2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #5: Technology Management III

September 6, 2023

Arif Subhan, CCE
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About the host/moderator

Katherine Navarro is a Biomedical Engineer with the VHA Office of Healthcare Technology Management (HTM) where she supports the Biomedical Engineering field in the VA from a national level.

Katherine has been with the VA in the Healthcare Technology Management field for thirteen years. In 2020, Katherine began her new role for the Office of HTM, working virtually from San Antonio.

Katherine served as the chair of the ACCE's Body of Knowledge Committee from 2017 – 2019 and an ACCE Board Member at Large from 2020 – 2022, and as the ACCE Vice President since 2022.

Logistics

❖All attendees have their microphones muted during the presentation.

❖Questions to the faculty must be submitted via the "Q&A" feature in Zoom at any time. They will be addressed at the Q&A portion.

❖If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.

❖Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

ARIF SUBHAN, MS, CCE, FACCE, AAMIF

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- VA TCF Preceptor for clinical engineers/BMETs
- Adjunct Professor, Biomedical Engineering, University of Connecticut
- Lecturer, Biomedical Engineering, Southern California Institute of Technology
- Editorial Board member, BI&T, 24x7 Magazine, and Journal of Clinical Engineering
- Regular columnist, Journal of Clinical Engineering
- Ex-Chair, United States Certification Commission (USCC) - predecessor to AAMI Credentials Institute (ACI)
- Past President, American College of Clinical Engineering (ACCE)
- Co-Chair, AAMI Annual Conference Program Committee
- Faculty member, CCE and CBET exam review courses and international CE workshops since 2006
- Authored book chapters for the "Clinical Engineering Handbook", "Encyclopedia of Medical Devices and Instrumentation" and "A Practicum for Biomedical Engineering and Management Issues”
- Presenter at AAMI Conferences since 1992
- Former Senior Clinical Engineer, Masterplan (National Independent Service Organization)
- Former Chief Biomedical Engineer, VA Nebraska Western Iowa HealthCare System
- Former Chief Biomedical Engineer, VA South Texas Veterans Health Care System
- Former PTSM/EC Consultant, Hospital Association of Southern California
- 2013 ACCE Professional Development/ Managerial Excellence Award
- 2012 AAMI Leadership Award
- 2022 ACCE Tom O’Dea Advocacy Award

Learning Objectives

Technology Management III

- EMI/RFI Management
- Interpretation of Codes and Standards
- Clinical Systems Networking
- Coordinating Device Interoperability/Interfacing
- Clinical Device Use and/or Application
- Water Quality Management

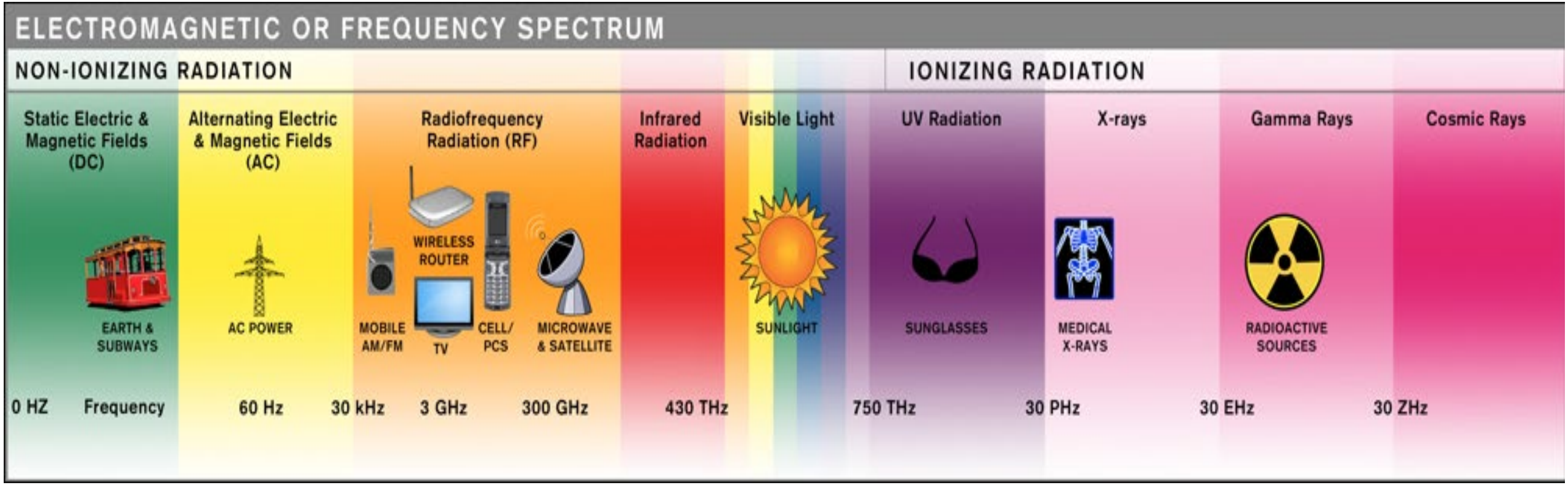
EMI and RFI

Electromagnetic Interference (EMI)

- EMI refers to the **disturbance or noise** caused by e**lectromagnetic radiation** in the electromagnetic spectrum, which includes a wide range of frequencies from extremely low frequency (ELF) to extremely high frequency (EHF).
- EMI can result from various sources, such as e**lectrical appliances, power lines, electronic devices, and even natural sources like lightning**. When these sources emit electromagnetic radiation, it can interfere with nearby electronic equipment or communication systems.
- EMI can be conducted (transmitted through physical connections) or radiated (transmitted through the air). It can affect both wired and wireless systems.

Radio-Frequency Interference (RFI)

- RFI is a **subset** of EMI that specifically refers to electromagnetic interference within the radio frequency (RF) portion of the electromagnetic spectrum. This typically covers frequencies from around 3 kHz (kilohertz) to 300 GHz (gigahertz).
- RFI is often associated with **radio communication systems, including AM and FM radio, TV broadcasts, cellular networks, Wi-Fi, and other wireless technologies**. When unwanted electromagnetic signals or noise at RF frequencies interfere with these systems, it's considered RFI.


ELECTROMAGNETIC OR FREQUENCY SPECTRUM
NON-IONIZING RADIATION
IONIZING RADIATION
Static Electric & Magnetic Fields (DC)
Alternating Electric & Magnetic Fields (AC)
Radiofrequency Radiation (RF)
Infrared Radiation
Visible Light
UV Radiation
X-rays
Gamma Rays
Cosmic Rays
EARTH & SUBWAYS
AC POWER
WIRELESS ROUTER
MOBILE AM/FM
TV
CELL/ PCS
MICROWAVE & SATELLITE
SUNLIGHT
SUNGLASSES
MEDICAL X-RAYS
RADIOACTIVE SOURCES
0 HZ
Frequency
60 Hz
30 kHz
3 GHz
300 GHz
430 THz
750 THz
30 PHz
30 EHz
30 ZHz

EMI and RFI References

https://resources.pcb.cadence.com/blog/2022-the-basics-of-emi-and-rfi

https://resources.pcb.cadence.com/blog/2022-the-basics-of-emi-and-rfi

https://www.machinedesign.com/medical-design/article/21248098/how-does-radiated-emi-impact-medical-devices

https://24x7mag.com/uncategorized/emirfi-management/

Management of Electromagnetic Interferences in Healthcare Facilities – A review

Gnahoua Zoabli[1], and Nabilath Akimey A.[2]

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[2]Institut de génie biomédical, Université de Montréal, Montréal, Québec

Abstract

Management of electromagnetic interference has become a major issue in Quebec hospitals. Several discussions on this issue have been held between managers of medical technologies departments. Some hospitals tend to allow a more widespread use of wireless technologies while others continue to formally ban them. As a contribution, we present a review of literature on devices that may transmit frequencies that can interfere with medical devices, such as pagers, cordless phones, cell phones, tablets, portable radio transceivers, tracking devices, laptop computers, telecommunications antennas and medical equipment. Because of its wide availability, portability and accessibility, cell phone is the most popular wireless technology in healthcare facilities. The greatest distance of immunity known to date is 6 m, excluding the combination effect of the agglomeration of several electromagnetic sources in the same area. From our literature review, it is safe to allow cell phones in a healthcare facility if the usage is made out of a nursing unit, regardless of the vocation (critical or general Medicine) or outside of a diagnostic or medical department (medical imaging and laboratories). By cons, for medical imaging technologists carrying a pocket dosimeter (immunity of 38 cm), the use of cell phones should be banned while still carrying the dosimeter. The nuisance caused by cell phones, their need for regular disinfection by their owners and the patient privacy safeguarding concerns should be considered by healthcare managers in preparation of regulations, procedures or policies on health and safety at work. A subsequent study should analyze electromagnetic interference of medical equipment between them. Hospitals that have already authorized the use of cell phones on the care units would benefit requiring phones with Flight mode enabled, pending the development of a Hospital mode that should inhibit, in addition, sound recording, video camera and force the phone ring mode to vibration.

Keywords: **Electromagnetic Interference, Health and Safety, Cell Phones, Hospital Mode, Privacy**.

http://www.zoabli.com/WC2015Tronto/G_ZOABLI_AKIMEY_Wireless%20security%20in%20healthcare_Jan_27_2015.pdf

Electromagnetic Compatibility (EMC)

Details

Category: Clinical Engineering

D Bozec[1], M P Robinson[2] and C A Marshman[1]

1. York EMC Services Ltd, The University of York, Heslington, York YO10 5DD
Principal contact: db@yorkemc.co.uk

2. Department of Electronics, The University of York, Heslington, York YO10 5DD

https://www.ebme.co.uk/articles/clinical-engineering/electromagnetic-compatibility-emc

Measurement	Typical voltage
Electrocardiography (ECG)	1mV
Electroencephalography (EEG)	100µV
Electromyography (EMG)	10µV
Evoked potentials	1µV

Table 1: Measured values of small physiological signals

https://www.ebme.co.uk/articles/clinical-engineering/electromagnetic-compatibility-emc

Any piece of equipment will fail if subjected to a **large** enough disturbances.

Digital circuits are generally more immune but fail more catastrophically when they eventually do so.

A wobbly picture on a monitor would probably be regarded as no more than a nuisance, whereas **failure of a ventilator, infusion pump or automated defibrillator could be fatal**.

https://www.ebme.co.uk/articles/clinical-engineering/electromagnetic-compatibility-emc

Management of Electromagnetic Interference at a Hospital

Y., David P.E., C.C.E., Ph.D.[1]; Bukhari, Abdul R.S. D.Sc.[2]; Paperman, David W.[3]

Author Information

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[2]Clinical Engineering Manager, Alaska Native Tribal Health Consortium, Alaska Clinical Engineering Services

[3]Biomedical Engineering Department Texas Children's Hospital Houston, Texas

Journal of Clinical Engineering: March 2000 - Volume 25 - Issue 2 - p 95-103

EMI/RFI Management

- **Electromagnetic compatibility (EMC)** - means a medical device is compatible with (no interference is caused by) its electromagnetic environment and it does not emit levels of electromagnetic energy that cause electromagnetic interference in other devices in the vicinity.

- A medical device can be vulnerable to electromagnetic interference **if the levels of electromagnetic energy in its environment exceed the electromagnetic immunity (resistance) to which the device was designed and tested**.

- The different forms of electromagnetic energy that can cause electromagnetic interference are conducted, radiated, and electrostatic discharge.

- Electromagnetic interference problems with medical devices can be very complex, not only from the technical standpoint but also from the view of public health issues and solutions.

https://www.fda.gov/radiation-emitting-products/radiation-safety/electromagnetic-compatibility-emc

EMI/RFI Management

The **FDA's Center for Devices and Radiological Health (CDRH)** has regulatory authority over several thousands of different kinds of medical devices, with thousands of manufacturers and variations of devices.

CDRH is at the forefront of examining medical device electromagnetic interference and providing solutions.

Extensive laboratory testing by CDRH, and others, has revealed that many devices can be susceptible to problems caused by electromagnetic interference.

Devices Connected to Hospital Wi-Fi Networks

Wireless Medical Devices

Radio frequency (RF) wireless medical devices perform at least one function that utilizes wireless RF communication such as **Wi-Fi, Bluetooth, and cellular/mobile phone** to support health care delivery.

Examples of functions that can utilize wireless technology include

controlling and programming a medical device,
monitoring patients remotely, or
transferring patient data from the medical device to another platform such as a cell phone.

Examples of areas that utilize RF Wireless technology includes WMTS and RFID

https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices

Wireless Medical Telemetry Service (WMTS)

Wireless Medical Telemetry Service (WMTS)

American Society for Healthcare Engineering of the American Hospital Association (ASHE/AHA)

About | Data | Licensing | Operations

The Wireless Medical Telemetry Service (WMTS) is in the 608 – 614, 1395 – 1400, and 1427 – 1432 MHz range. WMTS spectrum is used for remote monitoring of a patient's health. Wireless medical telemetry systems include devices to measure patients' vital signs and other important health parameters (*e.g.*, pulse and respiration rates) and devices that transport the data via a radio link to a remote location, such as a nurses' station, equipped with a specialized radio receiver. For example, wireless cardiac monitors are often used to monitor patients following surgery.

Rule Part

47 C.F.R, Part 95

Federal Communications Commission (FCC)

The Federal Communications Commission (FCC) o**versees the use of the public Radio Frequency (RF) spectrum** within which RF wireless technologies operate.

FDA's policies on wireless medical devices are coordinated with the FCC and provide medical device manufacturers with more predictability and a better understanding of regulatory requirements for medical devices that utilize these technologies.

Joint Statement on Wireless Medical Devices - U.S. Food and Drug Administration, Federal Communications Commission

https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices

Risk Management at Health Care Facilities

Most well-designed and maintained RF wireless medical devices perform adequately.

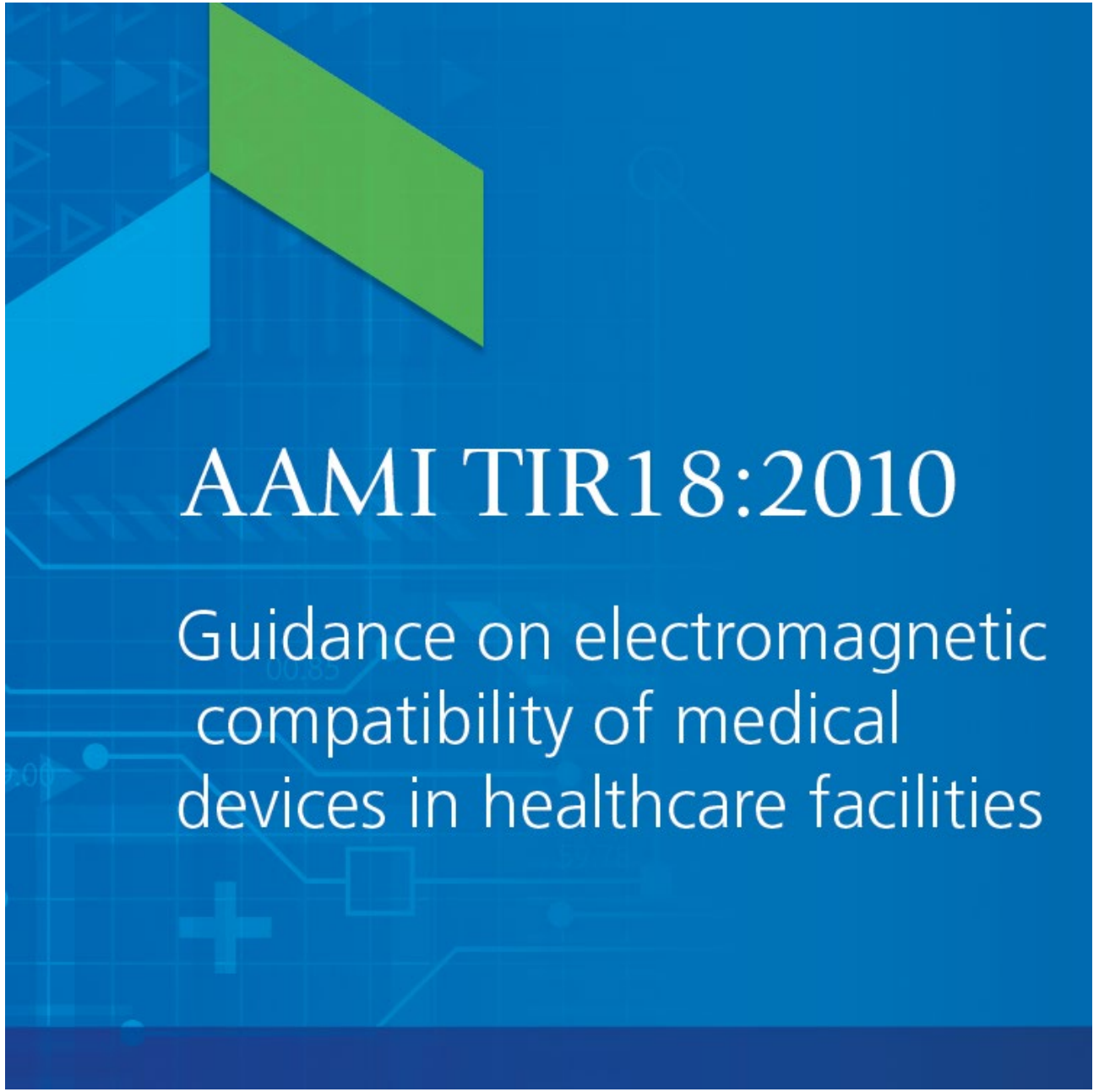
However, the increasingly crowded RF environment and competition from non-medical wireless technology users could impact the performance of RF wireless medical devices.

FDA recommends that health care facilities develop appropriate processes and procedures to assess and manage risks associated with the integration of RF wireless technology into medical systems.

Risk Management at Health Care Facilities

Health care facilities should also consider the following:

- Selection of wireless technology
- Quality of service
- Coexistence
- Security
- Electromagnetic Compatibility (EMC)


AAMI TIR18:2010
Guidance on electromagnetic compatibility of medical devices in healthcare facilities

AAMI Technical Information Report (TIR) provides information, guidance, and general recommendations regarding **electromagnetic compatibility (EMC) of medical devices** and the **use of RF wireless technology in healthcare facilities** to promote patient safety.

Provide a broad range of information about EMC of medical devices for clinical and biomedical engineers and other technical personnel; healthcare administrators, including heads of hospital departments; medical staff; and healthcare associations.

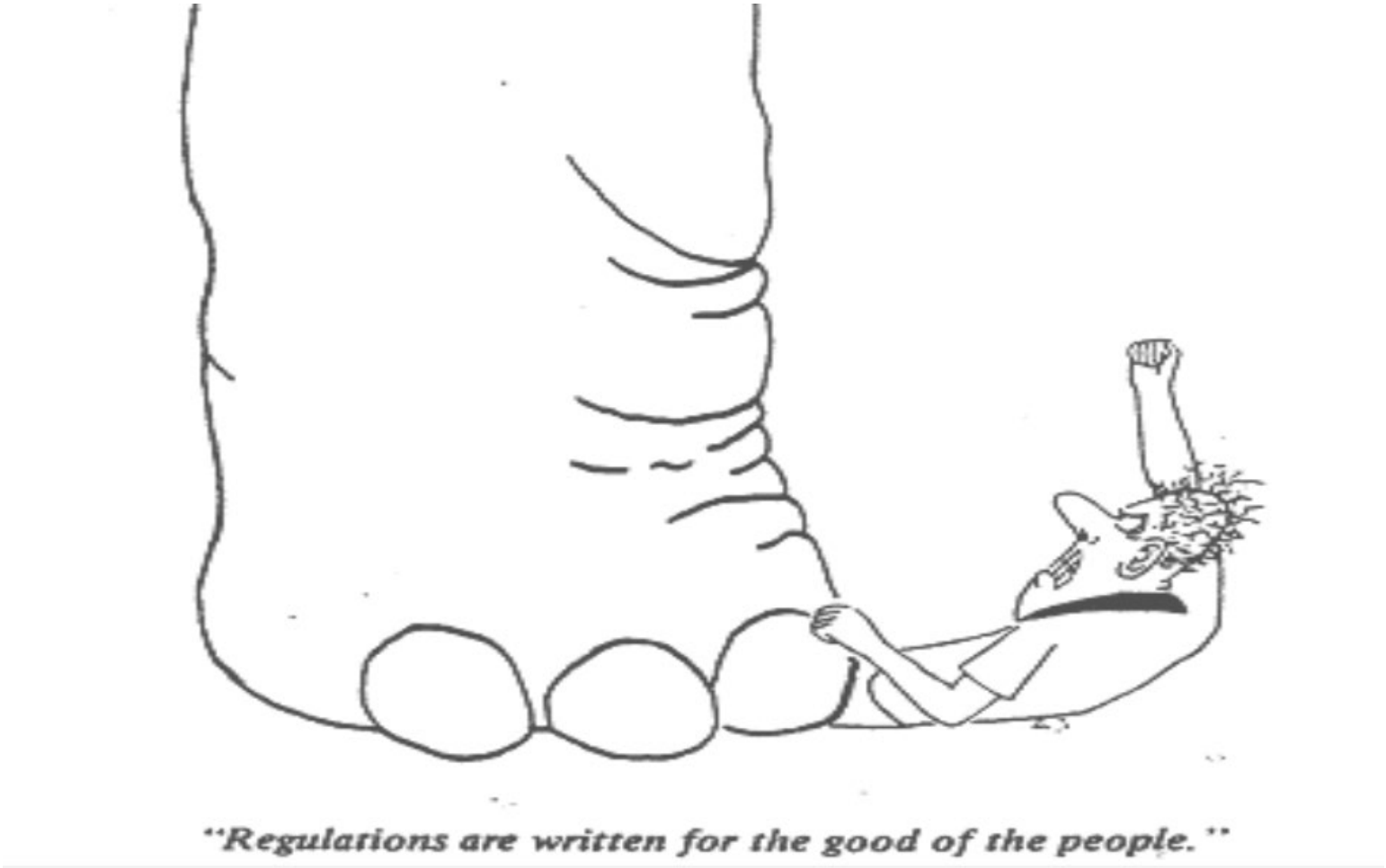
Assist healthcare organizations **evaluate their electromagnetic (EM) environment and implement actions needed to minimize electromagnetic interference (EMI) problems and manage the EM environment, including wireless RF sources**.

