

GUIDELINE FOR COMPLYING WITH LOCAL, STATE & FEDERAL LAWS

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PREAMBLE

This document provides an overview of how to comply with local, state and federal laws.

QUALIFICATIONS

There are over 1000 organizations including various state and federal agencies that promulgate voluntary and mandatory standards for the health care field in general, resulting in many thousands of standards, clinical practice guidelines, laws, and regulations. These organizations also promulgate a variety of requirements for different types of equipment (e.g. imaging, nuclear, anesthesia and respiratory), electrical safety, fire safety, power distribution, medical-gas systems, clinical laboratories, and blood banks.

The major federal organizations that have a direct impact on clinical engineering include the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), and the Federal Communications Commission (FCC). In addition, there are various laws and regulations for employment like Americans with Disability Act (ADA) and organizations like Equal Employment Opportunity Commission (EEOC).

The major voluntary organizations include the Joint Commission on Accreditation of Healthcare Organization (JCAHO), American Osteopathic Association (AOA), College of American Pathologists (CAP), American Association of Blood Banks (AABB), National Fire Protection Association (NFPA), and Association for the Advancement of Medical Instrumentation (AAMI). Some of the standards published by these organizations are incorporated into various federal, state and local regulations.

There are state/local agencies that have a direct impact on clinical engineering including the state health departments (e.g. Department of Health Services (DHS) in California) that enforce California Code of Regulations (CCR), California Office of Statewide Health Planning and Development (OSHPD) that enforces regulations pertaining to health facility construction.

GUIDELINES

1. Clinical engineer must provide leadership in the regulatory compliance requirements that pertain to the use of medical equipment in the hospital.
2. He/she must be actively involved in the process that deals with different local, state and federal agencies.

REFERENCES

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