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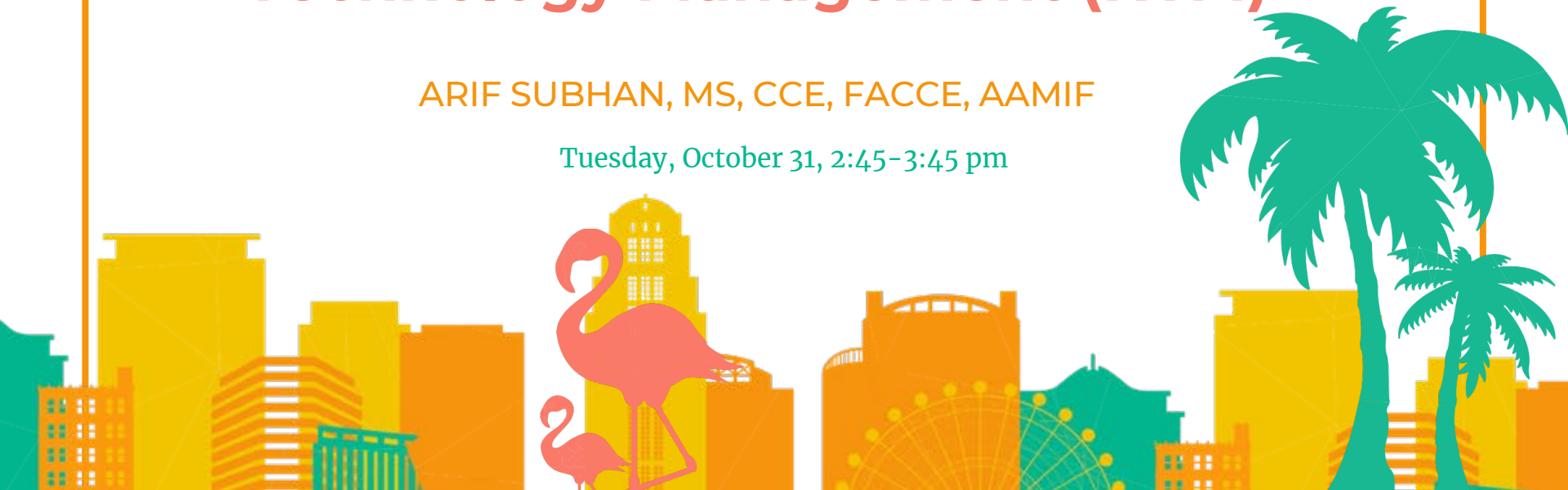
Orlando, FL • October 29-31, 2023

Codes, Standards and Regulations that Pertain to Healthcare Technology Management (HTM)

ARIF SUBHAN, MS, CCE, FACCE, AAMIF

Tuesday, October 31, 2:45-3:45 pm



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Session Description

As healthcare technology management (HTM) professionals, we should have a **good understanding and knowledge** of the different **codes, standards and regulations** that pertain to the **use of medical equipment in the hospital**. There are **many** organizations, including various **state and federal** agencies, which promulgate **voluntary** and **mandatory** standards for the health care field, in general, resulting in many **thousands** of **standards, clinical practice guidelines, laws and regulations**.

These organizations also promulgate a variety of requirements for different types of equipment (e.g., imaging, nuclear, anesthesia, and respiratory), **electrical safety, fire safety, power distribution, medical-gas systems, clinical laboratories and blood banks**.

This session will provide an overview of the codes, standards and regulations pertaining to HTM.

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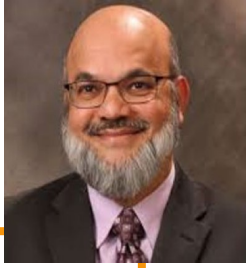

ARIF SUBHAN

- Former Chief Biomedical Engineer, VA South Texas Health Care System & Nebraska Western-Iowa Health Care System
- Former Senior Clinical Engineer, Masterplan (national ISO with 1400 accounts in 30 states)
- Former President, American College of Clinical Engineering
- Adjunct Professor, Biomedical Engineering, University of Connecticut
- Columnist, Journal of Clinical Engineering
- Member Editorial Boards – AAMI BI&T journal, 24x7 magazine, Journal of Clinical Engineering
- Author of Book chapters for the "Clinical Engineering Handbook", "Encyclopedia of Medical Devices and Instrumentation" and "A Practicum for Biomedical Engineering and Management Issues"
- Recipient:
    - 2022 ACCE Tom O'Dea Advocacy Award
    - 2013 ACCE Professional Development/Managerial Excellence Award
    - 2012 AAMI Clinical/Biomedical Engineering Achievement Award