ANSI/AAMI/IEC 60601-1-2:2014

Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests

https://store.aami.org/s/store#/store/browse/detail/a152E000006lExAQAU

Interpretation of Codes and Standards



"Regulations are written for the good of the people."

Codes, Standards & Regulations

- The terms “codes,” “standards,” and “regulations” are often used interchangeably.

What is a Standard?

- Establishes a minimum level of performance.
- To standardize test methods, specifications, definitions, or practices.
- Most standards are voluntary.

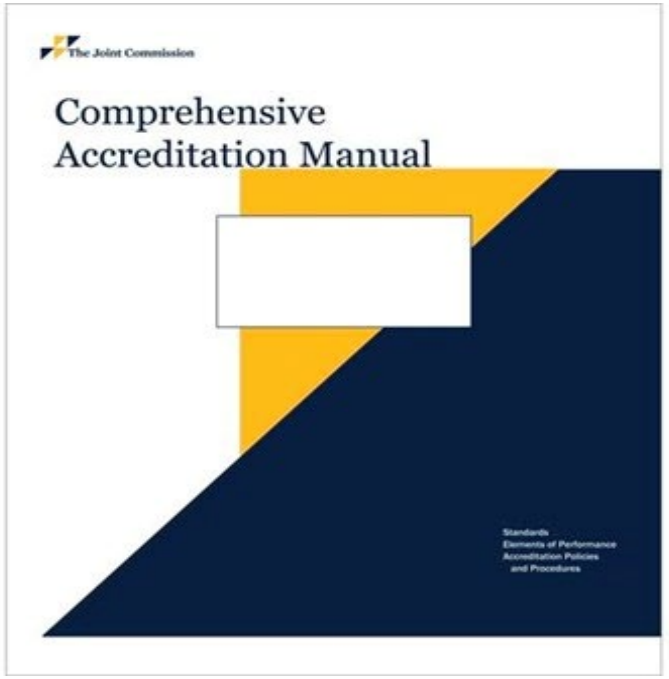
Examples

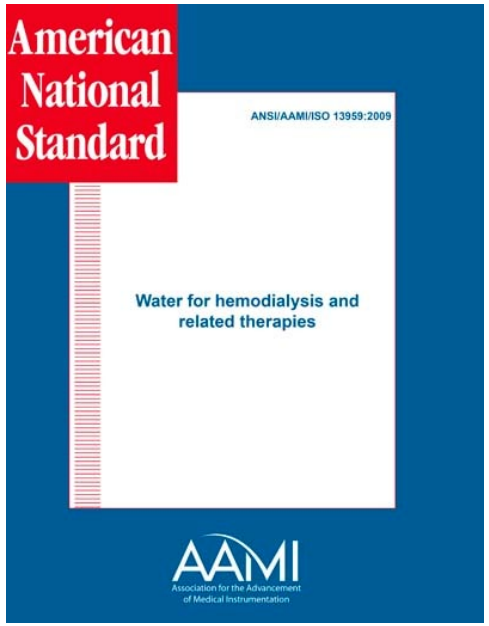
Standards developed by Joint Commission, NFPA, AAMI, CAP, AABB, etc.

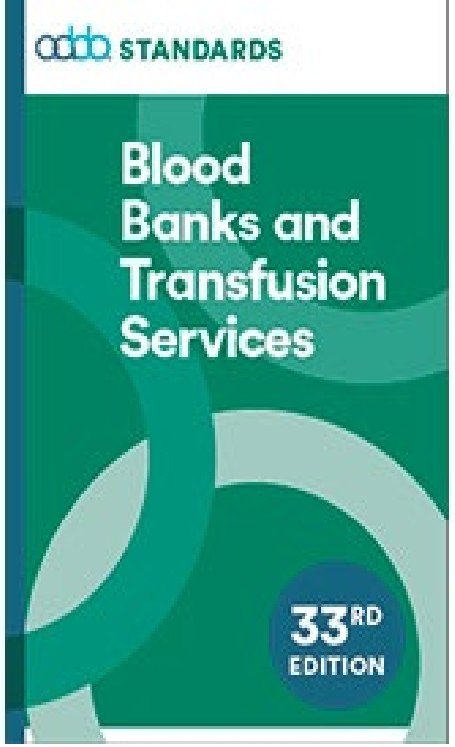
When is Compliance with a Standard required?

Compliance is mandatory only when required by an **authority having jurisdiction** (AHJ*).

“*An organization, office, or individual responsible for enforcing the requirements of a code or standard, or for approving equipment,…”


The Joint Commission
Comprehensive Accreditation Manual
Standards
Elements of Performance
Accreditation Policies
and Procedures


American National Standard
ANSI/AAMI/ISO 13959:2009
Water for hemodialysis and related therapies
AAMI
Association for the Advancement of Medical Instrumentation


STANDARDS
Blood Banks and Transfusion Services
33RD EDITION


ANSI/AAMI EQ56:2013
Recommended practice for a medical equipment management program


AAMI
Standard

1. Physical plant standards specified in applicable Articles of this Chapter shall govern over the codes and standards incorporated by reference in subsection (B); and
2. If a conflict occurs among the codes and standards incorporated by reference in subsection (B), the more restrictive codes and standards shall govern over the less restrictive.

B. The following physical plant health and safety codes and standards are incorporated by reference as modified, are on file with the Department, and include no future editions or amendments:

1. Guidelines for Design and Construction of Health Care Facilities (2018 ed.), published by the American Society for Healthcare Engineering and available from The Facility Guidelines Institute at www.fgiguidelines.org;
2. The following National Fire Codes (2012), published by and available from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269, and at www.nfpa.org/catalog:
   a. NFPA70 National Electrical Code,
   b. NFPA101 Life Safety Code, and
   c. 2012 Supplements;
3. ICC/A117.1-2017, American National Standard: Accessible and Usable Buildings and Facilities (2017), published by and available from the International Code Council, Inc., Publications, 4051 W. Flossmoor Road, Country Club Hills, IL 60478-5795, and at www.iccsafe.org;
4. International Building Code (2018), published by and available from the International Code Council, Inc., Publications, 4051 W. Flossmoor Road, Country Club Hills, IL 60478-5795, and at www.iccsafe.org, with the following modifications:
   a. Section 101.1 is modified by deleting "of [NAME OF JURISDICTION]",
   b. Sections 103.1 through 103.4.1 are deleted,
   c. Sections 104.1 through 104.7 are deleted,
   d. Sections 105.1 through 105.4.1 are deleted,
   e. Sections 106.1 through 106.6.3 are deleted,
   f. Sections 107.1 through 107.7 are deleted,
   g. Sections 108.1 through 108.7.3 are deleted,
   h. Sections 109.1 through 109.7 are deleted,
   i. Sections 110.1 through 110.4 are deleted, and
   j. Appendix B is deleted;
6. International Plumbing Code (2018), published by and available from the International Code Council, Inc., Publications, 4051 W. Flossmoor Road, Country Club Hills, IL 60478-5795, and at www.iccsafe.org, with the following modifications:
   a. Section 101.1 is modified by deleting "of [NAME OF JURISDICTION]",
   b. Sections 103.1 through 103.4.1 are deleted,
   c. Sections 104.1 through 104.7 are deleted,
   d. Sections 105.1 through 105.4.1 are deleted,
   e. Sections 106.1 through 106.6.3 are deleted,
   f. Sections 107.1 through 107.7 are deleted,
   g. Sections 108.1 through 108.7.3 are deleted,
   h. Sections 109.1 through 109.7 are deleted,
   i. Sections 110.1 through 110.4 are deleted, and
   j. Appendix A is deleted;
7. International Fire Code (2018), published by and available from the International Code Council, Inc., Publications, 4051 W. Flossmoor Road, Country Club Hills, IL 60478-5795, and at www.iccsafe.org, with the following modifications:
   a. Section 101.1 is modified by deleting "of [NAME OF JURISDICTION]",
   b. Sections 102.3 and 102.5 are deleted,
   c. Sections 103.1 through 103.4.1 are deleted,
   d. Sections 104.1 through 104.11.3 are deleted,
   e. Sections 105.1 through 105.7.25 are deleted,
   f. Sections 106.1 through 106.5 are deleted,
   g. Sections 107.1 through 107.4 are deleted,

Limitations

- Standards/codes/regulations are b**ased on past experience** and can inhibit modernization or **limit** progress.

- Usually their scope is limited and could be inappropriate for unforeseen situations – important to know the **origin, background and last revision date**.

- Participation in the development of standards/regulations requires time and money which many individuals and small organization cannot afford.

Checklist in Using a Standard

- Who developed it?
- How was it developed?
- When was it developed?
- When was it last revised?
- When will it be revised?
- Where has it been used?
- Is it mandatory? According to whom?
- What are possible limitations?
- Why should it be used?

Codes

What is a Code?

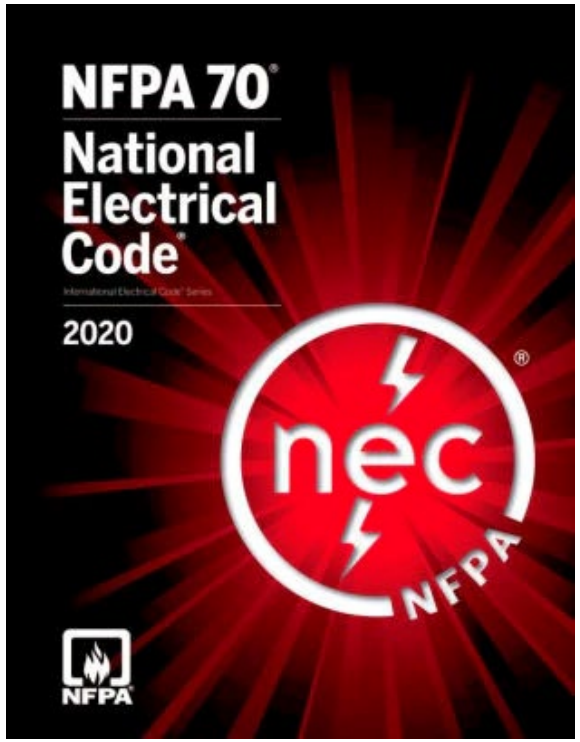
- System of standards relating to a particular topic.
- It may be adopted by government or private entities in whole or in part.
- Enforcement of the code lies with the government (local, state, or federal), turning the standards into regulatory documents.

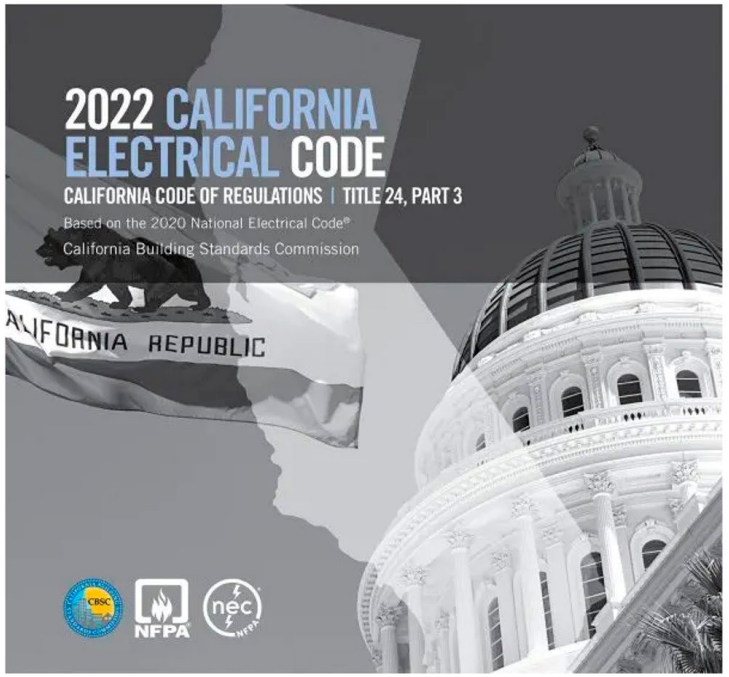
Examples

NFPA 70	National Electrical Code
NFPA 99	Health Care Facilities Code
NFPA 101	Life Safety Code

When is Compliance with a code required?

Compliance is mandatory only when required by an authority having jurisdiction (AHJ).





2022 California Electrical Code (Title 24 Part 3) is a fully-integrated California-specific electrical code based on the **2020 National Electrical Code**.

Quality, Safety & Oversight - Certification & Compliance

Nursing Homes

Community Mental Health Centers

Critical Access Hospitals

End Stage Renal Disease Facility Providers

Hospices

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)

Clinical Laboratories

Life Safety Code & Health Care Facilities Code Requirements

Life Safety Code & Health Care Facilities Code Requirements

Feedback

This page provides basic information about Medicare and/or Medicaid provider compliance with National Fire Protection Association (NFPA) 101 Life Safety Code (LSC) and NFPA 99 Health Care Facilities Code (HCFC) requirements and includes links to applicable laws, regulations, and compliance information. Please see LSC/HCFC Laws, Regulations, and Compliance Information link below in the Downloads section.

The LSC is a set of fire protection requirements designed to provide a reasonable degree of safety from fire. It covers construction, protection, and operational features designed to provide safety from fire, smoke, and panic. The HCFC is a set requirements intended to provide minimum requirements for the installation, inspection, testing, maintenance, performance and safe practices for facilities, material, equipment and appliances. The LSC and HCFC, which is revised periodically, is a publication of NFPA, which was founded in 1896 to promote the science and improve the methods of fire protection.

The basic life safety from fire requirement for facilities participating in the Medicare and Medicaid programs is compliance with the 2012 edition of the NFPA LSC and HCFC. CMS partners with State Agencies (SA) to assess facilities for compliance with the LSC requirements. SAs may enter into sub-agreements or contracts with the State Fire Marshal offices or other State agencies responsible for enforcing State fire code requirements. Under these agreements, the designated State fire authority generally agrees to:

Regulations

- A document that is issued by a **government entity**.
- It may **include in whole or in part a standard** or in lieu of inclusion, **reference** to a standard.
- It has the force of law from the **start**.

<u>Examples</u>

Code of Federal Regulations (CFR)

California Code of Regulations (CCR)

Arizona Administrative Code

Code of Federal Regulations

A point in time eCFR system

eCFR

READER AIDS

Welcome to the new eCFR! Check out our *Getting Started* guide to make the most of the new site.

Go to CFR Reference ex: 1 CFR 1.1 Go

Titles

Titles	Last Amended	Recent Changes
Title 1 :: General Provisions	May 04, 2022	view changes
Title 2 :: Grants and Agreements	May 19, 2022	view changes
Title 3 :: The President	Mar 17, 2015	
Title 4 :: Accounts	May 01, 2018	
Title 5 :: Administrative Personnel	Jun 01, 2022	view changes
Title 6 :: Domestic Security	Aug 09, 2022	view changes
Title 7 :: Agriculture	Aug 10, 2022	view changes
Title 8 :: Aliens and Nationality	Jul 11, 2022	view changes
Title 9 :: Animals and Animal Products	Jul 19, 2022	view changes
Title 10 :: Energy	Aug 08, 2022	view changes

/title-6

Are Joint Commision Standards Mandatory

No but many third-party payers require Joint Commission Accreditation.

Joint Commission is an independent, not-for-profit organization. When congress passed the Social Security Amendments of 1965 (Public Law 89-97), there was a provision in the law that **permitted** hospitals accredited by the Joint Commission to be "**deemed**" in compliance with the "Medicare Conditions of Participation" for hospitals.

This provides hospitals with an alternate path that many consider preferable to a survey done by the individual state survey agencies on behalf of the Centers of Medicaid and Medicare Services (CMS) to qualify for Medicare and Medicaid reimbursement.

The *Conditions of Participation* for hospitals are contained in *42 CFR 482*.

(6) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(7) A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access;

(8) When a sprinkler system is shut down for more than 10 hours, the hospital must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(9) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) The sill height in special nursing care areas of new occupancies must not exceed 60 inches.

(c) ***Standard: Building safety.*** Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(d) ***Standard: Facilities.*** The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 216, 07-21-23)

Transmittals for Appendix A

Survey Protocol

Introduction

- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

§482.1 Basis and Scope

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

§482.11 Condition of Participation: Compliance with Federal, State and Local Laws

§482.12 Condition of Participation: Governing Body

§482.13 Condition of Participation: Patient's Rights

§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program

§482.22 Condition of Participation: Medical staff

§482.23 Condition of Participation: Nursing Services

§482.24 Condition of Participation: Medical Record Services

§482.25 Condition of Participation: Pharmaceutical Services

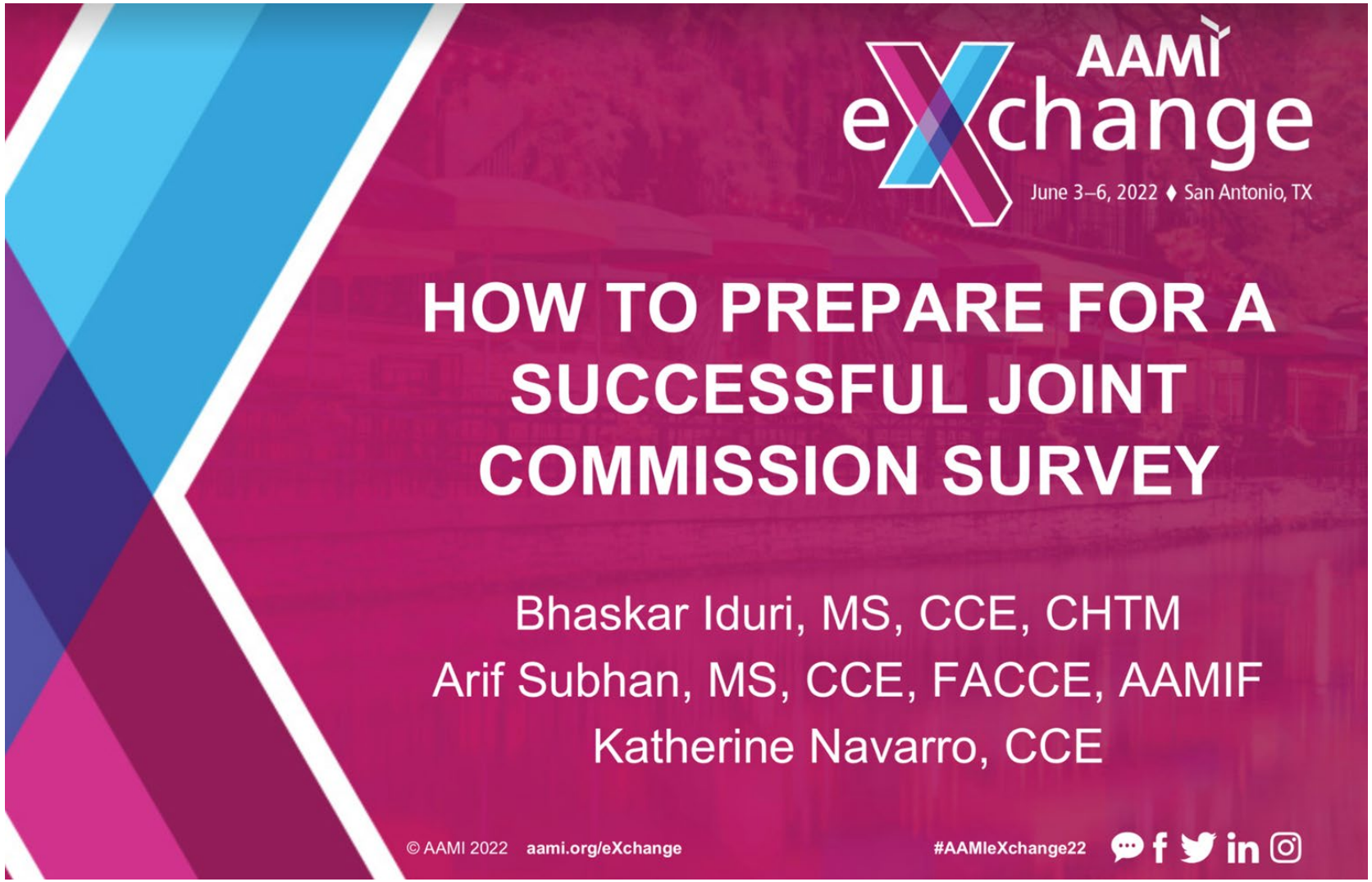
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

Types of Organizations involved with Codes, Standards & Regulations

1. Voluntary organizations
2. Federal agencies
3. State agencies
4. Local agencies

Voluntary Organizations

- The Joint Commission
- College of American Pathologists (CAP)
- American Association of Blood Banks (AABB)
- National Fire Protection Association (NFPA)
- Association for the Advancement of Medical Instrumentation (AAMI)
- American Osteopathic Association (AOA)
- Underwriters Laboratories (UL)
- International Electrotechnical Commission (IEC)
- International Organization for Standardization (ISO)
- American National Standards Institute (ANSI)
- Accreditation Association of Ambulatory Health Care (AAAHC)



https://vimeo.com/720457602/49498e8860

The presentations start at 14:30.

