition to maintaining and/or enhancing existing IT systems, CDRH leverages commercial off the shelf (COTS) software and services, government off the shelf (GOTS) and FDA technologies and initiatives to help achieve those objectives. Two examples for FY 2013 are the Unique Device Identification (UDI) database and the adverse event reporting system (CDRH FAERS).

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2008 through FY 2012 for the Devices and Radiological Health Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	\$275,284,000	\$237,734,000	\$37,550,000	1,564
FY 2009 Actual	\$345,311,000	\$298,536,000	\$46,775,000	1,707
FY 2010 Actual	\$369,971,000	\$313,452,000	\$56,519,000	1,801
FY 2011 Actual	\$378,509,000	\$322,182,000	\$56,327,000	1,902
FY 2012 Enacted	\$375,989,000	\$322,672,000	\$53,317,000	1,866

Summary of the Budget Request

The FY 2013 budget request for the Devices and Radiological Health Program is \$386,766,000. This amount is an increase of \$10,777,000 above the FY 2012 Enacted Level. The Center for Devices and Radiological Health amount in this request is \$285,168,000 supporting 1,413 FTE. The Field amount is \$101,598,000 supporting 531 FTE.

The FY 2012 Enacted funding for the Devices and Radiological Health Program is \$375,989,000, which includes \$280,655,000 for the Center for Devices and Radiological Health Center activities and \$95,334,000 for the Devices and Radiological Health Program Field activities.

The FY 2012 Enacted funding allows the Devices and Radiological Health Program to protect and promote public health by ensuring the safety and effectiveness of medical devices that Americans rely on every day while facilitating scientific innovations that extend and improve lives. To accomplish its regulatory responsibilities, the Devices and Radiological Health Program executes the activities of the following mission-essential subprograms:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement, and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA)

The initiative proposed under the FY 2013 budget request supports HHS, FDA and Presidential public health priorities to advance medical countermeasures. This investment fosters the rapid and reliable development of medical countermeasures to respond to public health threats and ensure Americans have access to the medical devices needed to counter a deliberate chemical, biological, radiological or nuclear (CBRN) attack or a naturally occurring epidemic.

Budget Request

Pay Increase (Commissioned Corps): (Total Program: +\$227,000)

The request for \$319,127,000 in total BA for the Devices and Radiological Health Program reflects a pay increase for the Commissioned Corps. The Center's portion of this increase is \$169,000, and the Field's portion is \$57,000.

Data Consolidation and IT Savings (Total Program: -\$2,851,000)

The request for \$319,127,000 in total budget authority for the Devices and Radiological Health Program also reflects data consolidation and IT savings reduction of -\$2,851,000 for FY 2013. The Center's portion of these savings is -\$2,133,000, and the Field's portion is -\$717,000.

The Devices and Radiological Health Program will achieve the savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- Implementing strategic reductions of process submission enhancements to CDRH e-submission systems
- Implementing strategic reductions of support and planned improvements to CDRH systems
- Streamlining user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance

Services (MARCS) program, and providing the support architecture for other integrated systems

- Economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems

Rent Absorption (-\$1,644,000 / -8 FTE)

The Devices and Radiological Health Program will absorb part of the cost of the FY 2013 inflationary rent increase, resulting in the loss of eight FTE for CDRH public health activities.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

Premarket Device Review

Center Activities – (FY 2012 Enacted Amount: \$133,382,559 (BA: \$110,820,346 / UF: \$22,562,213)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$5,185,266 / 31 FTE)

FY 2013 Increase for MDUFA: (+\$4,703,266 / 29 FTE)

2013 Initiatives

Advancing Medical Countermeasures (MCM) Initiative: (+\$482,000 / 2 FTE)

Objective 1 – Optimizing the Review Process for MCM by Establishing Public Health and Security Action Teams (PHSATs): (+\$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to operationalize its Public Health and Security Action Team to support pediatric, pregnancy, and special population issues and next-generation assessment of MCM safety and efficacy during public health emergencies. In addition, FDA will implement authorities to foster the development and deployment of MCMs including: (1) strengthening its program to provide technical assistance to the developers of the highest-priority MCMs; and (2) establishing a program to issue pre-event EUAs.

Objective 3 – Optimizing the Legal, Regulatory and Policy Framework for Effective Public Health Response: (+\$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to continue to work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM

development and availability to ensure these adequately support emergency preparedness and response. These efforts include strengthening its program to implement authorities to enhance rapid deployment and pre-event planning and positioning of MCMs.

Field Activities – (FY 2012 Enacted Amount: \$8,465,000 (BA: \$7,457,000 / UF: \$1,008,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$221,000 / 0 FTE)

FY 2013 Increase for MDUFA: (+\$221,000 / 0 FTE)

Postmarket Safety

Center Activities – (FY 2012 Enacted Amount: \$50,032,538 (BA: \$44,307,671 / UF: \$5,724,867)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$1,193,392 / 5 FTE)

FY 2013 Increase for MDUFA: (+\$1,193,392 / 5 FTE)

Field Activities – (FY 2012 Enacted Amount: \$791,000 (BA: \$739,000/ UF: \$52,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$0 / 0 FTE)

Compliance, Enforcement, and Radiation Safety

Center Activities – (FY 2012 Enacted Amount: \$37,212,387 (BA: \$37,212,387 / UF: \$0)

FY 2013 Total Change from FY 2012 Enacted Level: (\$0 / 0FTE)

