<u>MEDICAL DEVICE ACT IN-SERVICE</u>

A **medical device** is a product which is used for medical purposes in patients, in diagnosis, therapy or surgery. Whereas *medicinal products* (also called *pharmaceuticals*) achieve their principal action by pharmacological, metabolic or immunological means. *Medical devices* act by other means like physical, mechanical, physico-chemical or chemical means. *Medical devices* are included in the category: *Medical technology*.

Medical devices include a wide range of products varying in complexity and application. Examples include tongue depressors, medical thermometers, blood sugar meters, total artificial hearts, fibrin scaffolds, stents, and X-ray machines. The global market of medical devices reached roughly 209 billion US Dollar in 2006 and is expected to grow with an average annual rate of 6 - 9% through 2010.

Medical Device Definition

A device is:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

The Food and Drug Administration has recognized three classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device.

Class I: General controls

Class I devices are subject to the least regulatory control. Class I devices are subject to "General Controls" as are Class II and Class III devices. General controls include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices. Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury. Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Class II: General controls with special controls

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. A few Class II devices are exempt from the premarket notification. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance. Devices in Class II are held to a higher level of assurance than Class I devices, and are designed to perform as indicated without causing injury or harm to patient or user. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

Class III: General controls and premarket approval

A Class III device is one for which insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices. Such a device needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Examples of Class III devices which currently require a premarket notification include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.

Medical devices incorporating RFID

In 2004, the FDA authorized marketing of two different types of medical devices that incorporate radio-frequency identification, or RFID. The first type is the SurgiChip tag, an external surgical marker that is intended to minimize the likelihood of wrong-site, wrong-procedure and wrong-patient surgeries. The tag consists of a label with passive transponder, along with a printer, an encoder and a RFID reader. The tag is labeled and encoded with the patient's name

and the details of the planned surgery, and then placed in the patient's chart. On the day of surgery, the adhesive-backed tag is placed on the patient's body near the surgical site. In the operating room the tag is scanned and the information is verified with the patient's chart. Just before surgery, the tag is removed and placed back in the chart.

The second type of RFID medical device is the implantable radiofrequency transponder system for patient identification and health information. One example of this type of medical device is the VeriChip, which includes a passive implanted transponder, inserter and scanner. The chip stores a unique electronic identification code that can be used to access patient identification and corresponding health information in a database. The chip itself does not store health information or a patient's name.

Practical and information security considerations
Companies developing RFID-containing medical devices must consider product development issues common to other medical devices that come into contact with the body, are implanted in the body, or use computer software. For example, as part of product development, a company must implement controls and conduct testing on issues such as product performance, sterility, adverse tissue reactions, migration of the implanted transponder, electromagnetic interference, and software validation.

Medical devices that use RFID technology to store, access, and/or transfer patient information also raise significant issues regarding information security. The FDA defines "information security" as the process of preventing the modification, misuse or denial of use, or the unauthorized use of that information. At its core, this means ensuring the privacy of patient information.

Four components of information security

The FDA has recommended that a company's specifications for implantable RFID-containing medical devices address the following four components of information security: confidentiality, integrity, availability and accountability (CIAA).

- Confidentiality means data and information are disclosed only to authorized persons, entities and processes at authorized times and in the authorized manner. This ensures that no unauthorized users have access to the information.

- Integrity means data and information are accurate and complete, and the accuracy and completeness are preserved. This ensures that the information is correct and has not been improperly modified.

- Availability means data, information and information systems are accessible and usable on a timely basis in the required manner. This ensures that the information will be available when needed.

- Accountability is the application of identification and authentication to ensure that the prescribed access process is followed by an authorized user.

Although the FDA made these recommendations in the context of implantable RFID-containing medical devices, these principles are relevant to all uses of RFID in connection with pharmaceuticals and medical devices.

List of medical devices
High-risk devices
High-risk devices are life supports, critical monitoring, energy emitting and other devices whose failure or misuse is reasonably likely to seriously injure patient or staff. Examples include:

- Anesthesia units
- Anesthesia ventilators
- Apnea monitors
- Argon enhanced coagulation units
- Aspirators
- Auto transfusion units
- Cardiac defibrillator, external or internal

- Fetal monitors
- Heart-lung machine
- Incubators
- Infusion pump
- Invasive blood pressure units
- Pulse oximeters
- Radiation-therapy machines

- Electrosurgical unit
- External pacemaker
- Stent
- Ventilator

Medium-risk devices

These are devices including many diagnostic instruments whose misuse, failure or absence (e.g. out of service) with no replacement available would have a significant impact on patient care, but would not be likely to cause direct serious injury. Examples include:

- ECG
- EEG
- Treadmills
- Ultrasound sensors
- Phototherapy units
- Endoscopes
- Human-implantable RFID chips
- Laparoscopic insufflators
- Phonocardiographs
- Radiant Warmers
- Surgical drill and saws
- Lytic bacteriophages
- Zoophagous agents

Low-risk devices

Devices in this category are those whose failure or misuse is unlikely to result in serious consequences. Examples include:

- Electronic thermometer
- Breast pumps
- Surgical microscope
- Ultrasonic nebulizers
- Sphygmomanometers
- Surgical table
- Surgical lights.
- Temperature monitor
- Aspirators
- X-ray diagnostic equipment
- Lensometer
- Keratometer

Standardization and regulatory concerns

Starting in the late 1980s the FDA increased its involvement in reviewing the development of medical device software. The precipitant for change was a radiation therapy device (Therac-25) that overdosed patients because of software coding errors. FDA is now focused on regulatory oversight on medical device software development process and system-level testing.

A 2011 study by Dr. Diana Zuckerman and Paul Brown of the National Research Center for Women and Families, and Dr. Steven Nissen of the Cleveland Clinic, published in the Archives of Internal Medicine, showed that most medical devices recalled in the last five years for "serious health problems or death" had been previously approved by the FDA using the less stringent, and cheaper, 501(k) process. In a few cases the devices had been deemed so low-risk that they did not need FDA regulation. Of the 113 devices recalled, 35 were for cardiovascular issues. This may lead to a reevaluation of FDA procedures and better oversight.

Packaging standards

Medical device packaging is highly regulated. Often medical devices and products are sterilized in the package. The sterility must be maintained throughout distribution to allow immediate use by physicians. A series of special packaging tests is used to measure the ability of the package to maintain sterility. Relevant standards include: ASTM D1585- Guide for Integrity Testing of Porous Medical Packages, ASTM F2097- Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products, EN 868 Packaging materials and systems for medical devices which are to be sterilized. General requirements and test methods, ISO 11607 Packaging for terminally sterilized medical devices, and others.

Package testing needs to conducted and documented to ensure that packages meet regulations and all end-use requirements. Manufacturing processes need to be controlled and validated to ensure consistent performance.