Life Safety Code surveyors assess the use of power strips in healthcare facilities. However, the following guidance is provided as reference for healthcare surveyors as they survey physical environment along with other CoP requirements. Any observed power strip deficiencies should be conveyed to the LSC surveyors for citation.

If line-operated medical equipment is used in a patient care room/area, inside the patient care vicinity:

- UL power strips would have to be a permanent component of a rack-, table-, pedestal-, or cart-mounted & tested medical equipment assembly
- Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1
- Power strips cannot be used for non-medical equipment

If line-operated medical equipment is used in a patient care room/area, outside the patient care vicinity:

- UL power strips could be used for medical & non-medical equipment with precautions as described in the memo
- Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1
- Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363

If line-operated medical equipment is not used in a patient care room/area, inside and outside the patient care vicinity:

- UL power strips could be used with precautions

Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363. In non-patient care areas/rooms, other UL strips could be used with the general precautions.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

Page 375

https://assets.tripplite.com/white-paper/ul-60601-1-power-strips-white-paper-en.pdf

Deemed Status

For a healthcare organization to partake in and get payment from the **Medicare or Medicaid programs**, it must be certified as complying with the Conditions of Participation (CoP), or standards, stated in the federal regulations. In order to obtain this certification, a site survey is conducted by a state agency on behalf of the Centers for Medicare & Medicaid Services (CMS).

There are **alternatives** to the state agency site survey. One of the national accrediting organizations, e.g., The Joint Commission, the American Osteopathic Association (AOA), and Det Norske Veritas (DNV), also has and implements standards that meet the federal Conditions of Participation.

CMS may grant an accrediting organization "deeming" authority. The healthcare organization therefore would have "deemed status" if it is surveyed by one of these "deeming" national accrediting organizations. The healthcare organization in this case will **not** be subject to the Medicare survey and certification process.

https://www.cms.gov/files/document/qso-21-12-ao-clia.pdf
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

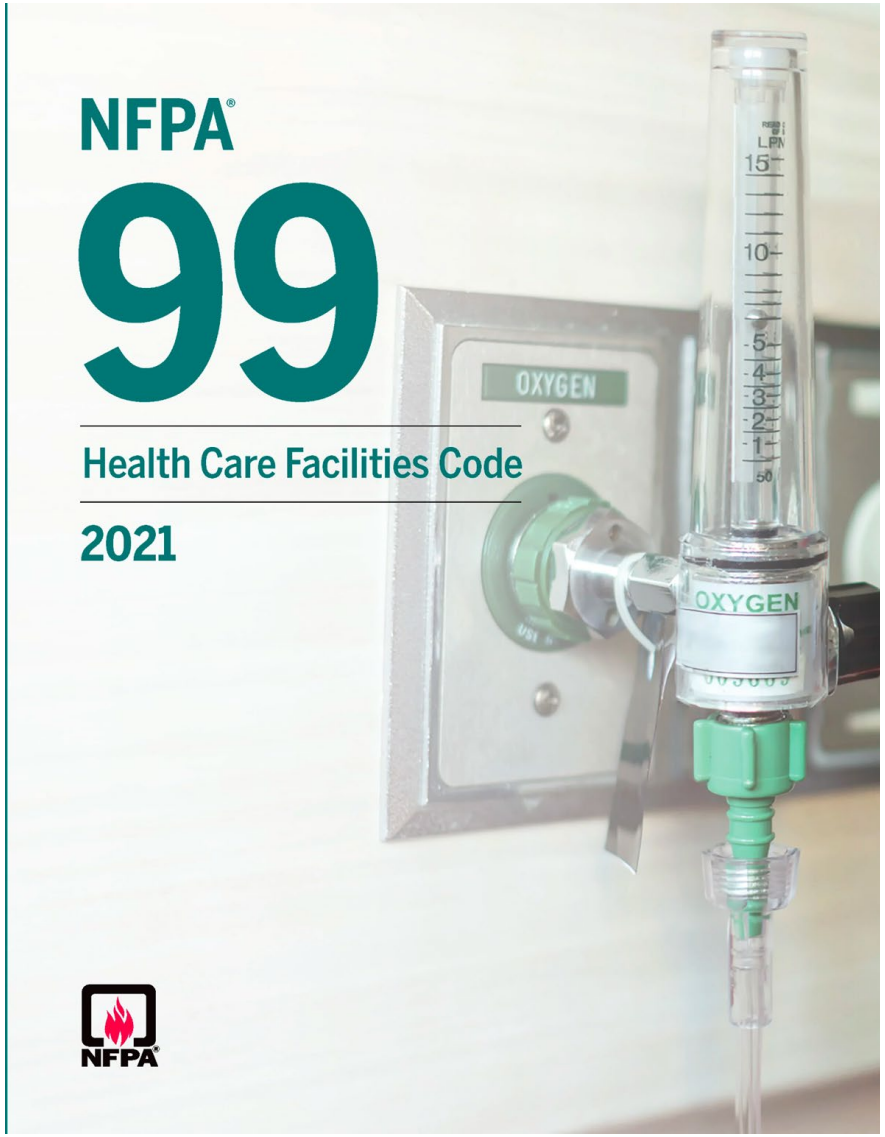
CMS-Approved Accrediting Organizations

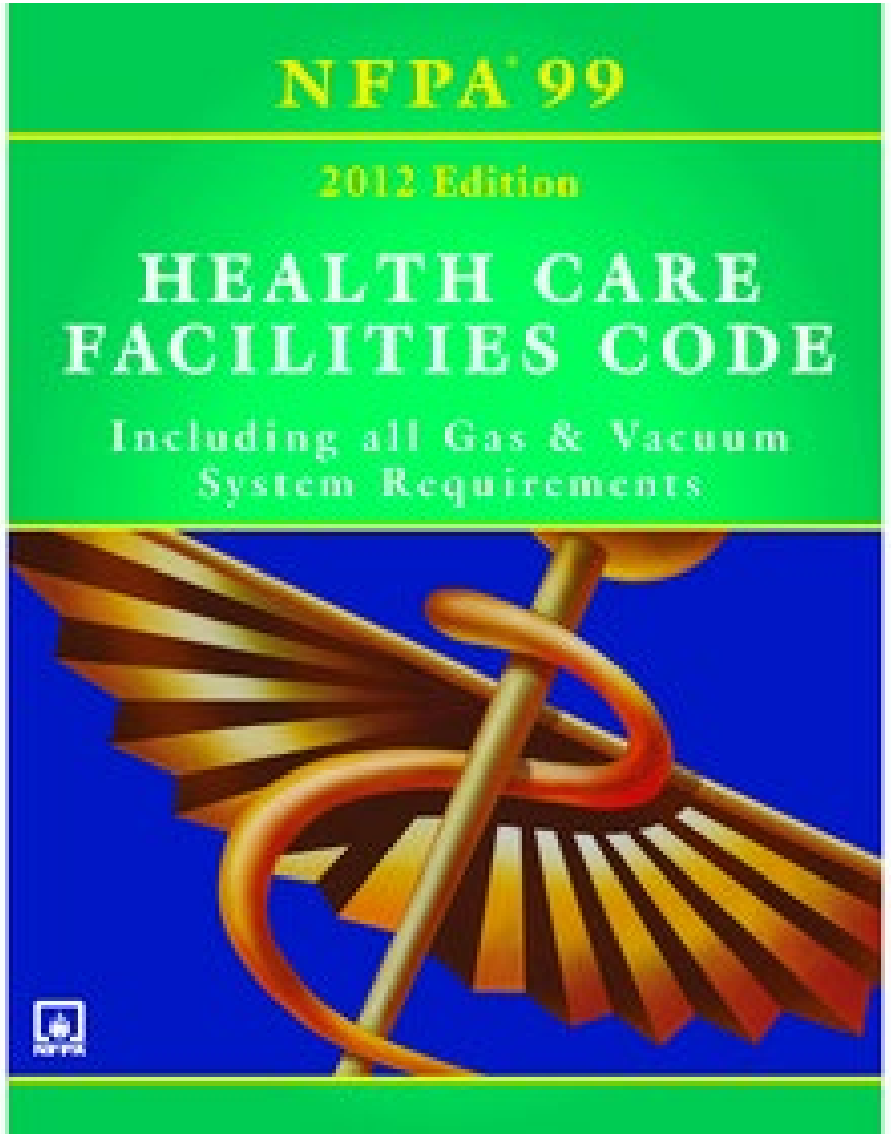
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- DNV - Healthcare (DNV)
- The Joint Commission (TJC)
- Other organizations

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

National Fire Protection Association (NFPA)

- Established in 1896.
- 300 codes and standards intended to minimize the possibility and effects of fire and other risks.
- NFPA codes and standards influence virtually **every** building, process, service, design, and installation in US.
- **NFPA 70, NFPA 99 and NFPA 101** are of interest to clinical engineers and BMETs.


NFPA
99
Health Care Facilities Code
2021
OXYGEN
OXYGEN
NFPA


NFPA 99
2012 Edition
HEALTH CARE FACILITIES CODE
Including all Gas & Vacuum System Requirements

NFPA 99 Purpose & Application

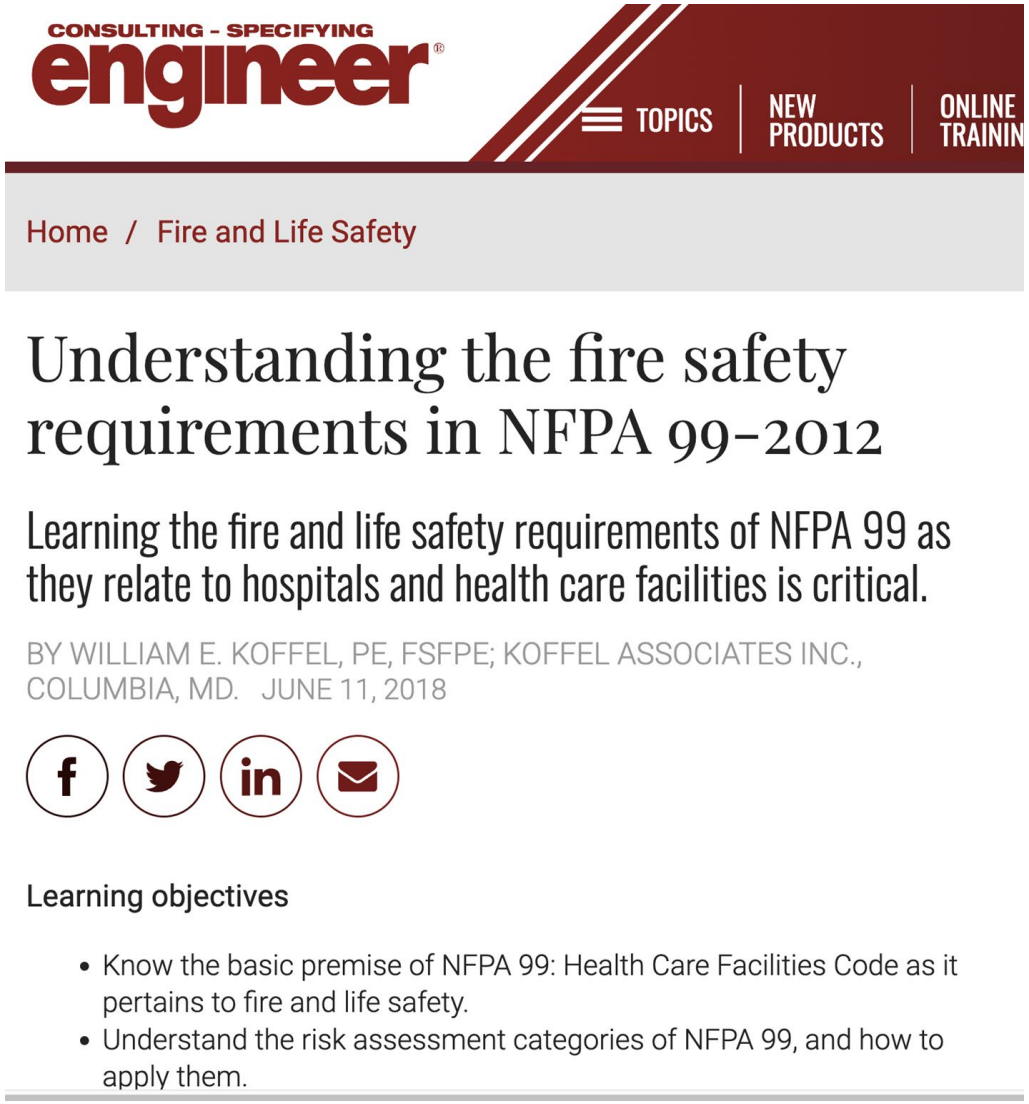
1.2 Purpose. The purpose of this code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards.

1.3 Application.

1.3.1 This code shall apply to all health care facilities other than home care and veterinary care.

1.3.1.1 This document is intended for use by those persons involved in the design, construction, inspection, and operation of health care facilities and in the design, manufacture, and testing of appliances and equipment used in patient care rooms of health care facilities.

https://www.csemag.com/articles/nfpa-99-health-care-facilities-code-overview/



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Home / Fire and Life Safety

Understanding the fire safety requirements in NFPA 99-2012

Learning the fire and life safety requirements of NFPA 99 as they relate to hospitals and health care facilities is critical.

BY WILLIAM E. KOFFEL, PE, FSFPE; KOFFEL ASSOCIATES INC., COLUMBIA, MD. JUNE 11, 2018

Learning objectives

- Know the basic premise of NFPA 99: Health Care Facilities Code as it pertains to fire and life safety.
- Understand the risk assessment categories of NFPA 99, and how to apply them.

https://www.csemag.com/articles/understanding-the-fire-safety-requirements-in-nfpa-99-2012/

Chapter 10 Electrical Equipment

10.1* Applicability.

10.1.1 This chapter shall apply to the performance, maintenance, and testing of electrical equipment in new and existing health care facilities.

10.3 Testing Requirements — Patient Care–Related Electrical Appliances and Equipment.

10.3.1* Physical Integrity. The physical integrity of the power cord assembly composed of the power cord, attachment plug, and cord-strain relief shall be confirmed by visual inspection.

10.3.2* Resistance.

10.3.2.1 For appliances that are used in the patient care vicinity, the resistance between the appliance chassis, or any exposed conductive surface of the appliance, and the ground pin of the attachment plug shall be less than 0.50 ohm under the following conditions:

(1) The cord shall be flexed at its connection to the attachment plug or connector.
(2) The cord shall be flexed at its connection to the strain relief on the chassis.

10.3.6* Lead Leakage Current Tests and Limits — Portable Equipment.

10.3.6.1 The leakage current between all patient leads connected together and ground shall be tested with the power plug connected normally and the device powered on.

N **10.3.6.2** The leakage current between all patient leads connected together and ground shall be measured with the ground switch open and with the ground switch closed.

10.3.6.3 An acceptable test configuration shall be as illustrated in Figure 10.3.6.3.

10.3.6.4 The leakage current shall not exceed 100 µA for ground wire closed and 500 µA ac for ground wire open.

Which agencies reference and enforce NFPA 99

- The Joint Commission
- Accreditation Commission for Health Care, Inc.
- CMS - Medicare Conditions of Participation (42 CFR 482)
- DNV
- Arizona Administrative Code - Title 9
- Texas Administrative Code - Title 25
- Other States, Cities and private organizations

Health Care Facilities Code, 2012 (NFPA 99, 2012)

States adopting the NFPA 99, 2012	With Amendments	Without Amendments
Alabama		✓
Alaska		✓
Arizona		✓
Phoenix		✓
Arkansas		✓
California		✓
Los Angeles City		✓
San Francisco		✓
Colorado		✓
Denver		✓
Connecticut		✓
Delaware		✓

https://up.codes/code/nfpa-99-health-care-facilities-code-2012

Federal Agencies

- Food & Drug Administration (FDA)
- Federal Communication Commission (FCC)
- Occupational Safety & Health Administration (OSHA)
- Nuclear Regulatory Commission (NRC)
- Centers for Medicare and Medicaid Services (CMS)

Food & Drug Administration (FDA)

- Safe Medical Devices Act (SMDA) of 1990
- Medical Device Recalls
- Blood Banks
- Title 21, 1020.30 (Reports of Assembly)
- Mammography Quality Standards Act (MQSA)

Medical Device Reporting Regulation History

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- Introduction
- Summary of MDR Regulation
- Changes Affecting the MDR Regulation (Federal Register final rule published on December 11, 1995)
    - Modernization Act Changes
- Federal Register Summaries
- Reporting Problems with Medical Devices

https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/medical-device-reporting-regulation-history

The Safe Medical Devices Act **(SMDA)** requires **user facilities to report**:

- **device-related deaths** to the FDA and the device manufacturer;
- **device-related serious injuries** to the manufacturer, or to FDA if the manufacturer is not known; and
- **submit to FDA on an annual basis** a summary of all reports submitted during that period.

Los Angeles Times

SCIENCE & MEDICINE

Shiley Heart-Valve Recipients Are Focus of Worldwide Search : Health: The Irvine firm has hired non-profit Medic Alert to track down 55,000 patients at risk of death if their implants fail.

BY LESLIE BERKMAN

JAN. 20, 1991 12 AM PT

https://www.latimes.com/archives/la-xpm-1991-01-20-fi-986-story.html

Los Angeles Times

Harms said he will lobby the FDA to allow independent registries such as Medic Alert's to satisfy the Safe Medical Devices Act of 1990 that was signed into law Nov. 28. The federal law will make manufacturers of life-sustaining implants responsible for maintaining patient registries. This will be a major task, since about 1.5 million medical devices are implanted each year in the United States alone.

Medical Device Tracking

Guidance for Industry and Food and Drug Administration Staff

Document issued on March 27, 2014.

This document supersedes Medical Device Tracking issued on January 25, 2010.

For questions about this document contact Deborah Yoder at 301-796-6109 or by electronic mail at deborah.yoder@fda.hhs.gov or contact the Division of Analysis and Program Operations at 301-796-5530.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Analysis and Program Operations

https://www.fda.gov/media/71205/download

Importance of Device Tracking

Device tracking enables FDA to require a manufacturer to **promptly identify product distribution information** and **remove a device from the market**.

Section 519(e) states the Agency may require tracking for a class II or class III devices
(A) the **failure** of which would be reasonably likely to have **serious adverse health consequences**; or
(B) which is
i. intended to be **implanted** in the human body for **more than one year**; or
ii. is a **life sustaining or life supporting device** used **outside** a device user facility.

