CDRH Milestones

1938
Federal Food, Drug, and Cosmetic (FD&C) Act is enacted. One of the provisions of the new Act, which supersedes the original Food and Drugs Act of 1906, is to extend coverage to devices, making it illegal to sell therapeutic devices that are dangerous or marketed with false claims.

1948
Radiological Health Unit was established by the Bureau of State Services, U. S. Public Health Service.

1950
September 21 – A jury finds in favor of the government on a misbranding charge against a device that purportedly was a treatment for a variety of conditions, including insomnia, rheumatism, heart attack, dandruff, and paralysis, and the defendant was fined $1000. The first case tried against a medical device under the Food, Drug, and Cosmetic Act.

1966
Division of Radiological Health was renamed the National Center for Radiological Health.

1968
October 18 - Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) was signed by President Johnson.

December 20 – National Center for Radiological Health becomes the Bureau of Radiological Health as a component of the Environmental Control Administration, Consumer Protection and Environmental Health Service, with a budget of 15.5 million.

1969
October 30 - President Nixon issues a message to Congress calling for certain minimum standards and for premarket clearance for certain medical devices. The then Department of Health, Education, and Welfare (HEW) formed The Committee becomes known as the “Cooper Committee. Dr. Cooper’s Committee calculated that 10,000 injuries were attributable to “therapeutic devices” and more than 700 of these injuries were fatal. In 1970 the group calls for the inventory and classification of all existing medical devices as the first step toward drafting protective legislation.

December 25 – The first radiation product performance standard for television receivers was issued.

1971
January 20 –Office of Manpower and Budget transfers 318 Bureau employees and over $7,000,000 to the new Environmental Protection Agency. Included in the transfer are the Southeastern and Southwestern Radiological Health Laboratory facilities.

May 17 - PHS Bureau of Radiological Health transferred to FDA. It's mission: protect against unnecessary human exposure to radiation from electronic products in the home, industry, and healing arts.

1974
February 15 – The Bureau of Medical Devices and Diagnostic Products is established.

1975
Breast Exposure Nationwide Trends (BENT) - a national program to locate facilities giving excessively high radiation exposures and to assist them in reducing the exposures.

December – First civil penalty levied under the Radiation Control for Health and Safety Act. The action calls for a $2000.00 fine against an assembler of diagnostic x-ray systems for failure to report the assembly of certified components into diagnostic x-ray systems, as required by the Federal performance standard.

1976
May 28 – Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938 are enacted, to assure safety and effectiveness of medical devices, including certain diagnostic and laboratory products.

1977
May 24 – Bureau of Medical Devices and Diagnostic Products is renamed the Bureau of Medical Devices and is reorganized to adopt an organizational structure more suited to implementing the Amendments. Among the changes is the establishment of an Office of Small Manufacturers Assistance, as required by the Amendments. This office will help small manufacturers of medical devices to comply with the law, by providing technical and other non-financial assistance.

1978
February – Bureau issues compliance enforcement guidance for laser light show and displays.

April 21 – Performance standard proposed for mercury vapor lamps.

July 21 – Good Manufacturing Practice (GMP) regulations are published in the Federal Register, they become effective December 18, based on the 1976 Medical Device Amendments, the regulations apply to all medical devices and diagnostic products, including those of foreign manufacture intended for U.S. import. In addition to the general controls, more stringent production requirements are imposed on “critical devices”, I.E., those that are intended for surgical implantation or for supporting or sustaining life and whose failure can result in a significant injury.

December 18 - GMP regulations became effective. These “umbrella” regulations set minimum quality assurance requirements for the approximately 4800 companies in the medical device industry.

1979
December 18 - GMP regulations became effective. These “umbrella” regulations set minimum quality assurance requirements for the approximately 4800 companies in the medical device industry.

1980
July 16 - The Investigational Device Exempt rule became effective - devices intended solely for investigational use to develop safety and effectiveness data may be exempted from certain requirements of the Act.

1982
First major Congressional oversight hearing on FDA’s medical device program and implementation of 1976 Device amendments.

October 8 – Bureau of Radiological Health and Bureau of Medical Devices merge to become the National Center for Devices and Radiological Health.

1984
March 19 – National Center for Devices and Radiological Health is renamed Center for Devices and Radiological Health.

July – FDA mandated to register implanted cardiac pacemakers and pacemaker leads paid for by Medicare.

Sept. 14, 1984, Medical Device Reporting (MDR) regulation published, requiring that manufacturers or importers maintain files when one of their devices may have caused or contributed to a death or serious injury, or when a malfunction had a occurred that could cause a death or serious injury, and to report these to the FDA in a timely manner.

1990
November 28 - The Safe Medical Devices Act (SMDA) required medical device user facilities to report to the FDA, the manufacturer, or both whenever they believe there is a probability that a medical device has caused or contributed to a death, illness, or injury. A medical "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility that is not a physician's office.

1991
May 3 – Commissioner approves Center’s first Cooperative Research and Development Agreement (CRADA) under the Federal Technology Transfer Act. CDRH and Drexel University will cooperatively develop techniques and test methods for detecting holes in latex films used to produce surgical and examination gloves and condoms.

1992
October 27 - The Mammography Quality Standards Act is signed into law, requiring all mammography facilities in the United States to be accredited and federally certified as meeting

quality standards effective Oct. 1, 1994 . After initial certification, facilities must pass annual inspections by federal or state inspectors.

1997
June 1 - The Quality System Regulation took effect.

FDA Modernization Act mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices.

1998
Congressional reauthorization of Mammography Quality Standards Act.

1999
April 29 – Final Rules for the Mammography Quality Standards Act are published.

1999
April 29 – Final Rules for the Mammography Quality Standards Act are published.

2002
October - Medical Device User Fee and Modernization Act (MDUFMA).

November 17 – Office of Invitro Diagnostic Device Evaluation and Safety (OIVD) formed to promote total product life cycle regulation of medical devices.

2004
October 25 - Congressional reauthorization of Mammography Quality Standards Act for the second time.

2005
August 1 – President Bush signs the Medical Device User Fee Stabilization Act of 2005.

Updated January 9, 2006