Field Activities – (FY 2012 Enacted Amount: \$68,474,000 (BA: \$68,474,000/ UF: \$0)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$7,185,000 / 39 FTE)

FY 2013 Proposed User Fees (Medical Product Reinspection): (+\$3,579,000 / 24 FTE)

FY 2013 Proposed User Fees (International Courier): (+\$3,606,000 / 15FTE)

Device Innovation and Regulatory Science

Center Activities – (FY 2012 Enacted Amount: \$50,896,397 (BA: \$46,006,476 / UF: \$4,889,921)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$1,260,341 / 6 FTE)

FY 2013 Increase for MDUFA: (+\$1,019,341 / 5 FTE)

2013 Initiatives

Advancing Medical Countermeasures (MCM) Initiative: (+\$241,000 / 1 FTE)

Objective 2 – Advancing Regulatory Science for MCM Development and Evaluation: (+\$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to sustain extramural MCM regulatory science partnerships with industry, academia and U.S. government partners to enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. Focus areas for FDA investments in regulatory science include: 1) developing methods to assess product quality and assays to support the release of MCMs; 2) developing and assessing advanced diagnostic tests; and 3) novel manufacturing platforms.

Field Activities – (FY 2012 Enacted Amount: \$1,784,000 (BA: \$1,784,000 / UF: \$0)
FY 2013 Total Increase above FY 2012 Enacted Level: (+\$0 / 0 FTE)

Mammography Quality Standards Act (MQSA)

Center Activities – (FY 2012 Enacted Amount: \$9,131,120 (BA: \$3,128,120 / UF: \$6,003,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$0 / 5 FTE)

Field Activities – (FY 2012 Enacted Amount: \$15,820,000 (BA: \$2,743,000 / UF: \$13,077,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+\$0 / 0 FTE)

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 President's Budget
Expedited PMA Received	7 ^{1/}	6	6
Expedited PMA Approved	3 ^{2/}	4	4
Expedited PMA – Performance	90% ^{3/}	60%	60%
PMAs Received (PDP and PMA)	45	45	45
PMAs Approved (PDP and expedited)	30	30	30
Original PMA performance	90% ^{3/}	60%	60%
PMA Supplement Panel Tracks Received	8	12	12
PMA Supplement Panel Track Approved	9	10	10
Panel Track PMA Supplement Performance	90% ^{3/}	60%	60%
Humanitarian Device Exemptions Received	8	6	6
Humanitarian Device Exemptions Approved	3	4	4
Average HDE FDA Review Time (FDA days approval)	294	300	400
PMA Supplements Received	148	160	160
PMA Supplements Approved	153	155	150
510(k)s Received (Trad., Special, Abbrev., 3 rd party)	3,839	4,100	4,100
510(k)s Completed (All Decisions)	3,922	3,700	3,500
510(k) performance	98% ^{3/}	80%	80%
Investigational Device Exemptions Received	227	240	240
Investigational Device Exemptions Decisions	236	230	230
% Acted on Within 30 Days	100%	99%	99%
Investigational IDE Supplements	3,764	3,900	3,900
IDE Supplements (Approved/Total Decisions)	3,781	3,800	3,800
% Acted on Within 30 Days	100%	100%	100%
Total Standards Recognized for Application Review	939	980	1020

^{1/} Received submissions based on the FY 2011 receipt cohort

^{2/} Approved submissions based on the FY 2011 decision cohort

^{3/} FY 2011 performance figures are estimates as the cohort is not yet mature enough to report complete figures.

**Combined Field Activities – ORA
Program Activity Data**

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	2,529	2,709	2,709
Bioresearch Monitoring Program Inspections	317	302	302
Pre-Market Inspections	56	68	68
Post-Market Audit Inspections	39	46	46
GMP Inspections	1,713	1,567	1,567
Inspections (MQSA) FDA Domestic (non-VHA)	329	549	549
Inspections (MQSA) FDA Domestic (VHA)	37	43	43
Domestic Radiological Health Inspections	104	205	205
Domestic Field Exams/Tests	193	193	193
Domestic Laboratory Samples Analyzed	211	211	211
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	408¹	473	473
Foreign Bioresearch Monitoring Inspections	17	31	31
Foreign Pre-Market Inspections	30	33	33
Foreign Post-Market Audit Inspections	16	19	19
Foreign GMP Inspections	335	380	380
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	35	40	40
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	2,937	3,182	3,182
IMPORTS			
Import Field Exams/Tests	20,925	20,925	20,925
Import Laboratory Samples Analyzed	1,170	1,170	1,170
Import Physical Exam Subtotal	22,095	22,095	22,095
Import Line Decisions	9,584,415	10,411,972	11,310,984
Percent of Import Lines Physically Examined	0.23%	0.21%	0.20%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	8,123	8,277	8,287
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	45	45	45
Inspections (MQSA) by State Contract	7,004	7,147	7,147
Inspections (MQSA) by State non-Contract	1,103	1,110	1,115
GMP Inspections by State Contract	16	20	25
State Partnership GMP Inspections	45	50	55
State Contract Devices Funding	\$77,516	\$182,200	\$193,100
State Contract Mammography Funding	\$9,144,255	\$9,964,320	\$10,562,170
Total State Funding	\$9,221,771	\$10,146,520	\$10,755,270
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	11,105	11,504	11,514

¹ The FY 2011 actual unique count of foreign inspections includes 11 OIP inspections (6 for China and 5 for India).