V. Medical Devices Requiring Tracking

FDA has issued tracking orders to manufacturers of the following devices, listed in alphabetical order according to the product code – preferred name:

Product Code - Preferred Name	*Procode*
Aortic valve prosthesis, percutaneously delivered	NPT
Breast prosthesis, non-inflatable, internal, silicone gel filled	FTR
Defibrillator, auxiliary power supply (AC OR DC) for low energy DC defibrillator	MPD
Defibrillator, automated, external, wearable	MVK
Defibrillator, automatic, implantable, cardioverter, with cardiac resynchronization (CRT-D)	NIK
Defibrillator, DC, high energy (including paddles)	DRK
Defibrillator, DC, low energy (including paddles)	LDD
Defibrillator, implantable cardioverter (NON-CRT)	LWS
Defibrillator, implantable, dual chamber	MRM
Defibrillator, over-the-counter, automated, external	NSA
Defibrillators, automated external (AEDs) (non-wearable)	MKJ
Electrode, pacemaker, permanent	DTB
Electrode, pacing and cardioversion, temporary, epicardial	NHW
Electrodes, defibrillator, permanent	NVY
Electrodes, pacemaker, drug-eluting, permanent, right ventricular (RV) or right atrial (RA)	NVN
Endovascular graft system, aortic aneurysm treatment	MIH
Heart valve, mechanical	LWQ
Heart valve, non-allograft tissue	LWR
Heart valve, replacement	DYE
Mandibular prosthesis, condyle, temporary	NEI
Monitor, apnea, home use	NPF
Monitor, breathing frequency	BZQ
Pacemaker battery	DSZ
Pacemaker, lead adapter	DTD
Pacemaker, pulse generator (NON-CRT) implantable	LWP
Pacemaker, pulse generator, implantable	DXY
Pulmonary valve prosthesis, percutaneously delivered	NPV
Pulmonic valved conduit	MWH
Pulse generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)	NKE
Pulse generator, permanent, implantable	NVZ
Pulse generator, single chamber, single	LWW
Pulse generator, dual chamber, pacemaker, external	OVJ
Pulse generator, single chamber, sensor driven, implantable	LWO
Pump, infusion or syringe, extra-luminal	FIH
Pump, infusion, implanted, programmable	LKK
Shunt, protosystemic, endoprosthesis	MIR
Stimulator, autonomic nerve, implanted (depression)	MUZ
Stimulator, cerebellar, implanted	GZA
Stimulator, diaphragmatic/ phrenic nerve, implanted	GZE
Stimulator, diaphragmatic/phrenic nerve, laparoscopically implanted	OIR
Stimulator, electrical, implanted, for Parkinsonian symptoms	NHL
Temporomandibular joint, implant	LZD
Transmandibular implant	MDL
Ventilator, continuous, home use	NOU
Ventilator, continuous, non-life-supporting	MNS
Ventilator, continuous, minimal ventilatory support, facility use	MNT

Implementing the Safe Medical Devices Act in a Hospital

R. GLEN McQUIEN
MED+EQUIP Services, San Ramon, California
MARVIN SHEPHERD, P.E. (Safety)
DEVTEQ, Walnut Creek, California

Implementation of the *Safe Medical Devices Act* (SMDA) by a "medical device user facility" requires the introduction of new responsibilities, processes, and accountabilities. The complexity of a program will vary with the number of devices included, as well as the medical activities of the particular facility. The implementation of the SMDA is described in a 145-bed, acute care, county hospital, along with some of the practical problems and solutions associated with its implementation. Both the event reportability section and the tracking section of SMDA have been implemented. The greatest difficulty in the event reportability section lies in the ambiguous definitions that determine event reportability. This ambiguity may be clarified when the final regulations are published. In respect to device tracking, questions remain unanswered that relate to the manufacturer-facility interface and disposition of explanted devices.

Index Under: FDA; Safe Medical Devices Act (SMDA); User Facility, Device Tracking, Regulations;

Journal of Clinical Engineering 19(1):p 29-38, January 1994.

Feature Article

SMDA '90: User Facility Requirements of the Final Medical Device Reporting Regulation

MARVIN SHEPHERD, P.E.
DEVTEQ, Walnut Creek, California

Although major require-

The **FDA**'s Final Regulation for submitting Medical Device Reports (MDRs) of adverse incidents was published on December 11, 1995, and becomes effective on April 11, 1996. Some of the major changes include: the requirement that user facilities report user errors if an adverse event otherwise meets the requirements for reportability; the 10-day window for reporting now begins when the user facility becomes aware of the event; and a new report form is required for making semi-annual reports. FDA believes that user facilities are not required to perform device-related accident investigations; manufacturers have this

Journal of Clinical Engineering. 21(2):114-148, March-April 1996.

Classification of Recalls

FDA assigns the recall a classification (**I, II, or III**) to indicate the relative degree of **risk**.

Class I: A situation where there is a reasonable chance that a product will **cause serious health problems or death**.

Class II: A situation where a product may cause a temporary or reversible health problem or where there is a **slight chance that it will cause serious health problems or death**.

Class III: A situation where a product is **not likely to cause any health problem or injury**.

https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

FDA U.S. FOOD & DRUG ADMINISTRATION

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Medical Device Recalls

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Medical Device Recalls

- 2022 Medical Device Recalls
- 2021 Medical Device Recalls
- 2020 Medical Device Recalls

The FDA posts summaries of information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.

Use the yearly lists to find information about Class I medical device recalls and some Class II and III recalls of interest to patients. The links give details about what to do if you own or use one of these products. If you wish to find information on a recall, or a correction or removal action that has not yet been classified, you can search the Medical Device Recalls Database.

Please note that the FDA lists medical device recall notices by the date that it posts the recall rather than the recall initiation date. You can find the date that a firm initiated a recall in the text of the recall notice.

Content current as of:
08/09/2022

Regulated Product(s)
Medical Devices

Recalls

https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls

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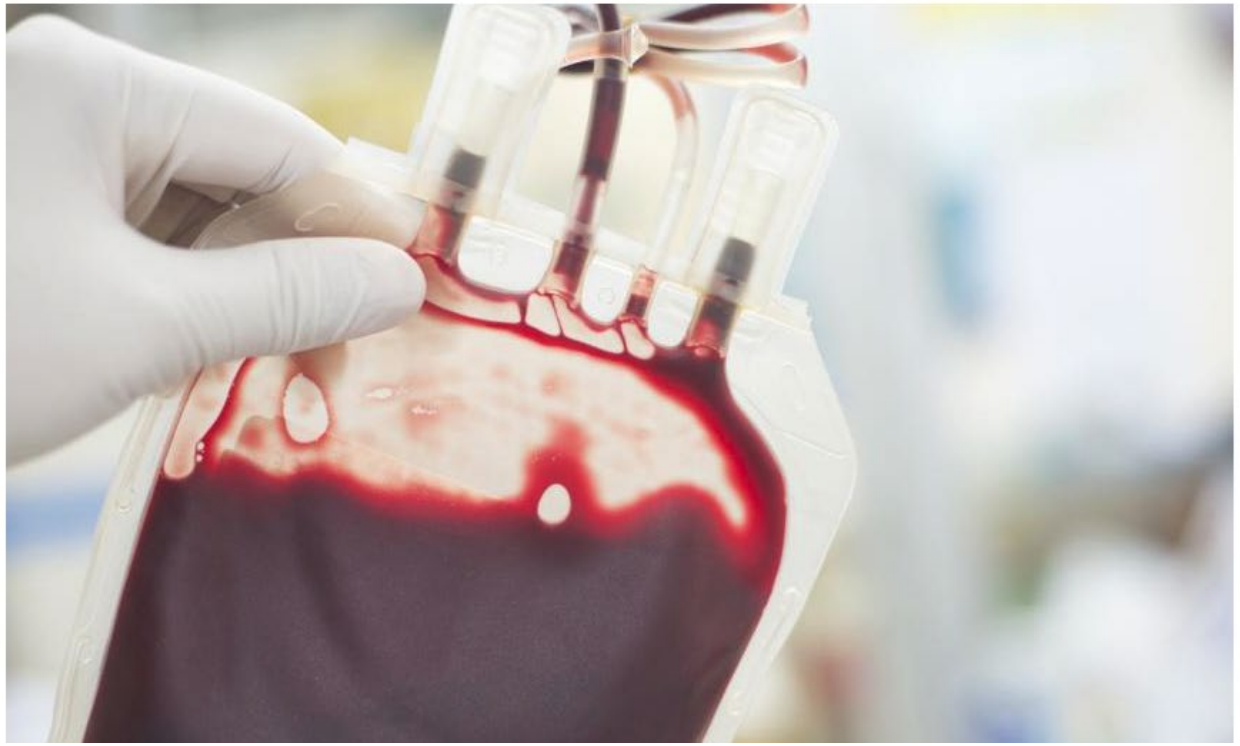
Blood Grouping and Phenotyping Reagents

Questions about Blood

Approved Blood Products

Regulation of the Blood Supply



Content current as of:
07/12/2021

Regulated Product(s)
Biologics
Blood Products

https://www.fda.gov/vaccines-blood-biologics/blood-blood-products

Blood Banks

The **Center for Biologics Evaluation and Research (CBER) regulates** the **collection of blood and blood components** used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components, such as clotting factors, and establishes standards for the products themselves.

CBER also regulates related products such as cell separation devices, blood collection containers and HIV screening tests that are used to prepare blood products or to ensure the safety of the blood supply.

CBER develops and enforces quality standards, **inspects** blood establishments and monitors reports of errors, accidents and adverse clinical events.

Blood Banks

FDA inspects all blood facilities at least every two years, and "problem" facilities are inspected more often.

All owners or operators of establishments that manufacture blood products are required to register with the FDA, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act, unless they are exempt under 21 CFR 607.65.

A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted.

[Code of Federal Regulations]
[Title 21, Volume 7]
[CITE: 21CFR606]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER F - BIOLOGICS

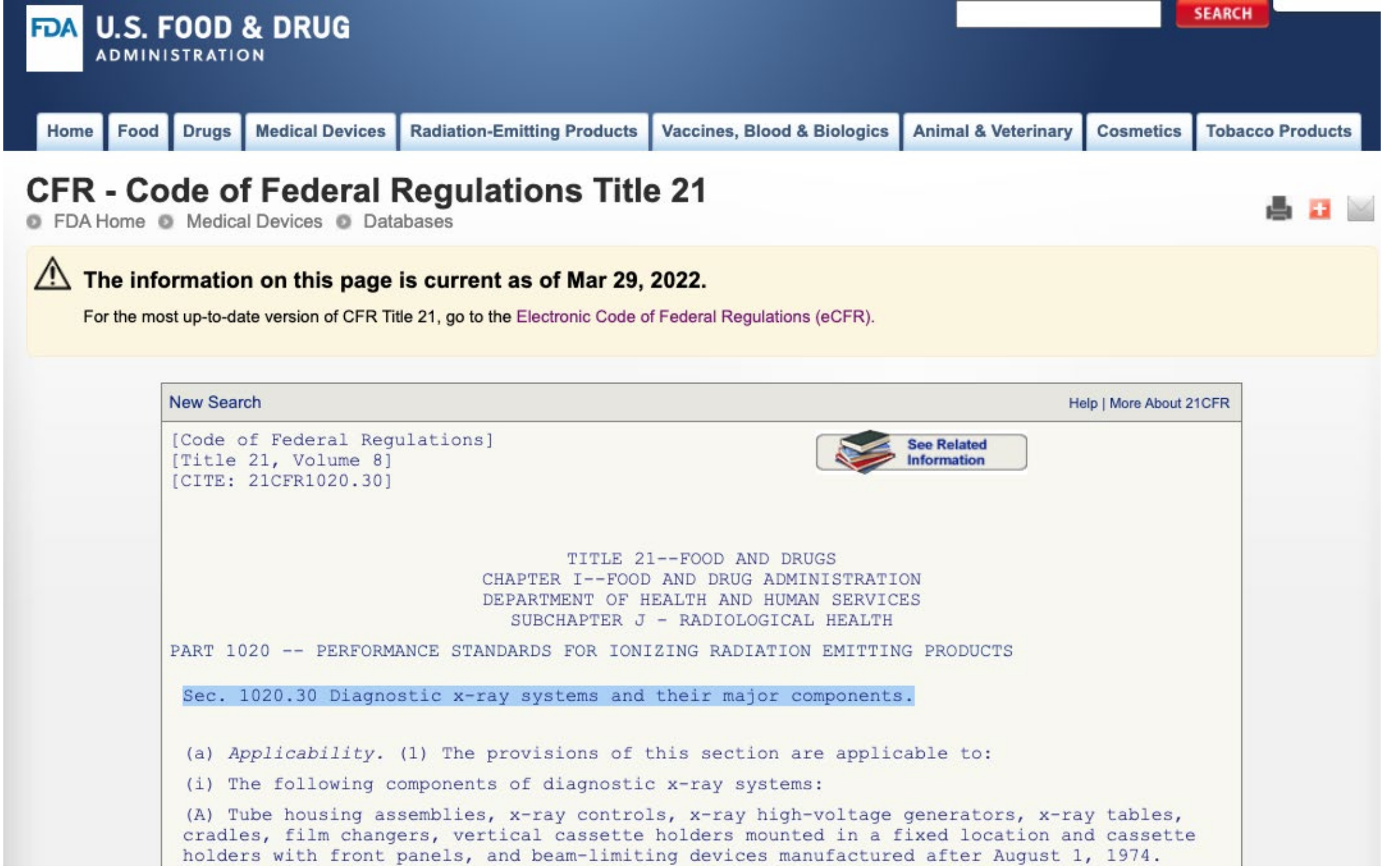
PART 606 CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

Sec. 606.60 Equipment.

(a) Equipment used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be maintained in a clean and orderly manner and located so as to facilitate cleaning and maintenance. The equipment shall be observed, standardized and calibrated on a regularly scheduled basis as prescribed in the Standard Operating Procedures Manual and shall perform in the manner for which it was designed so as to assure compliance with the official requirements prescribed in this chapter for blood and blood products.

(b) Equipment that shall be observed, standardized and calibrated with at least the following frequency, include but are not limited to:

Equipment	Performance check	Frequency	Frequency of calibration
Temperature recorder	Compare against thermometer	Daily	As necessary.
Refrigerated centrifuge	Observe speed and temperature	Each day of use	Do.
Hematocrit centrifuge			Standardize before initial use, after repairs or adjustments, and annually. Timer every 3 mo.
General lab centrifuge			Tachometer every 6 mo.
Automated blood-typing machine	Observe controls for correct results	Each day of use	
Hemoglobinometer	Standardize against cyanmethemoglobin standard	.....do	
Refractometer	Standardize against distilled water	.....do	
Blood container scale	Standardize against container of known weight	.....do	As necessary.
Water bath	Observe temperature	.....do	Do.
Rh view box	.....do	.....do	Do.
Autoclave	.....do	Each time of use	Do.
Serologic rotators	Observe controls for correct results	Each day of use	Speed as necessary.
Laboratory thermometers			Before initial use.
Electronic thermometers			Monthly.
Vacuum blood agitator	Observe weight of the first container of blood filled for correct results	Each day of use	Standardize with container of known mass or volume before initial use, and after repairs or adjustments.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For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).
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[CITE: 21CFR1020.30]
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER J - RADIOLOGICAL HEALTH
PART 1020 -- PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS
Sec. 1020.30 Diagnostic x-ray systems and their major components.
(a) Applicability. (1) The provisions of this section are applicable to:
(i) The following components of diagnostic x-ray systems:
(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

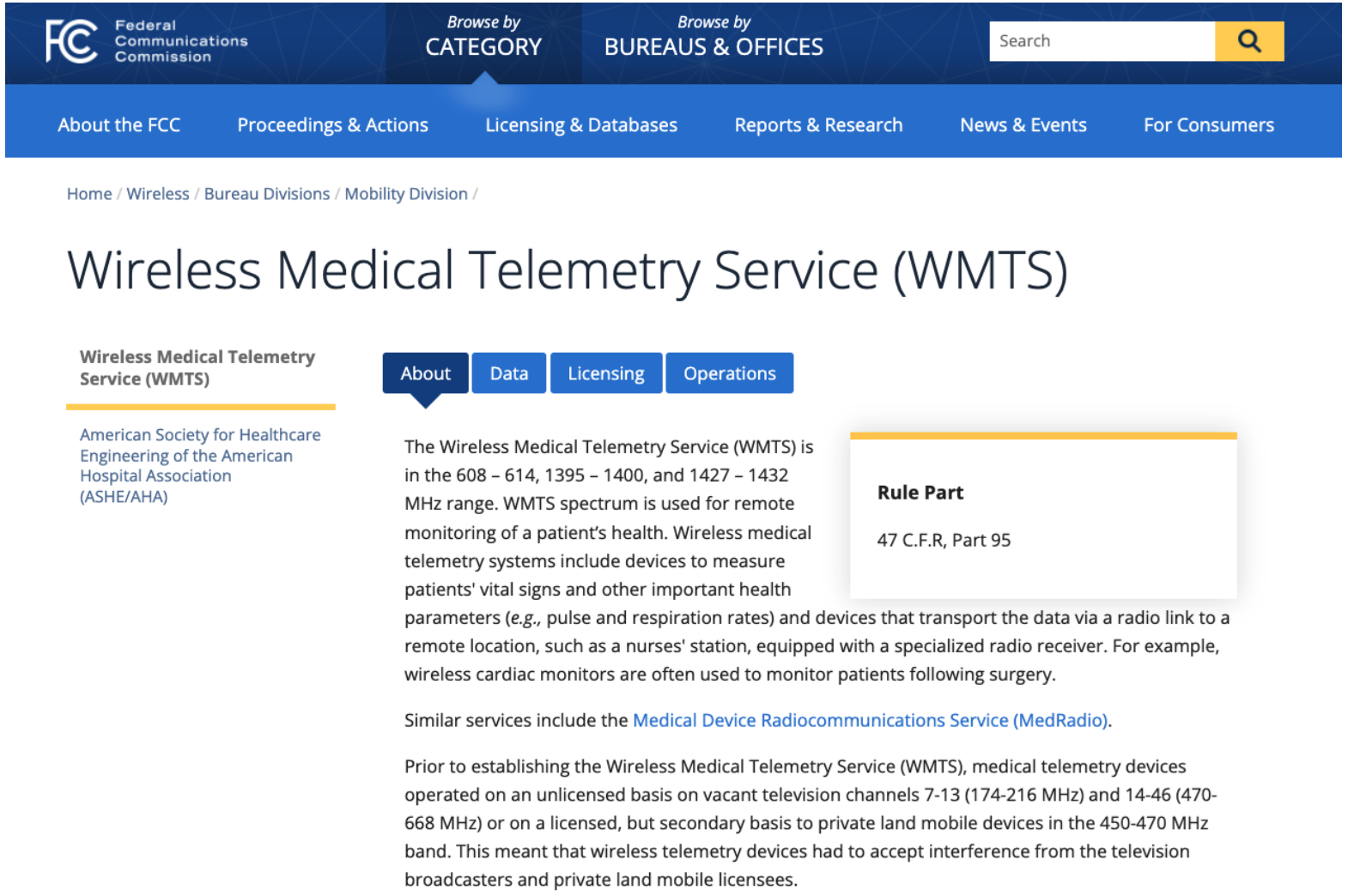
(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

Mammography Quality Standards Act (MQSA)

- Law since 1992 - establish **national quality standards for mammography**.
- All facilities must be **accredited** by an approved accreditation body.
- Each certified mammography facility to utilize the services of a **qualified medical physicist** to survey the facility's equipment and to oversee the **equipment-related quality control (QC) program** used by the facility (21 CFR 900.12(d),(e); see Attachment A).
- Each certified facility undergo an **annual** on-site physics consultation and evaluation survey performed by a qualified medical physicist.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mammography-facility-surveys-mammography-equipment-evaluations-and-medical-physicist-qualification#1

Federal Communications Commission (FCC)



https://www.fcc.gov/wireless/bureau-divisions/mobility-division/wireless-medical-telemetry-service-wmts

https://www.fcc.gov/wireless/bureau-divisions/mobility-division/wireless-medical-telemetry-service-wmts/american-society

American Hospital Association™

ASHE™

Optimizing health care facilities

Wireless Medical Telemetry Service (WMTS)

ACCE

The Federal Communications Commission (FCC) created the Wireless Medical Telemetry System (WMTS) in response to growing concerns about interference from digital television transmitters and other equipment.

The FCC dedicated bands of frequencies to promote the interference-free use of medical telemetry systems important for patient monitoring.

The FCC mandated that all WMTS transmitters be registered, and appointed ASHE as the frequency coordinator to handle registration.

ASHE and its technical partner Comsearch provide frequency coordination services and device registration.

https://www.ashe.org/wmts

comsearch
A CommScope Company

ASHE
Optimizing health care facilities

WMTS

Wireless Medical Telemetry Service
Frequency Coordination System

User Information Guide
v11

March 2022

https://www.ashe.org/system/files/media/file/2022/03/wmts-user-guide.pdf

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AMERICAN COLLEGE OF CLINICAL ENGINEERING

Occupational Safety and Health Administration

OSHA's Mission

With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for workers by setting and enforcing standards and by providing training, outreach, education and assistance

OSHA is part of the United States Department of Labor.

OSHA Coverage

The OSH Act covers most private sector employers and their workers, in addition to some public sector employers and workers in the 50 states and certain territories and jurisdictions under federal authority.

https://www.osha.gov/aboutosha

UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety and Health Administration

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OSHA Laws & Regulations / OSH Act of 1970

OSH Act of 1970

Table of Contents | General Duty Clause | Complete OSH Act Version ("All-in-One")

SEC. 5. Duties

(a) Each employer --

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

29 USC 654

(2) shall comply with occupational safety and health standards promulgated under this Act.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct.

OSHA's quarterly occupational limits for radiation exposures (adult)

1910.1096(b)(1)

Except as provided in paragraph (b)(2) of this section, no employer shall possess, use, or transfer sources of ionizing radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from sources in the employer's possession or control a dose in excess of the limits specified in Table G-18:

TABLE G-18

	Rems per calendar quarter
Whole body: Head and trunk; active blood-forming organs; lens of eyes; or gonads	1 1/4
Hands and forearms; feet and ankles	18 3/4
Skin of whole body	7 1/2

29 CFR 1910.1096

REM

In radiation protection, the rem (an abbreviation for Roentgen Equivalent Man) is the non-SI unit of the equivalent dose, which is used predominantly in the USA.

