Chapter 5

Regulations and Standards

What are the differences between regulations and voluntary and regulatory standards?

A regulation is a \_\_\_\_\_\_\_\_\_\_\_\_\_\_ law or rule that is issued by a \_\_\_\_\_\_\_\_\_\_\_. A standard is a \_\_\_\_\_\_\_\_\_ method of \_\_\_\_\_\_\_\_\_\_\_ basic parameters for processes, services, and measurements. A Regulatory standards is a \_\_\_\_\_\_\_\_\_\_\_\_\_benchmark that is mandated by a governing agency and if not complied with, may cause a facility to be in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. A voluntary standard is a comparison benchmark that is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by a governing agency or professional organization that provides recommendations and guidelines \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**U.S. FDA**

**FDA- Food and Drug Administration**

Federal agency responsible for ensuring that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ are safe and effective for public use. The FDA regulates the \_\_\_\_\_\_\_\_\_\_\_\_\_\_of all medical devices, and requires the pre-market clearance of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. It also regulates the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ used to process critical and semi-critical devices.

**Medical Device Classification**

Class I Devices: Include \_\_\_\_\_\_\_\_\_\_\_\_\_ devices such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. They are subject to general controls, such as registration and device listing, medical device reporting, and quality system regulation and labeling.

Class II Devices: Considered to pose \_\_\_\_\_\_\_\_\_\_\_\_\_ risks great enough to warrant a high level of regulation. Include most types of sterilization equipment, and biological and chemical indicators. Subject to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ .

Class III Devices: The most stringently regulated devices, including \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ devices.

MedWatch Program – a safety information and adverse event \_\_\_\_\_\_\_\_\_\_\_ system that serves healthcare professionals and the public by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ serious problems suspected to be associated with the drugs and medical devices.

Medical Device Recalls

Class I: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reasonable chance that the product will cause \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The manufacturer must notify customers , and direct them to notify the product recipients. Notification must include the name of the device, lot or serial number, reason for recall, and instructions to correct, avoid, or minimize the problem. The company must also \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to notify the public. The FDA may also issue its own press release or \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_---.

Class II: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Possibility that the product will cause a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ health problem, or there is a remote chance that the device will cause serious health problems. The manufacturer must \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and sometimes asks them to notify the products recipients. Generally neither the FDA nor the manufacturer issue a press release.

Class III: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Little chance that using or being exposed to the product will cause health problems. The product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ FDA law, so there is need to take an action to address the problem. The manufacturer must notify customers and neither the FDA nor the manufacturer issue a press release.

Define the following acronyms and list the Regulations and Standards they administer:

|  |  |
| --- | --- |
| Acroynm | Regulations and Standards Administered? |
| CDC |  |
| DOT |  |
| EPA |  |
| OSHA |  |

List the names of the following professional organizations and their functions:

|  |  |
| --- | --- |
| Professional association-define the acronyms | Function |
| AAMI |  |
| ANSI |  |
| AORN |  |
| APIC |  |
| ISO |  |
| Joint Commission |  |
| NFPA |  |
| USP-NF |  |
| WHO |  |
| ECHN |  |
| SGNA |  |

What are the differences between regulations and voluntary and regulatory standards?

A regulation is a mandatory law or rule that is issued by a governing body. A standard is a uniform method of defining basic parameters for processes, services, and measurements. Regulatory standards is a comparison benchmark that is mandated by a governing agency and if not complied with, may cause a facility to be in violation and liable for legal penalty. Voluntary standard is a comparison benchmark that is strongly recommended by a governing agency or professional organization that provides recommendations and guidelines to provide better patient care.

U.S. FDA

FDA- Food and Drug Administration

Federal agency responsible for ensure that foods, cosmetics, human and veterinary drugs, biological products, medical devices, and electronic products that emit radiation are safe and effective for public use. The FDA regulates the manufacture of all medical devices, and requires the pre-market clearance of new medical devices. It also regulates the sterilants and high level disinfectants used to process critical and semi-critical devices.

Medical Device Classification

Class I Devices: Include low risk devices such as most hand-held surgical instruments and ultrasonic cleaners. They are subject to general controls, such as registration and device listing, medical device reporting, and quality system regulation and labeling.

Class IIDevices: Considered to pose potential risks great enough to warrant a high level of regulation. Include most types of sterilization equipment, and biological and chemical indicators. Subject to performance standards, post-market surveillance studies, and specific guidelines or special labeling.

Class III Devices: The most stringently regulated devices, including heart valves, pacemakers, and other life-sustaining devices.

MedWatch Program – a safety information and adverse event reporting system that serves healthcare professionals and the public by reporting serious problems suspected to be associated with the drugs and medical devices.

Medical Device Recalls

Class I: High Risk

Reasonable chance that the product will cause serious health problems or death. The manufacturer must notify customers , and direct them to notify the product recipients. Notification mush include the name of the device, lot or serial number, reason for recall, and instructions to correct, avoid, or minimize the problem. The company must also issue a press release to notify the public. The FDA may also issue its own press release or public health notice.

Class II: Less Serious Risk

Possibility that the product will cause a temporary of reversible health problem, or there is a remote chance that the device will cause serious health problems. The manufacturer must notify customers and sometimes asks them to inform the products recipients. Generally neither the FDA nor the manufacturer issue a press release.

Class III: Low Risk

Little chance that using or being exposed to the product will cause health problems. The product violates FDA law, there is need to take an action to address the problem. The manufacturer must notify customers and neither the FDA nor the manufacturer issue a press release.

Define the following acronyms and list the Regulations and Standards they administer:

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| Joint Commission |  |
| NEPS |  |
| USP-NF |  |
| WHO |  |
| ECHN |  |
| SGNA |  |