The rem represents the equivalent biological effect of the deposit of one hundred ergs (one rad) of gamma rays energy in a kilogram of human tissue.

https://www.radiation-dosimetry.org/what-is-roentgen-equivalent-man-rem-unit-definition/

U.S. Nuclear Regulatory Commision (NRC)

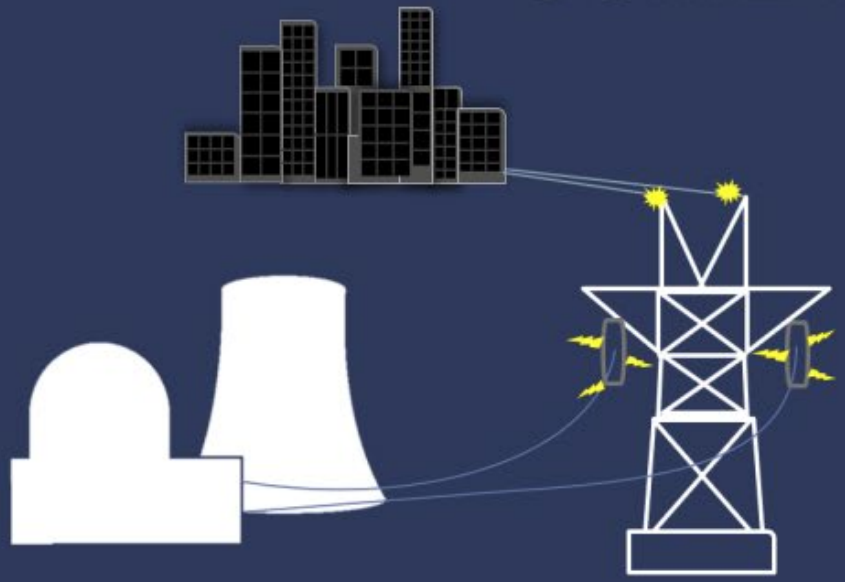
The U.S. Nuclear Regulatory Commission (NRC) was created as an independent agency by Congress in 1974 to ensure the **safe use of radioactive materials** for beneficial civilian purposes while protecting people and the environment.

The NRC regulates commercial nuclear power plants and other uses of nuclear materials, such as in nuclear medicine, through licensing, inspection and enforcement of its requirements.

https://www.nrc.gov/docs/ML2000/ML20003E672.pdf

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

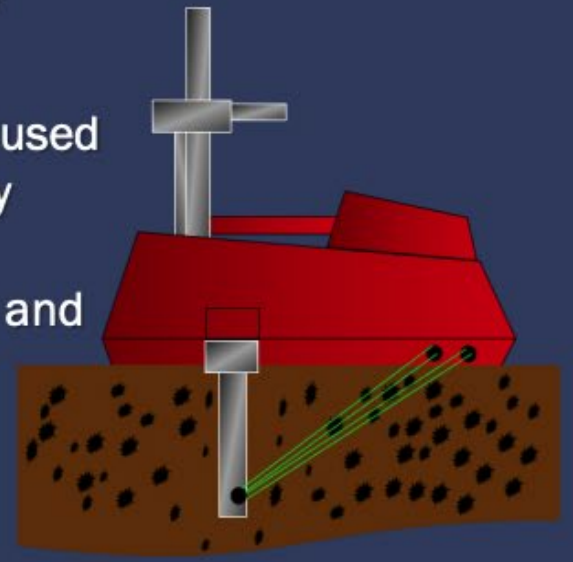
SOME NUCLEAR FACTS



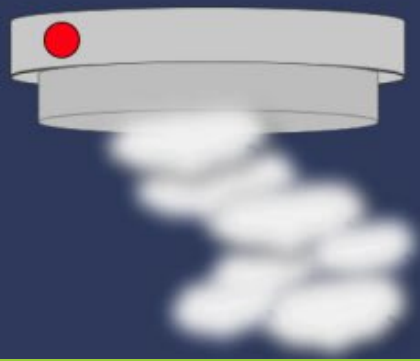
- Commercial nuclear power plants supply about 20 percent of electricity in the U.S.

- Nuclear materials are used in medicine for cancer treatment and diagnosis.

- Nuclear materials are widely used in industry, such as in density gauges, flow measurement devices, radiography devices and irradiators.



- Small amounts of radioactive material are used in common items such as smoke detectors, exit signs and some watches.

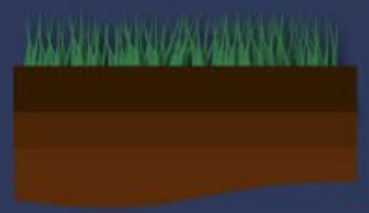


10

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

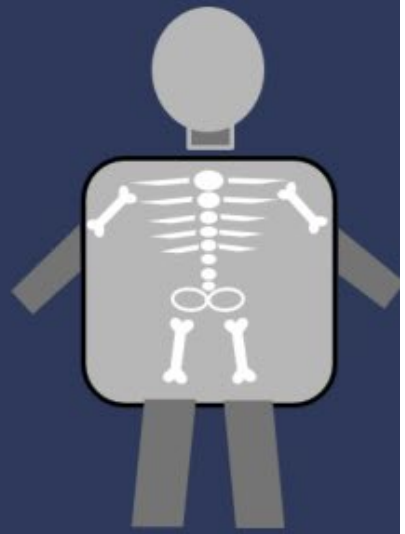
SOME RADIATION FACTS

Radiation occurs naturally in the soil, air and water.



The average person in the U.S. is exposed to about 620 millirem of radiation a year. Half of that exposure comes from natural sources (also called background radiation.)

The other half largely comes from nuclear medical exams and treatments.



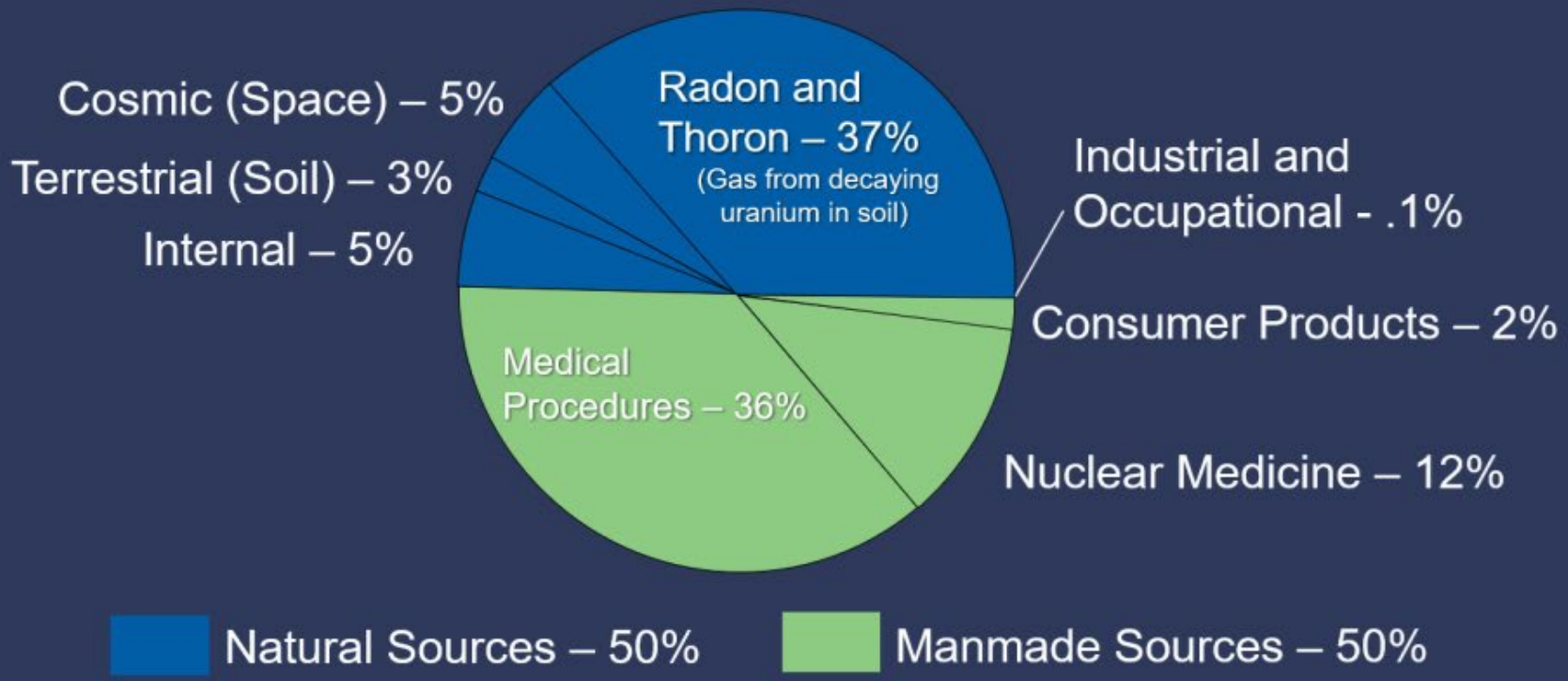
11

ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SOME RADIATION FACTS

Sources of Radiation Exposure in the United States



Source: NCRP Report No. 160 (2009)
www.NCRPpublications.org

12

Clinical Laboratory Improvement Amendments (CLIA)

US Congress passed the CLIA in 1988 as Public Law 100-578 to ensure the accuracy and reliability of all laboratory testing. CLIA establishes uniform quality standards for laboratories and applies to all entities that perform tests on human specimens.

The tests commonly performed in laboratories regulated under CLIA are tests on blood, urine, and other samples to detect cancer, HIV, diabetes, and other diseases.

The **Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing** (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).

CLIA covers approximately 330,000 laboratory entities.

https://24x7mag.com/standards/regulations/jc-laboratory-accreditation-program/

§ 493.1254 Standard: Maintenance and function checks.

(a) ***Unmodified manufacturer's equipment, instruments, or test systems.*** The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

(b) ***Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer.*** The laboratory must do the following:

(1)

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

(2)

(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

National Council on Radiation Protection and Measurements (NCRP)

Chartered by the U.S. Congress in 1964 as the National Council on Radiation Protection - Public Law 88-376

Report No. 147 (2004) presents recommendations and technical information related to the design and installation of structural shielding for facilities that use x rays for medical imaging.

1. Introduction and Recommendations

1.1 Purpose and Scope

The purpose of radiation shielding is to limit radiation exposures to employees and members of the public to an acceptable level. This Report presents recommendations and technical information related to the design and installation of structural shielding for facilities that use x rays for medical imaging. This information supersedes the recommendations in NCRP Report No. 49 (NCRP, 1976) pertaining to medical diagnostic x-ray facilities. It includes a discussion of the various factors to be considered in the selection of appropriate shielding materials and in the calculation of barrier thicknesses. It is mainly intended for those individuals who specialize in radiation protection; however, this Report also will be of interest to architects, hospital administrators, and related professionals concerned with the planning of new facilities that use x rays for medical imaging.

2. Fundamentals of Shielding for Medical X-Ray Imaging Facilities

Medical x-ray imaging - consists of primary and secondary radiation.

Primary radiation, also called the **useful** beam, is radiation emitted directly from the x-ray tube that is used for patient imaging. A primary barrier is a wall, ceiling, floor or other structure that will intercept radiation emitted directly from the x-ray tube. Its function is to attenuate the **useful beam** to appropriate shielding design goals.

Secondary radiation consists of x rays **scattered from the patient and other objects** such as the imaging hardware and leakage radiation from the protective housing of the x-ray tube. A secondary barrier is a wall, ceiling, floor or other structure that will intercept and attenuate **leakage and scattered radiations** to the appropriate shielding design goal.

Primary and secondary radiation exposure to individuals depends primarily on the following factors:

- the **amount** of radiation produced by the source
- the **distance** between the exposed person and the source of the radiation
- the amount of **time** that an individual spends in the irradiated area
- the amount of **protective shielding** between the individual and the radiation source

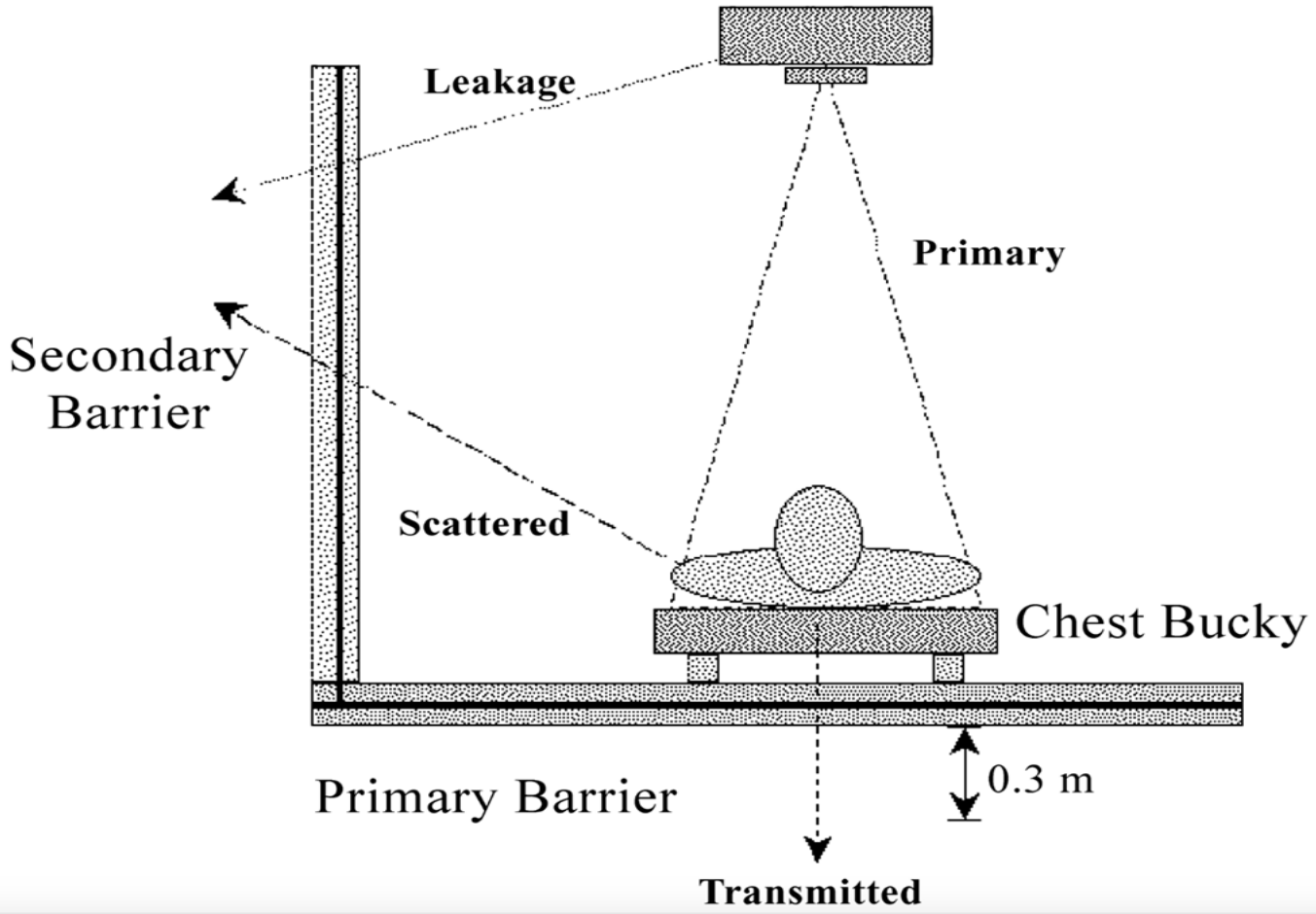
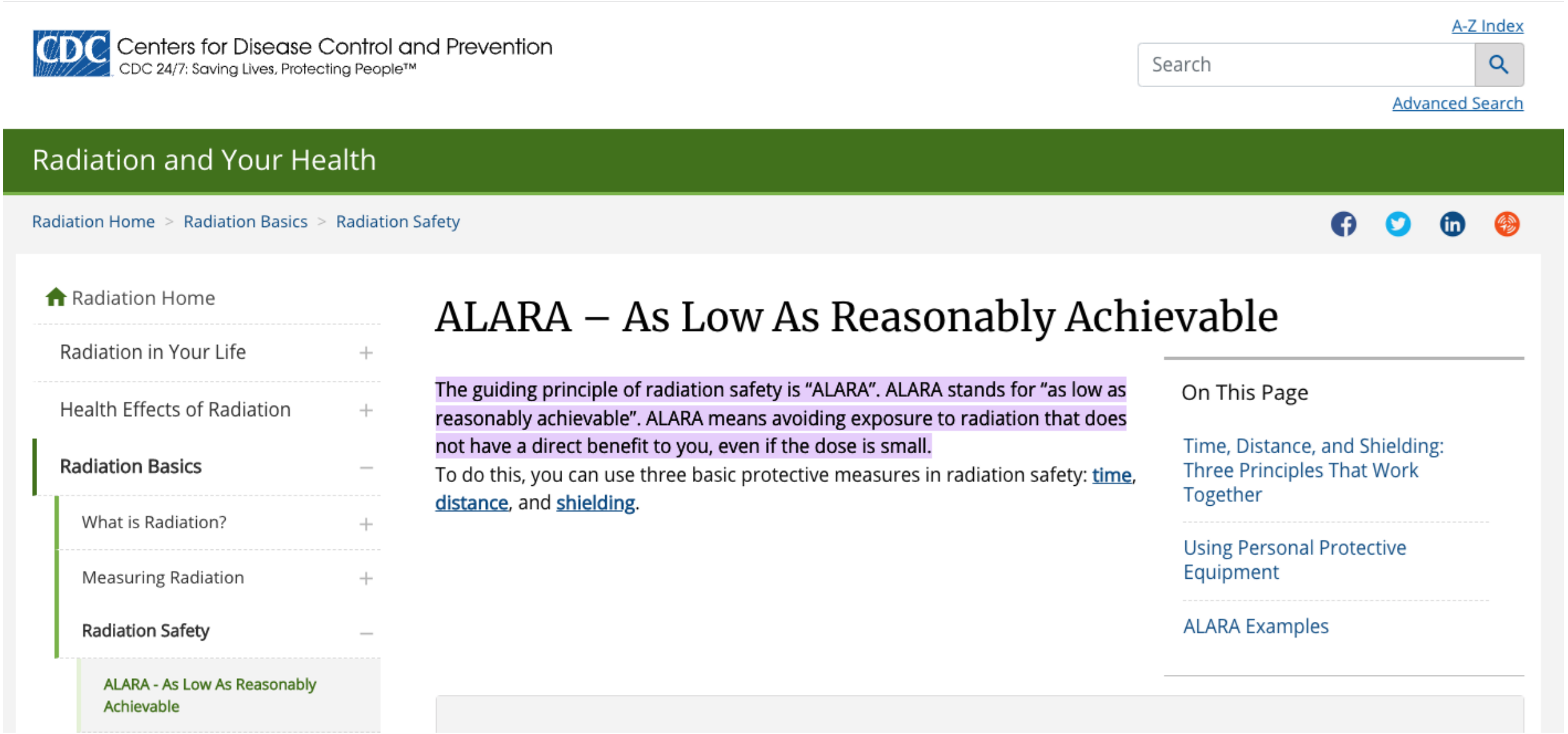
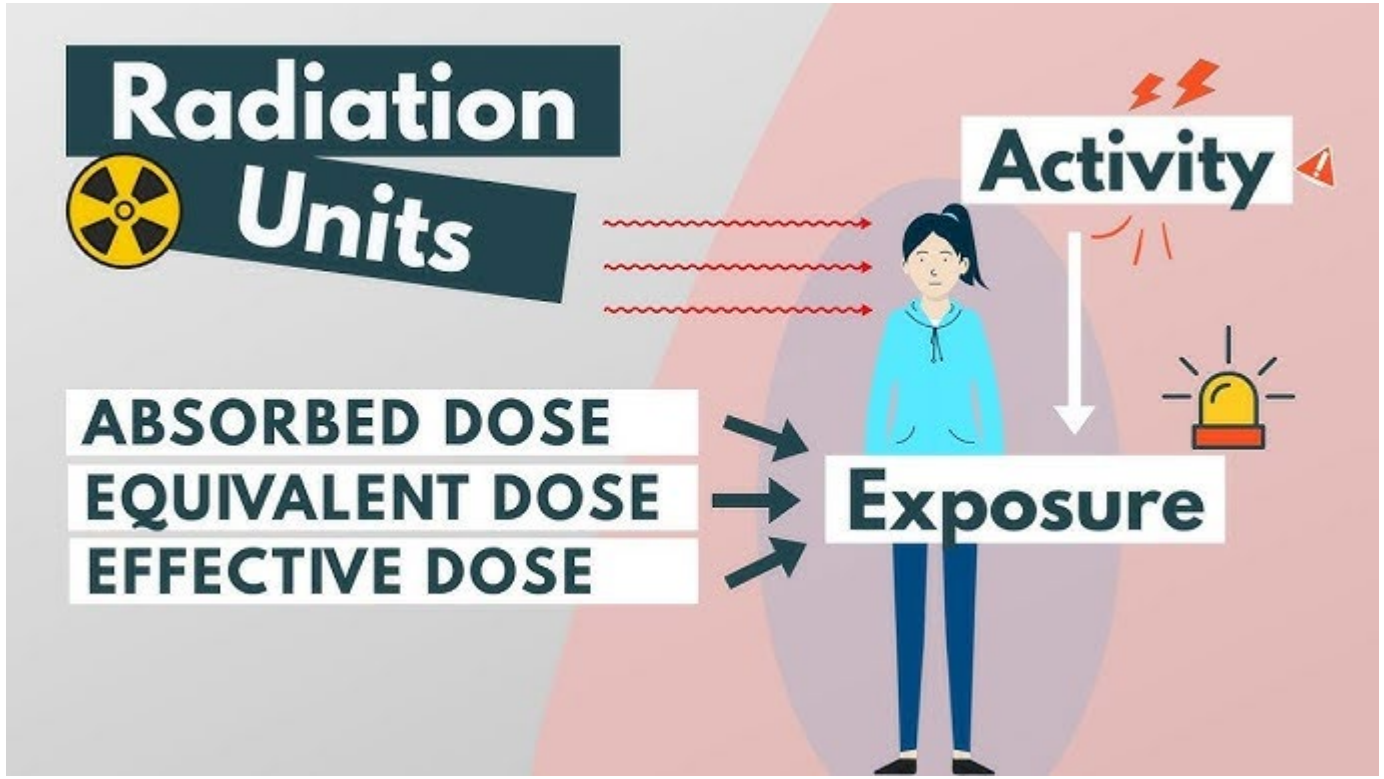


Figure 2.1 illustrates primary, scattered, leakage and transmitted radiation in a typical radiographic room.



https://www.cdc.gov/nceh/radiation/alara.html#:~:text=The%20guiding%20principle%20of%20radiation,if%20the%20dose%20is%20small.



Measuring Radiation Exposure: What is a Sievert? - YouTube

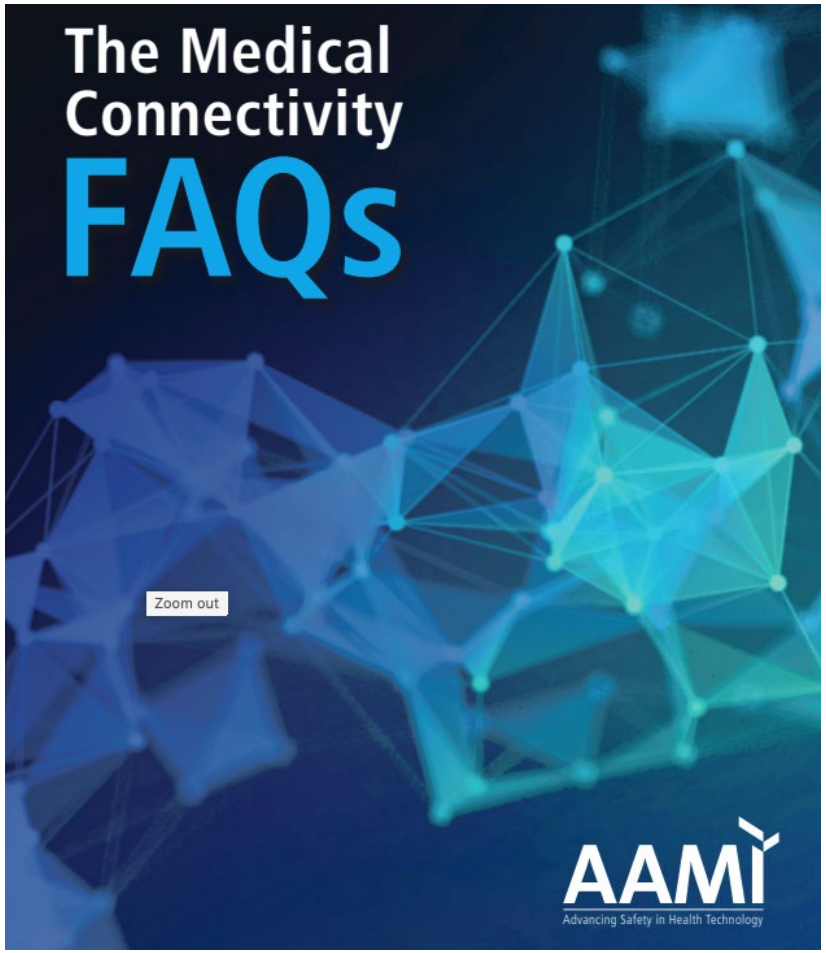
Imaging procedures and their approximate effective radiation doses*

Procedure	Average effective dose (mSv)	Range reported in the literature (mSv)
X-ray, panoramic dental	0.01	0.007–0.09
X-ray, chest	0.1	0.05–0.24
Mammogram	0.4	0.10–0.6
CT, chest	7	4.0–18

*The actual radiation exposure depends on many things, including the device itself, the duration of the scan, your size, and the sensitivity of the tissue being targeted.

Mettler FA, et al. "Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog," *Radiology* (July 2008), Vol. 248, pp. 254–63.

Clinical Systems Networking



https://www.aami.org/docs/default-source/aami-papers/medicalconnectivitypdf.pdf?sfvrsn=5b41fbed_2

The Medical Connectivity FAQs

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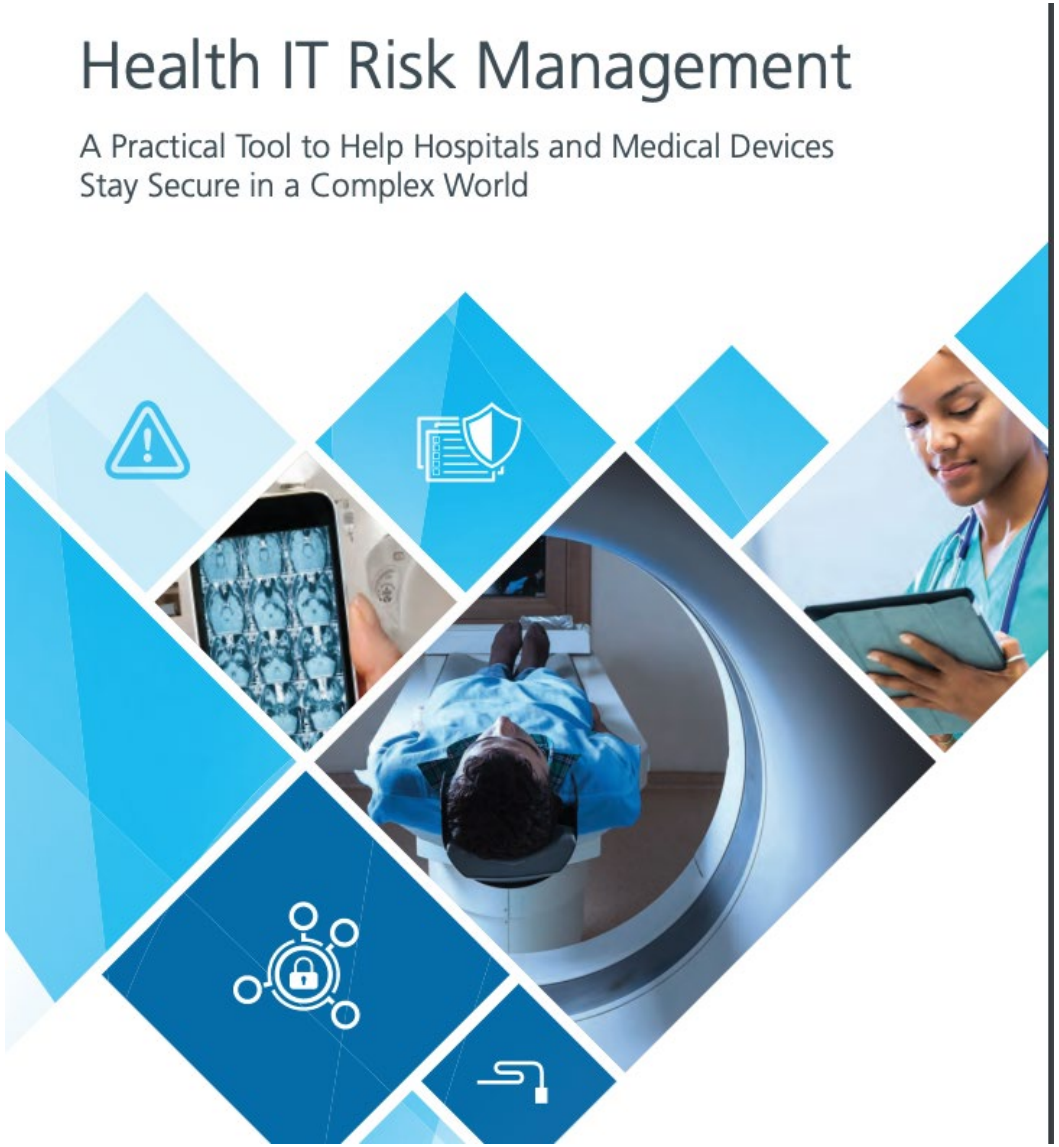


https://www.aami.org/docs/default-source/aami-papers/health_it_risk_management.pdf

BEST PRACTICES

Building a Reliable Wireless Medical Device Network

David Hoglund and Vince Varga

This paper focuses on the clinical, technical and financial benefits of using the enterprise wireless local area network (WLAN) for all patient monitoring, including bedside/transport and telemetry, hospital-wide. It describes the best industry practices for the initial design, testing, and enterprise deployment of a WLAN-enabled patient monitoring solution.

https://www.draeger.com/Products/Content/wifi-monitoring-wp-9068680-en-us.pdf

Coordinating Device Interoperability/Interfacing

Medical Device Interoperability

What is Medical Device Interoperability?

Medical device interoperability is the ability to safely, securely, and effectively exchange and use information among one or more devices, products, technologies, or systems.

This exchanged information can be used in a variety of ways including display, store, interpret, analyze, and automatically act on or control another product.

https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability#:~:text=What%20is%20Medical%20Device%20Interoperability,products%2C%20technologies%2C%20or%20systems

As electronic medical devices become increasingly connected to each other and to other technologies, the ability of connected systems to safely, securely and effectively exchange and use the information becomes critical.

Interoperable devices with the ability to share information across systems and platforms can:

- Improve patient care,
- Reduce errors and adverse events,
- Encourage innovation, and
- Enable more diverse study datasets.

Lab demo of the multi-modality system concept

Watch the video to learn more about how interoperability concepts based on SDC could help to improve ICU patient care in an isolation room.

Play video

Disclaimer

Disclaimer: The displayed solutions are for demonstration purposes only, are not for clinical use. They are not commercially available and their future availability can't be guaranteed.

https://youtu.be/mB3Byaix_tc

SDC standard

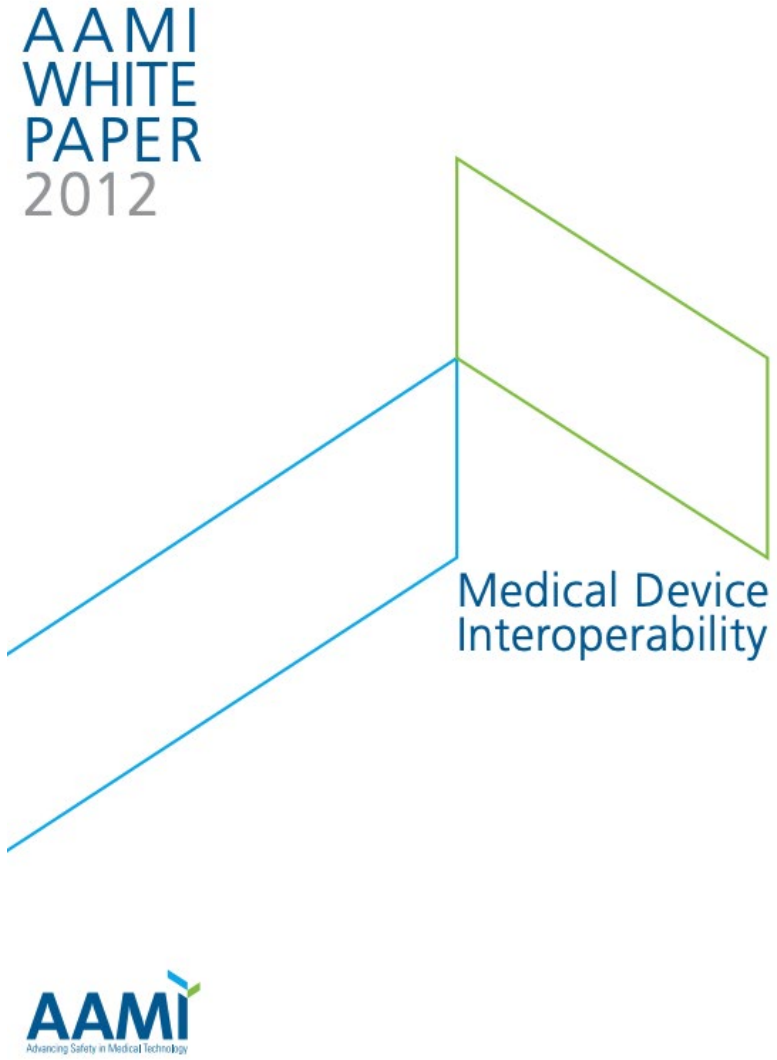
The standard "IEEE 11073-20702 – Health informatics – Point-of-care medical device communication Part 20702: Medical Devices Communication Profile for Web Services" (short "Medical DPWS" or "MDPWS") ensures basic interoperability between medical devices. MDPWS enable the secure exchange of data in distributed systems and the dynamic finding of networking partners. The standard is derived from the OASIS standard Devices Profile for Web Services (DPWS). MDPWS defines extensions and restrictions to meet the security requirements of networked medical devices.

IEEE 11073-20702-2016 – IEEE Standard for Health informatics–Point-of-care medical device communication Part 20702: Medical Devices Communication Profile for Web Services

Link: https://standards.ieee.org/standard/11073-20702-2016.html

SDC

SERVICE-ORIENTED DEVICE CONNECTIVITY



https://webstore.ansi.org/Documents/Medical-Device-Interoperability.pdf

Cybersecurity

Cybersecurity concerns rise along with the increasing medical device interoperability

All legally-marketed medical devices have benefits and risks.

FDA clears, authorizes, and approves devices to be marketed when there is a reasonable assurance that the devices are safe and effective for their intended use.

Medical devices are increasingly connected to the *Internet, hospital networks, and other medical devices* to provide features that improve health care and increase the ability of health care providers to treat patients.

https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity

Cybersecurity

These same features also increase *potential cybersecurity risks*.

Medical devices, like other computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device.

Threats and vulnerabilities cannot be eliminated and reducing cybersecurity risks is especially challenging.

Health care environment is complex, and manufacturers, hospitals, and facilities must work together to manage cybersecurity risks.

https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity

Manufacturer Disclosure Statement for Medical Device Security

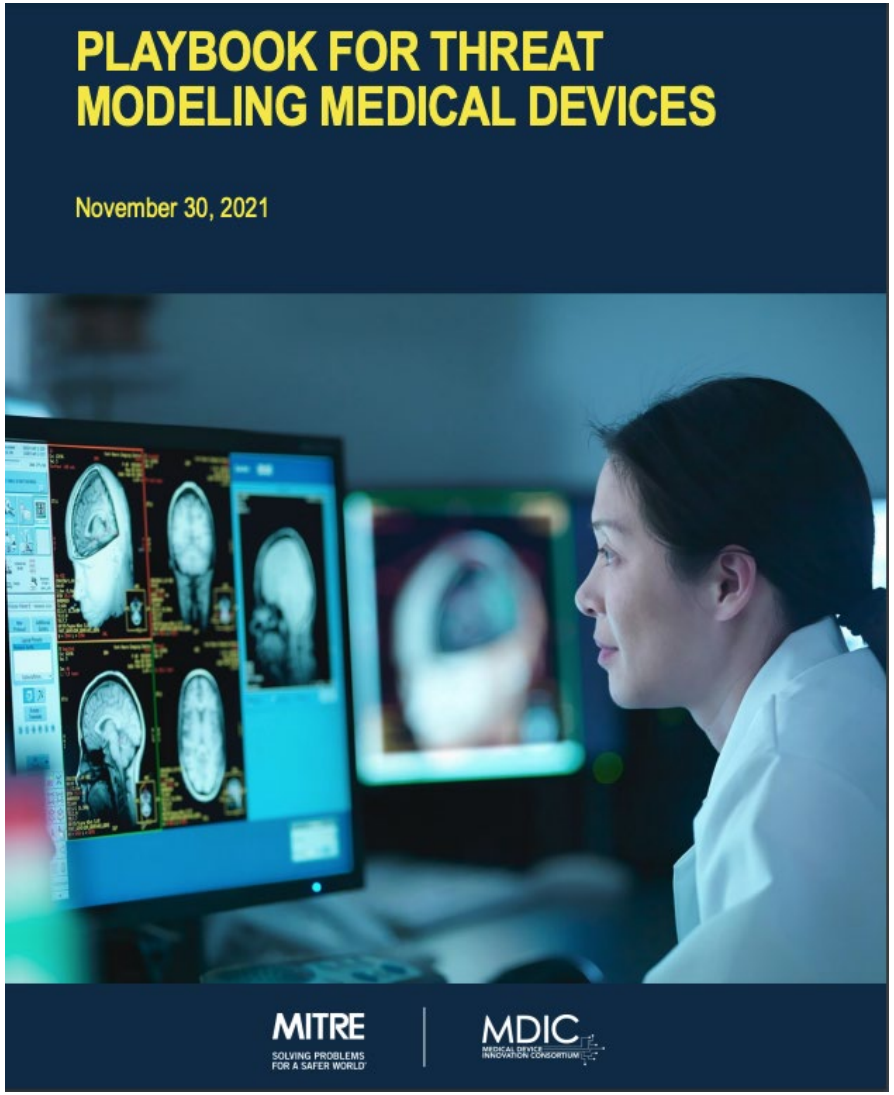
The *Manufacturer Disclosure Statement for Medical Device Security* (MDS^2) is a standardized form intended to be filled out by medical device manufacturers to communicate information about their devices' security and privacy characteristics to current device owners and potential buyers, typically healthcare delivery organizations.

Manufacturers provide the form upon request.

Information contained in the MDS^2 can aid your facility in the device procurement process as well as in risk management.

Getting the Most Out of the MDS2 Form. Published by ECRI

https://www.nema.org/standards/view/manufacturer-disclosure-statement-for-medical-device-security



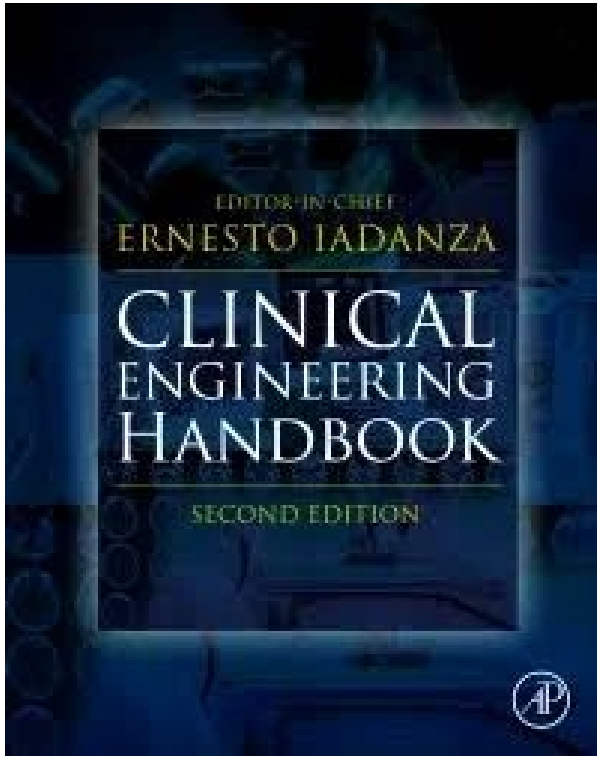
https://www.mitre.org/sites/default/files/publications/Playbook-for-Threat-Modeling-Medical-Devices.pdf

Chapter 81

The integration and convergence of medical and information technologies

Theodore Cohen

Clinical Engineering, UC Davis Health, Fair Oaks, CA, United States



Medical device interoperability

Medical device interoperability refers to information sharing from one device to another or between devices and EHRs. The West Health Institute (West Health Institute, 2013) defined medical device interoperability as:

… the ability for clinical medical devices to communicate in a consistent, predictable, and reliable way, allowing for the exchange of, and interaction with, data from other medical devices and with patient data sources and repositories, such as electronic health records (EHRs), in order to enhance device and system functionality.

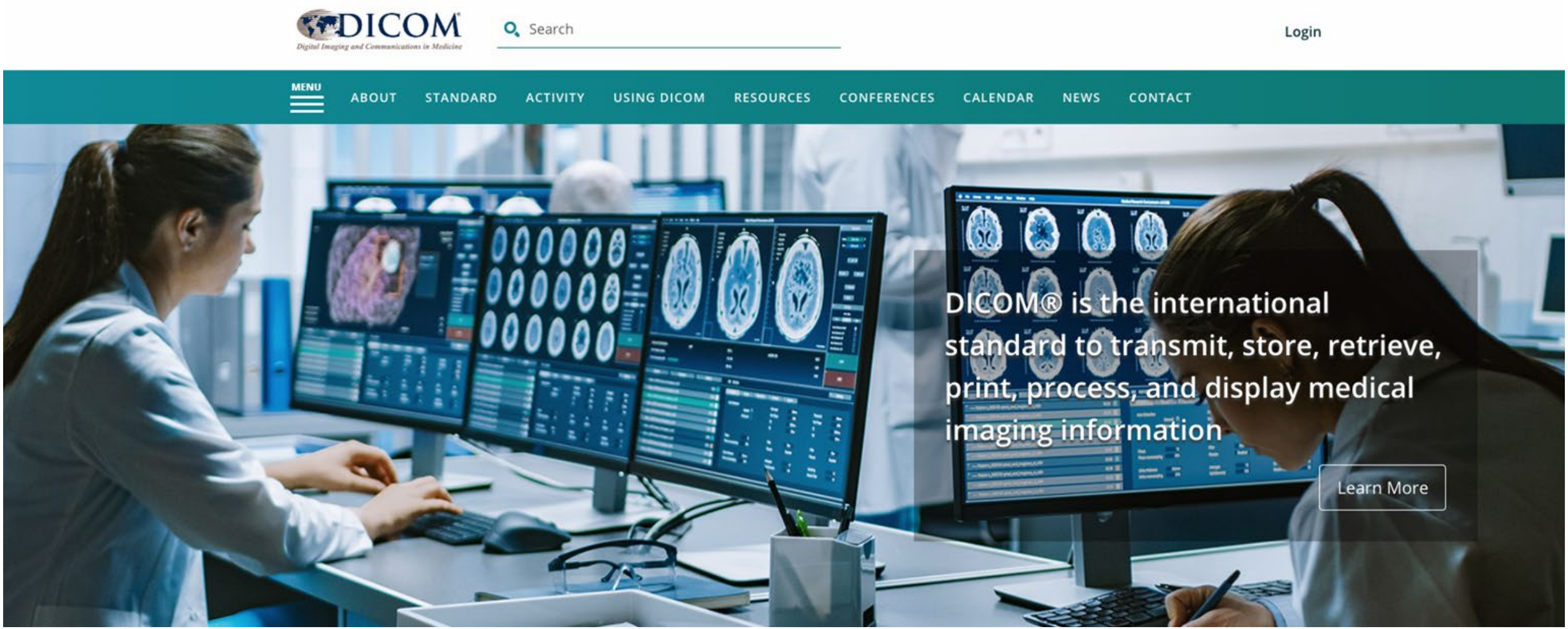
Data from many different types of medical devices have been integrated with the EHR including physiological monitors, vital sign monitors, ECG machines, infusion pumps, EEG devices, ventilators, anesthesia machines, and dialysis machines. Medical device interoperability facilitates the communication of test results and vital signs readings to clinicians.

It automates the integration of relevant information to inform ordering decisions, thus reducing ordering errors stemming from lack of patient information. Interoperability can address transcription and administrative errors by allowing EHRs, and integrated devices, to communicate in a quasi-seamless manner.

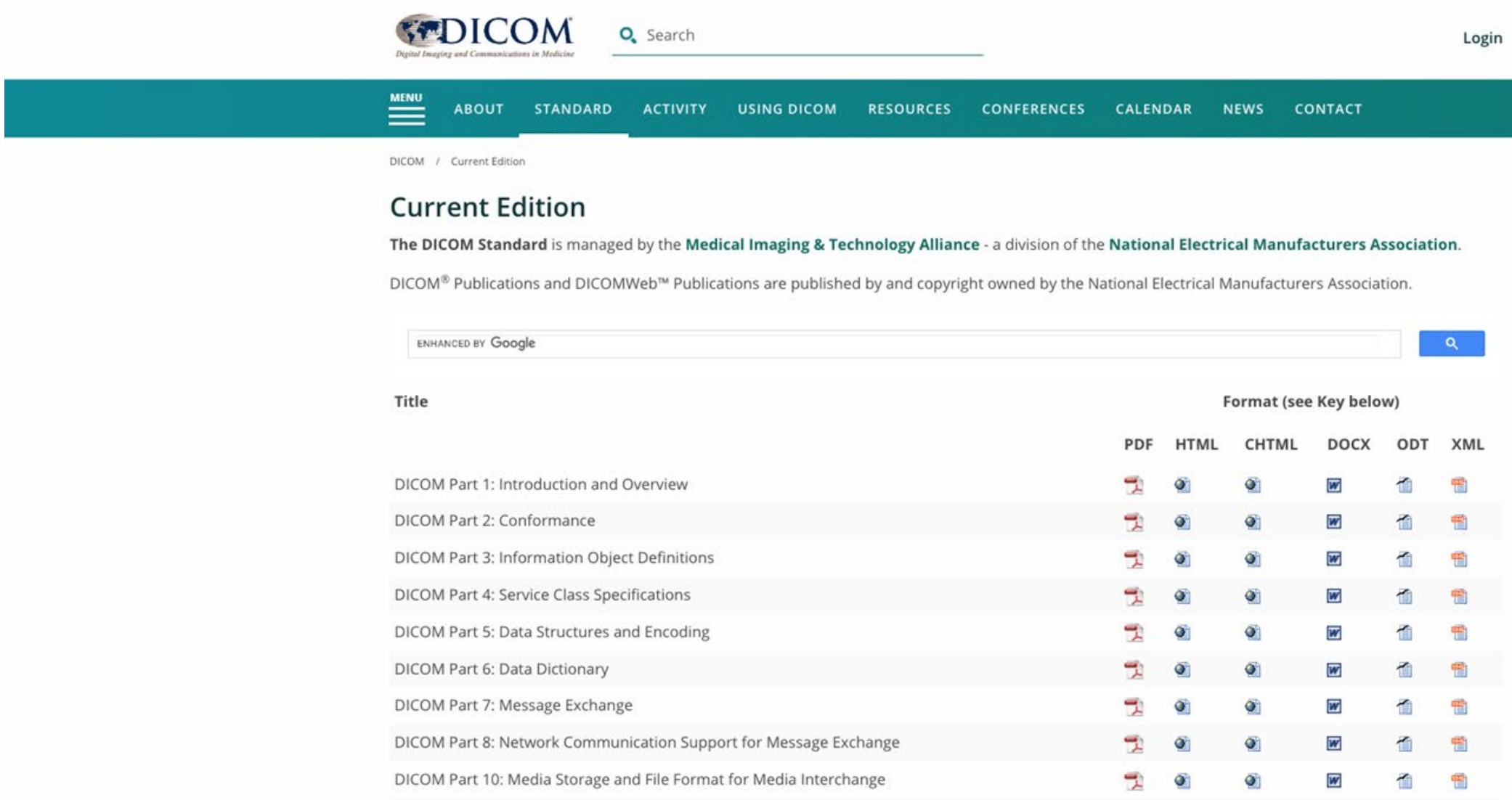
Interface standards

Since most medical device integration is between device(s) and the EHR, most frequently provided by different companies, standards need to be in place in order for these systems to communicate. The most common standard used for nonimaging data transfer is HL-7.

HL-7 is an international, nonprofit standards organization that provides a framework, and related standards, for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one system to another, setting the language, structure, and data types required for integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and products.



https://www.dicomstandard.org/


DICOM
Digital Imaging and Communications in Medicine
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ENHANCED BY Google
Title
Format (see Key below)
PDF
HTML
CHTML
DOCX
ODT
XML
DICOM Part 1: Introduction and Overview
DICOM Part 2: Conformance
DICOM Part 3: Information Object Definitions
DICOM Part 4: Service Class Specifications
DICOM Part 5: Data Structures and Encoding
DICOM Part 6: Data Dictionary
DICOM Part 7: Message Exchange
DICOM Part 8: Network Communication Support for Message Exchange
DICOM Part 10: Media Storage and File Format for Media Interchange

Clinical Device Use and/or Application

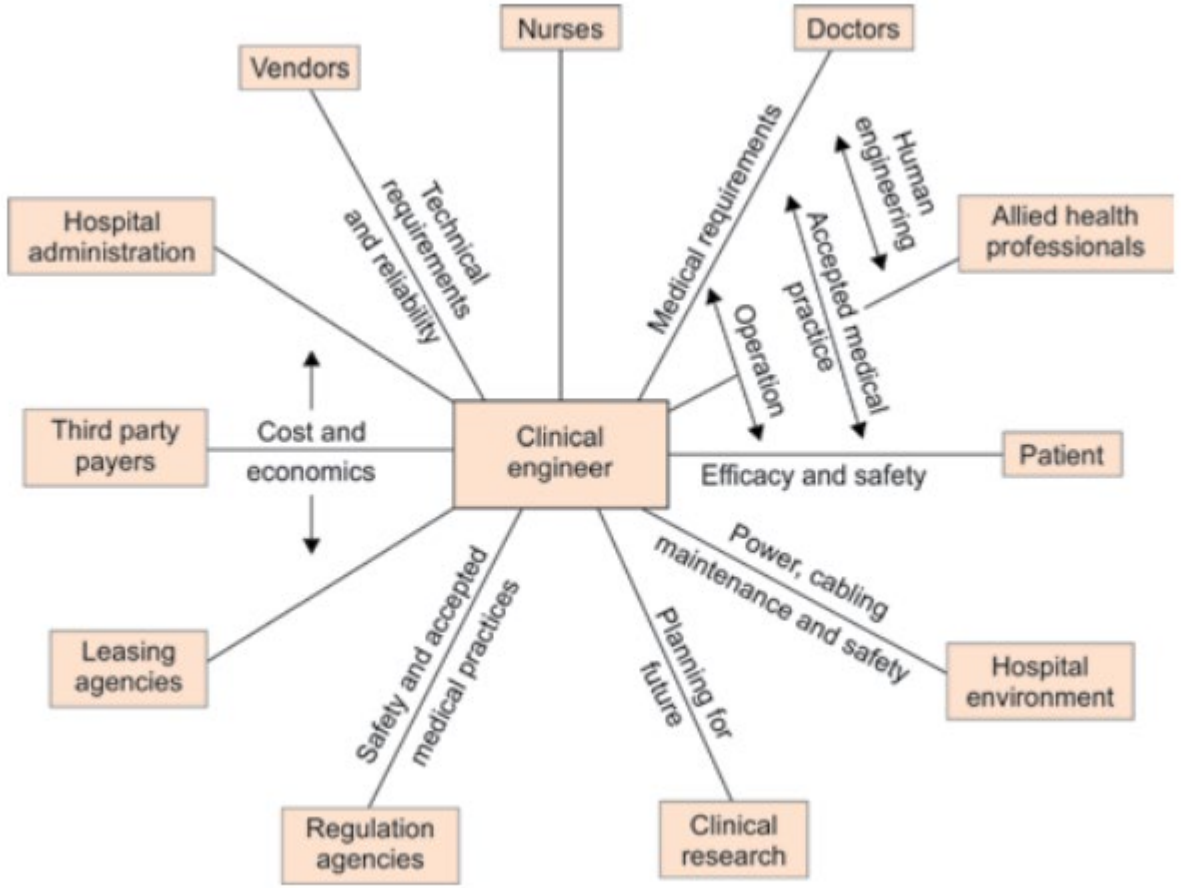


Fig. 1: Diagram illustrating the range of interactions in which a clinical engineer might be required to engage in a hospital setting

JRFHHA

10.5005/jp-journals-10035-1049

REVIEW ARTICLE

Planning and Designing of Clinical Engineering Department in a Hospital

[1]Madhav Madhusudan Singh, [2]Saroj Kumar Patnaik, [3]Pradeep Srivastva, [4]Harish K Satia, [5]Mahavir Singh

- Learning about the clinical application of the medical equipment
- What procedure is performed with equipment (anesthesia machine, ventilator, ESU, pacemaker, etc.)
- How are commonly used medical equipment used (Defibrillators, VSMs, CT, Surgical Robot, etc.)
- What is the perspective of the User (radiologist, RT, nurse, cardiologist, …)

- Learn what the output of the device means to the clinician (temperature, vital signs, EKGs, lab tests, images of CT/MRI/Mammography, etc.).

- Knowing the key players in the clinical area (RT in Resp, Anesthesiologist and Surgeon in OR, Interventional Radiologist in IR, etc.).

- Wide knowledge - ability to learn quickly.

- Manufacturer's website, Specifications, Videos, etc.

Clinicians are considering the use of anesthesia machines for patient ventilation - what is your role as a CE?

Differences between and anesthesia machine and ventilator
https://www.youtube.com/watch?v=ufaGUPs2fHo

APSF/ASA Guidance on Purposing Anesthesia Machines as ICU Ventilators

https://www.asahq.org/in-the-spotlight/coronavirus-covid-19-information/purposing-anesthesia-machines-for-ventilators

Off-Label Use of Anesthesia Machine
https://www.gehealthcare.com/-/jssmedia/gehc-anesthesia-covid-19-off-label-anesthesia-for-icu-ventilation-doc2379115-2020-3-23.pdf?rev=-1&hash=DE894991A129651A747CA13B361FD632

GUIDANCE DOCUMENT

Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

MARCH 2020

Download the Final Guidance Document

Final

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus

Hospital wants to open a swing space for Covid/non-Covid patients - what is your role as a CE?

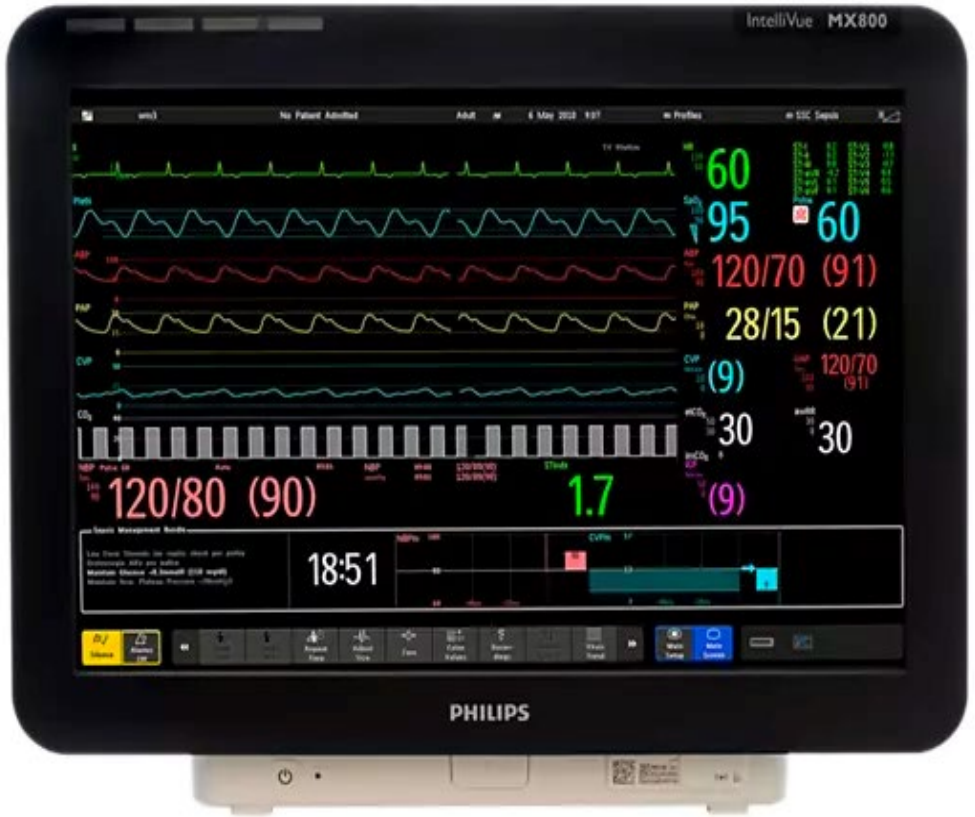
https://apps.who.int/iris/bitstream/handle/10665/336745/WHO-2019-nCoV-MedDev-TS-O2T.V2-eng.pdf?sequence=1&isAllowed=y

Hospital wants to open a swing space for Covid/non-Covid patients - what is your role as a CE?

"In response to the global pandemic crisis and the need for a model reference list of basic and priority medical devices required for the COVID-19 response, this project was developed by the World Health Organization (WHO), following the latest available evidence on COVID-19 clinical management and infection prevention and control (IPC)."

https://apps.who.int/iris/bitstream/handle/10665/336745/WHO-2019-nCoV-MedDev-TS-O2T.V2-eng.pdf?sequence=1&isAllowed=y

Hospital wants to set up temporary patient monitoring - what is your role as a CE?



Water Quality Management

Reducing Risk from Water

Water is the foundation of life; because of that, *wet environments pose a particular hazard of infection*, promoting microbial growth and serving as a source for antibiotic resistant pathogens, and healthcare-associated infections.

Tap water meets stringent safety standards in the United States, but it is not sterile. Certain numbers and types of bacteria and other microbes may be present when water leaves the tap. For typical household uses such as washing, bathing, drinking and food preparation, these microbes rarely pose a serious health risk.

sterile - free from bacteria or other living microorganisms; totally clean

https://www.cdc.gov/hai/prevent/environment/water.html

NATIONAL

Parts of Mississippi's capital remain without running water

Updated August 30, 2022 · 7:45 PM ET

THE ASSOCIATED PRESS

JACKSON, Miss. — Mississippi's capital city is grappling with multiple water problems — too much on the ground after heavy rainfall in the past week, and not enough safe water coming through the pipes for people to use.

Flint

Group will test 100 locations in Flint amid new concerns about water quality

Published: Sep. 01, 2022, 3:30 p.m.

Reducing Risk from Water

In contrast, in healthcare settings, the ways we use water are **more varied and patients might be more vulnerable to infection**.

Certain conditions within healthcare plumbing systems can even encourage microbial growth. This can lead to dangerously high levels of potential pathogens.

Moreover, the risk does not stop at the tap—every use of water in patient care settings must be scrutinized and evaluated for its risk to harbor and transmit healthcare-associated pathogens. Even hospital sink drains and toilets can pose a risk for harboring antibiotic resistant pathogens that can spread to patients and cause harm.

Water use in Dialysis

By reducing risk from water in the healthcare setting many infections and outbreaks can be avoided.

During an average week of hemodialysis, a patient can be exposed to 300-600 liters of water, providing multiple opportunities for potential patient exposure to waterborne pathogens.

https://www.cdc.gov/dialysis/guidelines/water-use.html

Water Use in Dialysis

Adverse patient outcomes including outbreaks associated with water exposure in dialysis settings have resulted from patient exposure to water via a variety of pathways; including improper formulation of dialysate with water containing high levels of chemical or biological contaminants, contamination of injectable medications with tap water, and reprocessing of dialyzers with contaminated water.

For the health and safety of hemodialysis patients, it is vital to ensure the water used to perform dialysis is safe and clean.

Outbreaks associated with Water Exposure in Dialysis

https://www.cdc.gov/dialysis/reports-news/outbreaks.html

AAMI Water Standards

AAMI in conjunction with the International Standards Organization (ISO) have established chemical and microbiological standards for the water used to prepare dialysate, substitution fluid, or to reprocess hemodialyzers for renal replacement therapy. The AAMI standards address:

- Equipment and processes **used to purify water** for the preparation of concentrates and dialysate and the reprocessing of dialyzers for multiple use.
- The devices used to **store and distribute** this water.
- The **allowable and action threshold levels** of water contaminants, bacterial cell counts, and endotoxins. Refer to specific reference listed for full details on maximum allowable chemical contaminates and bacterial/endotoxin limits.

AAMI Water Standards

Table. AAMI Water Standards

Reference Document	Allowable water Total Viable Count (TVC)	Action level water Total Viable Count (TVC)	Allowable Level water Endotoxin Unit (EU)	Action Level water Endotoxin Unit (EU)
AAMI RD52:2004 (Minimum regulatory requirement)	<200	≥50	<2	≥1
ANSI/AAMI/ISO 13959:2014 (Preferred recommendation)	<100	≥50	<0.25	≥0.125

Endotoxin - a toxin that is present inside a bacterial cell and is released when the cell disintegrates.
Total viable count (TVC) - test that estimates the total numbers of microorganisms, such as bacteria, yeast or mould species, that are present in a water sample.

Table 1. AAMI/ISO 13959:2014 Standards for Dialysis Water*

Contaminants	Max Concentration in mg/L (ppm) unless otherwise noted	Notes
Aluminum	0.01	Contaminants with documented toxicity in hemodialysis
Copper	0.1	
Fluoride	0.2	
Lead	0.005	
Nitrate (as N)	2	
Sulfate	100	
Zinc	0.1	
Calcium	2 (0.1 mEq/L)	Contaminants normally included in dialysate
Magnesium	4 (0.3 mEq/L)	
Potassium	8 (0.2 mEq/L)	
Sodium	70 (3.0 mEq/L)	
Antimony	0.006	Other Contaminants
Arsenic	0.005	
Barium	0.1	
Beryllium	0.0004	
Cadmium	0.001	
Chromium	0.014	
Mercury	0.0002	
Selenium	0.09	
Silver	0.005	
Thallium	0.002	
Maximum allowable chemical contaminant levels in water used to prepare dialysate, create concentrates from powder and reprocess dialyzers for multiple use.		
*The physician has the ultimate responsibility for ensuring the quality of water used for dialysis.		

Code of Federal Regulations

A point in time eCFR system

Title 42

Displaying title 42, up to date as of 9/01/2022. Title 42 was last amended 8/29/2022. view historical versions

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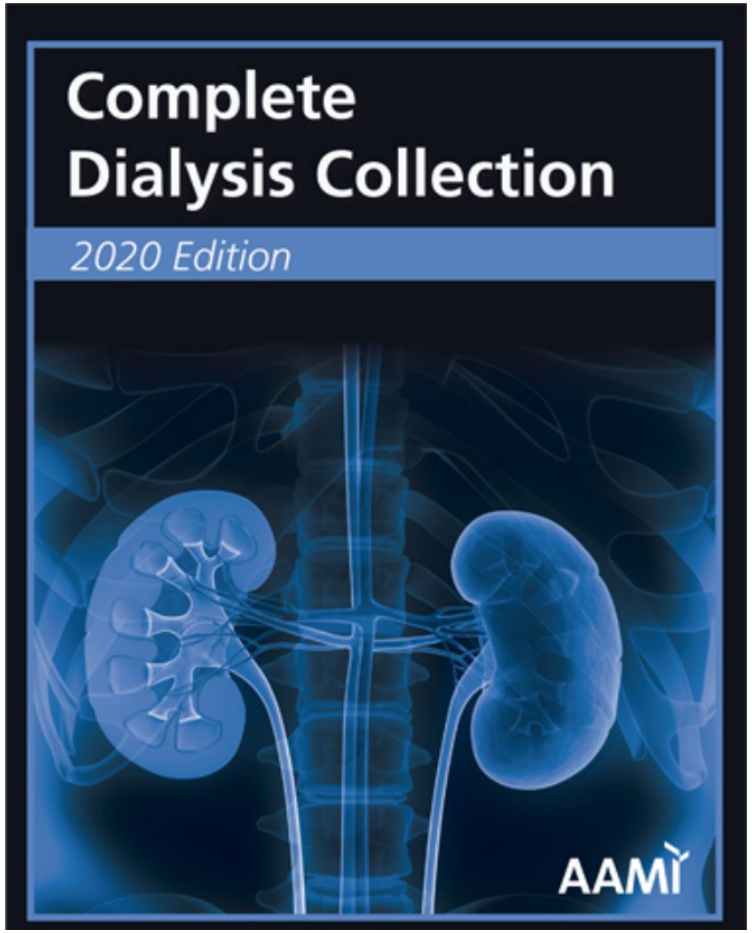
Timeline

§ 494.40 Condition: Water and dialysate quality.

The facility must be able to demonstrate the following:

(a) ***Standard: Water purity.*** Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis," ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.



This collection of AAMI dialysis standards and technical information reports includes the latest versions of all dialysis documents. AAMI adopted the 2019 ISO 23500 series of dialysis fluid standards as replacements for the ANSI/AAMI 2014 versions, which have been technically revised. AAMI also adopted the ISO 8637 series standards, which supersede the previous versions that had been published under separate designations. These are American National Standards. A crosswalk of the current and former designations of these standards is presented below and replaces the “Glossary of equivalent standards” sections in the documents that follow.

Español | Other Languages

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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Oral Health

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Dental Unit Water Quality

Print

Summary of Infection Prevention Practices in Dental Settings

Dental unit waterlines (i.e., plastic tubing that carries water to the high-speed handpiece, air/water syringe, and ultrasonic scaler) promote bacterial growth and development of biofilm due to the presence of long narrow-bore tubing, inconsistent flow rates, and the potential for retraction of oral fluids. Dental health care personnel and patients could be placed at risk of adverse health effects if water is not appropriately treated.

All dental units should use systems that treat water to meet drinking water standards (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria). Independent reservoirs—or water-bottle systems—alone are not sufficient. Commercial products and devices are available that can improve the quality of water used in dental treatment. Consult with the dental unit manufacturer for appropriate water maintenance methods and recommendations for monitoring dental water quality. During surgical procedures,1 use only sterile solutions as a coolant / irrigant using an appropriate delivery device, such as a sterile bulb syringe, sterile tubing that bypasses dental unit waterlines, or sterile single-use devices.
Guidance on dental unit water quality can be found in the Guidelines for Infection Control in Dental Health-Care Settings — 2003 [PDF – 1.21 MB], and the questions and answers on Dental Unit Water Quality.[/vc_column_text]

https://www.cdc.gov/oralhealth/infectioncontrol/summary-infection-prevention-practices/dental-unit-water-quality.html

CFU - **colony-forming units**.

It is a unit that we use for estimating the

number of viable bacteria or the fungal cells

in a sample.

heterotrophic

Capable of utilizing only organic materials as a source of food.

https://emergency.cdc.gov/han/2022/han00478.asp

Water Quality in Sterilization

Water impurities can jeopardize patient health, **decrease decontamination effectiveness and shorten the useful life of instrumentation**.

Automated reprocessing equipment functionality, effectiveness and life span are also negatively **impacted by impurities commonly found in water**.

The quality and consistency of the water used in a sterile processing department is critical.

https://multimedia.3m.com/mws/media/5375930/water-quality-impact-on-decontamination-mic-oct08.pdf


ANSI/AAMI
ST108:2023
Water for the processing
of medical devices
AAMI
aami.org/ST108

A **new** standard that establishes requirements for the **quality of water** used to **process medical devices**.

ANSI/AAMI ST108:2023, *Water for the processing of medical devices*, revises and replaces AAMI **TIR34:2014/(R)2021**, which provides information and guidance on water quality for device reprocessing.

ST108 provides clear requirements for every stage of medical device processing

The new standard:

1. Identifies the **categories of water quality** that should be used during each stage of sterile processing.
2. Provides a **risk analysis** and **establishes roles and responsibilities** for processing facilities.
3. Assesses water quality based on **factors** such as **pH, microbial level, conductivity, and other properties**.
4. Establishes **maintenance, monitoring, and quality improvement** procedures for water treatment systems.
5. Addresses e**mergency circumstances** such as service interruptions and boil water advisories.

AAMI TIR34 – Water for the Reprocessing of Medical Devices

How to ensure adequate water quality for your sterile processing department

https://www.evoqua.com/en/articles/AAMI-TIR34-water-for-medical-devices/

Test Your Knowledge

Q. 1 The following organizations develop standards except

a. Joint Commission
b. NFPA
c. AAMI
d. College of American Pathologists
e. Federal Government

Q. 2 A document that is issued by a government entity is called

a. Standard

b. Guidelines

c. Regulation

d. None of the above

Q. 3. The Joint Commission Standards are “mandatory”

a. Yes

b. No

c. No but many third-party organizations require Joint Commission Accreditation.

d. None of the above

Q. 4 The Joint Commission is

a. an independent, for-profit organization
b. an independent, not-for-profit organization
c. a government organization
d. none of the above

Q. 5 The following are federal agencies except

a. FDA
b. FCC
c. CMS
d. OSHA
e. The Joint Commission

Q.6 FDA inspects all blood facilities at least every

a. two years

b. three years

c. 18 months

d. four years

Q. 7 The Wireless Medical Telemetry Service (WMTS) is in the following range

a. 608 – 614 MHz
b. 1395 – 1400 MHz
c. 1427 – 1432 MHz
d. All of the above

Q. 8 The Laboratory equipment should be maintained

a. per alternative equipment maintenance (AEM) program
b. per manufacturer's recommendations
c. annually
d. None of the above

Q. 9 The alternative equipment maintenance (AEM) is not allowed for the following, and maintenance activities and frequencies must follow manufacturers' recommendations:

a.Equipment subject to federal or state law or Medicare Conditions of Participation
b.Imaging and radiologic equipment (diagnostic or therapeutic)
c.Medical LASER devices
d.New medical equipment with insufficient maintenance history to support the use of an AEM strategy
e.All of the above

Q.10 If line-operated medical equipment is used in a patient care room/area, inside the patient care vicinity the power strips providing power to medical equipment must be compliant with

a. UL 1363A or UL 60601-1
b. UL 1363A
c. UL 60601-1
d. NFPA 99

Q. 11 During an average week of hemodialysis, a patient can be exposed to _____of water

a. 100-120 liters
b. 300-600 liters
c. 300-600 gallons
d. 100-120 gallons

Q. 12 The standardized form intended to be filled out by medical device manufacturers to communicate information about their devices' security and privacy characteristics to current device owners and potential buyers is called

a. Manufacturer Declaration Statement for Medical Device Security (MDS^2)
b. Manufacturer Disclosure Statement for Medical Device Security (MDS^2)
c. Manufacturer Disclosure Statement for Medical Equipment Security
d. Manufacturer Disclosure Summary for Medical Device Security (MDS^2)

Tips for Preparing for CCE Written Exam

Review “Content Outline” in
https://accenet.org/CECertification/Documents/2023_CCE_Handbook.pdf

APPENDIX: Examination Content

Written Examination

1. The Examination for Certification in Clinical Engineering is a written examination composed of a maximum of 150 multiple-choice, objective questions with a total testing time of four (4) hours.
2. The content for both examinations is based on a “Body of Knowledge” (BOK) survey that is periodically performed by ACCE to determine the current knowledge and skill sets needed for competent clinical engineering practice. The most recent version of the BOK is found on the ACCE website at: ACCE 2021 Body of Knowledge Report.
3. The Board, with the advice and assistance of the Professional Testing Corporation (PTC), prepares the written examination using questions developed and reviewed by the Board for construction, accuracy, and appropriateness.
4. The questions for the written examination are also obtained from practicing clinical engineers and are reviewed for construction, accuracy, and appropriateness by the Board.
5. Some sections of the written examination may include questions on basic underlying knowledge including ones from anatomy, physiology, and the management and engineering sciences.
6. The distribution of questions in the written examination for Certification in Clinical Engineering will be weighted in approximately the following manner:

I.	Technology Management	35%
II.	Service Delivery Management	20%
III.	Product Development, Testing, Evaluation, & Modification	5%
IV.	IT / Telecom	10%
V.	Education of Others	5%
VI.	Facilities Management	5%
VII.	Risk Management / Safety	10%
VIII.	General Management	10%

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Content Outline

I. **TECHNOLOGY MANAGEMENT:** Technology assessment, Usability / Compatibility assessment, Product / vendor selection , Device integration planning, Life cycle analysis, Device / system upgrade planning, Return on investment (ROI) analysis, Healthcare technology strategic planning, Clinical trials management (non-investigational), Capital planning, Project management, Electromagnetic Interference (EMI) / Radio Frequency Interference (RFI) management , Clinical devices use and/or application, Pre-Clinical procedure set-up / testing, Participation in clinical procedures (e.g. surgery), Water quality management, Coordinating device interoperability / interfacing, Clinical systems networking, Interpretation of codes and standards, Other technology management responsibilities.

II. **SERVICE DELIVERY MANAGEMENT:** Technician / service supervision, Service contract management, Equipment repair and maintenance, Equipment acceptance, Equipment performance testing, Develop test / calibration / maintenance procedures, Maintenance software (CMMS) Administration, Parts/ supplies purchase and/or inventory management, Technical library / service manuals management, Other service delivery responsibilities.

III. **PRODUCE DEVELOPMENT, TESTING, EVALUATION, AND MODIFICATION:** Medical device concept development / invention, Human factors engineering, Medical device design, New product testing and evaluation, Device modifications, Product research and development, Product sales / sales support, Product / systems quality management, Regulatory compliance activities, Documentation development / management, Other product development responsibilities.

IV. **INFORMATION TECHNOLOGY (IT) / TELECOMMUNICATIONS:** Help Desk / dispatching / call tracking, Information Technology (IT) management, Telecommunications management, Integration of medical device data, Installation management, Configuration and change management, ISO/IEC 80001 (risk management of medical devices on a network), Continuity and capacity management, ISO/IEC 20000 (information technology service management ITSM), Release management, ITIL (information technology infrastructure library), Other IT / Telecommunications responsibilities.

V. **EDUCATION OF OTHERS:** Technician education, Engineering education, Device user / nurse training, Develop / manage staff training plan, International healthcare technology management, Other education responsibilities.

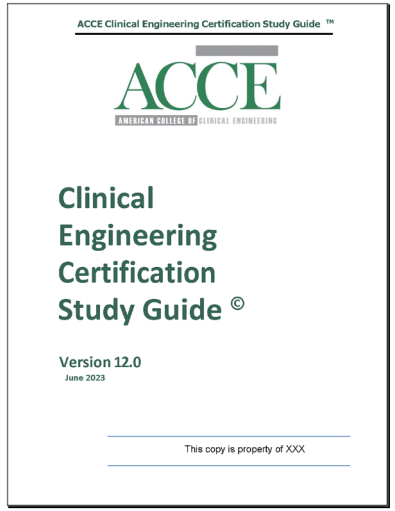
VI. **FACILITIES MANAGEMENT:** Building design, Building plan review, Medical gas system testing, Supervise / manage / direct facilities management, Facility / utility remediation planning, Emergency electrical power, Facility emergency preparedness activities, Other facility management responsibilities.

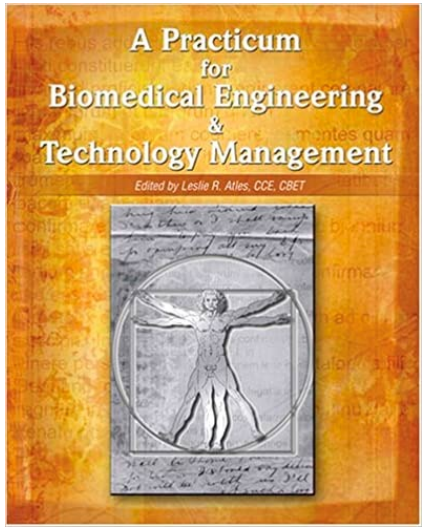
VII. **RISK MANAGEMENT /SAFETY:** Patient safety, Expert witness, Risk Management, Investigational Research (Human Use), Forensic investigations, Medical device incident reporting (SMDA) , Radiation safety, Root cause analysis, Failure mode and effects analysis, Fire protection/safety (Life Safety Code) , Product safety / hazard alerts / recalls, Infection control, Industrial hygiene, Work place safety practices (OSHA), Hazardous materials, Engineering assessment of medical device failures, Incident / untoward event investigation, Other risk management / safety responsibilities.

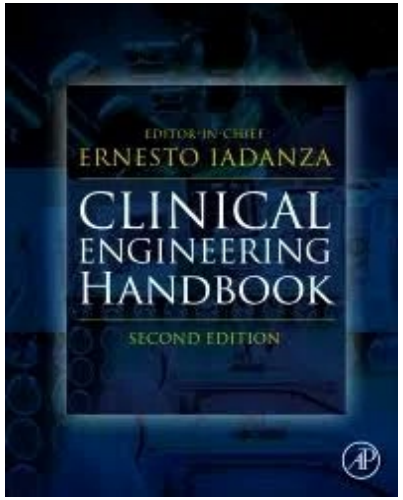
VIII. **GENERAL MANAGEMENT:** Staffing, Staff skills / competency assessment, Budget development / execution, Personnel management / supervision, Performance improvement / CQI, Policy / procedure management / development, Committee management, Business / operation plan development / management, Revenue producing activities, Other general management activities.

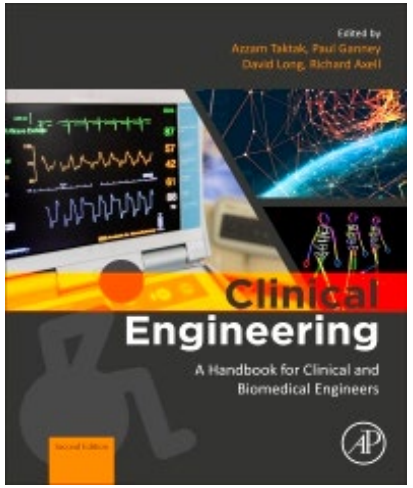
Resources

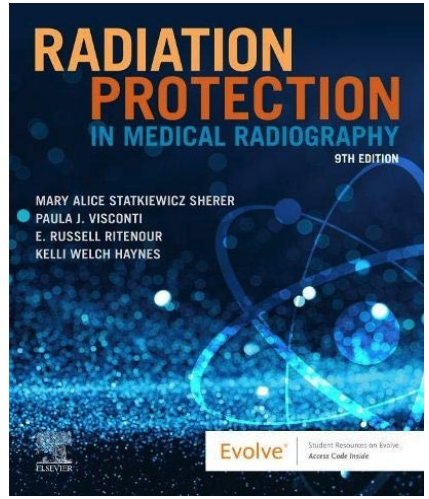
- *Journal of Clinical Engineering* - Articles on CCE Prep by Arif Subhan - since 2005
- https://24x7mag.com/ Search “Arif Subhan”
- ECRI articles
- ACCE News











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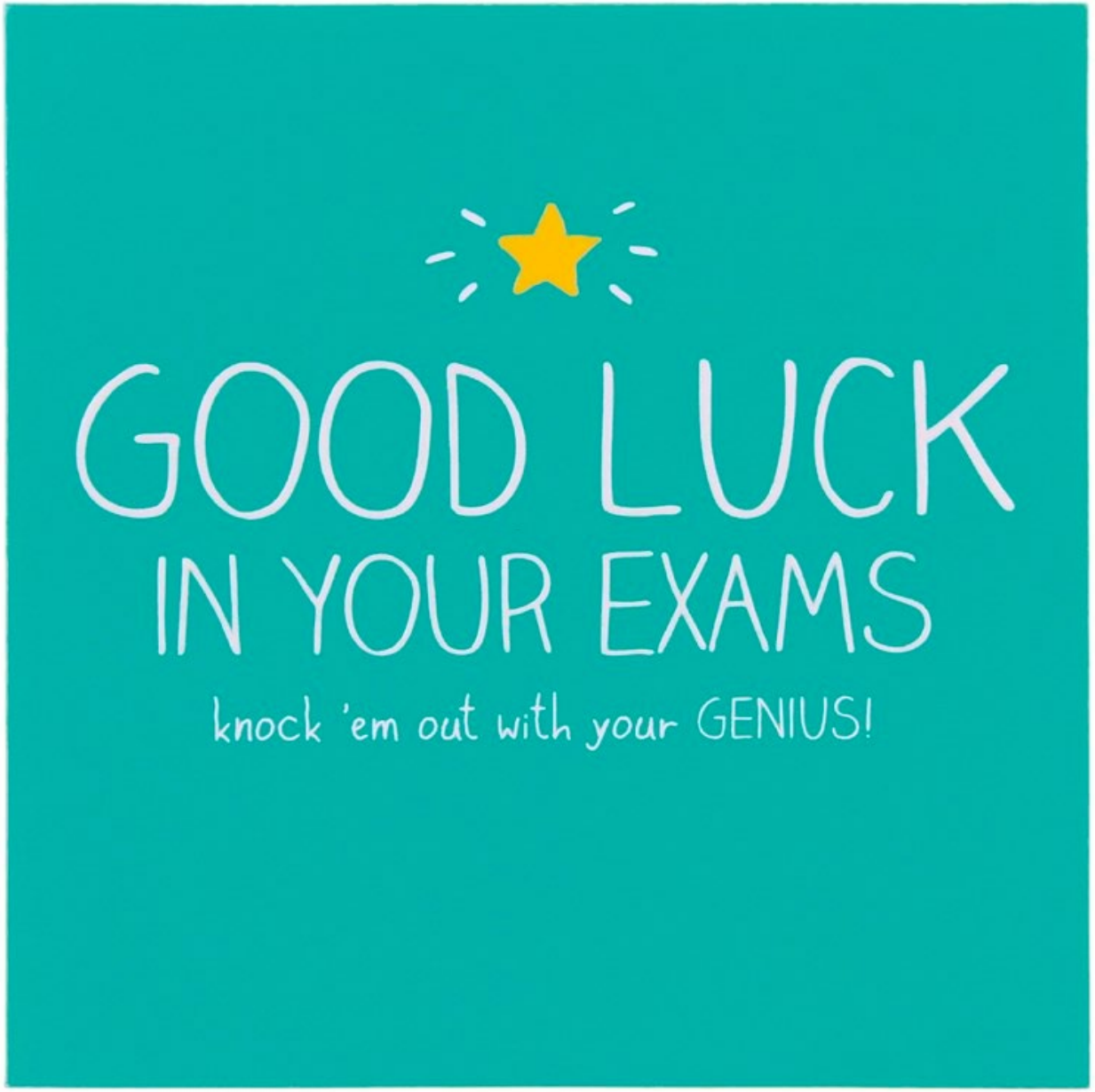
or scan the QR code:


GOOD LUCK
IN YOUR EXAMS
knock 'em out with your GENIUS!