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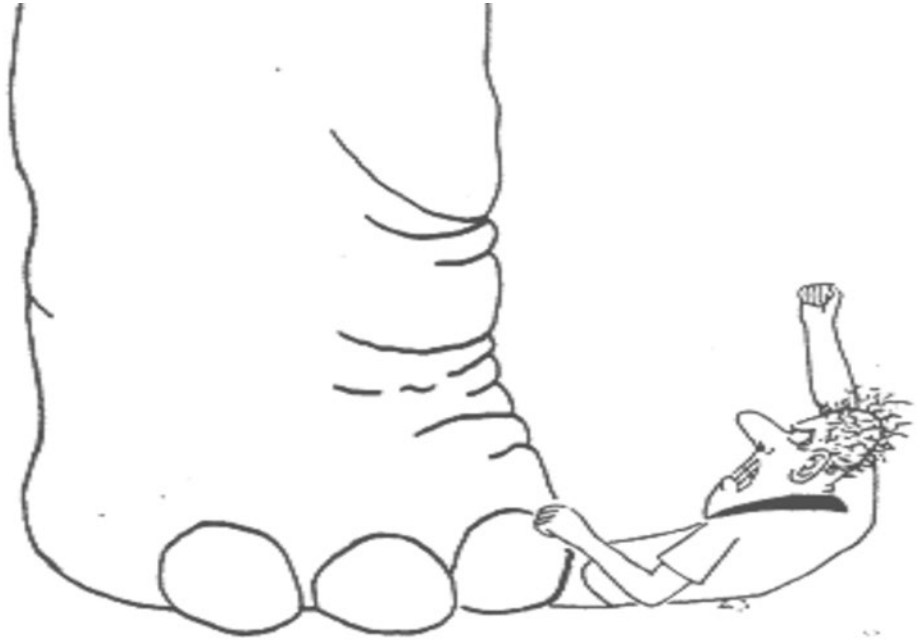
Polling Questions

How long have you been in the HTM profession?

- 0-10 years
- 11-20 years
- 20 + years

How do you rate your knowledge of Codes, Standards and Regulations?

- Fair
- Good
- Excellent



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

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Codes, Standards & Regulations

The terms *codes*, *standards*, *and regulations* are often used interchangeably.

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What is a Standard?

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

"Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators."

Examples

https://www.iso.org/standards.html

Joint Commission, NFPA, AAMI, CAP, AABB, IEC, etc.

When is Compliance with a Standard required?

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

AHJ – An organization, office, or individual responsible for enforcing the requirements of a code or standard, or for approving equipment,…

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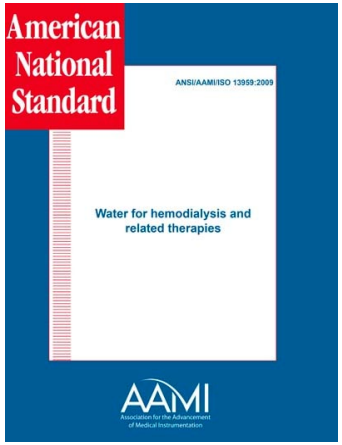

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES - HEALTH CARE INSTITUTIONS: LICENSING

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 based on **past experience** and can **inhibit** modernization or limit progress.

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 For 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?

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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).

When is Compliance with a code required?

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

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Codes

Examples

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

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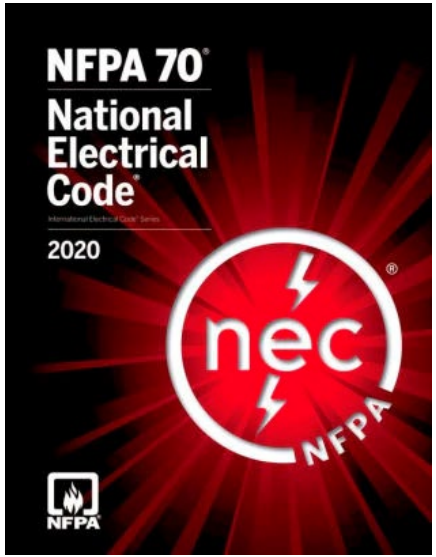

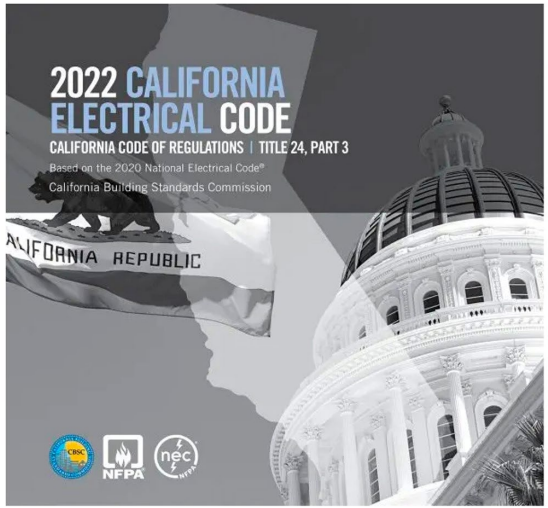

2022 California Electrical Code (Title 24 Part 3) is a fully-integrated California-specific electrical code based on the **2020 National Electrical Code**.

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/code or in lieu of inclusion, reference to a standard/code.
- It has the **force of law from the start**.

Examples

- Code of Federal Regulations (CFR)
- California Code of Regulations (CCR)
- Arizona Administrative Code
- Florida Administrative Code


Code of Federal Regulations
A point in time eCFR system
NATIONAL ARCHIVES
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
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

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Are Joint Commission 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*.

President Johnson signing the Medicare program into law, July 30, 1965. Shown with the President (on the right in the photo) are (left to right) Mrs. Johnson; former President Harry Truman; Vice-President Hubert Humphrey; and Mrs. Truman.

Photo courtesy of LBJ Presidential Library.

(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.

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

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

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

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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)

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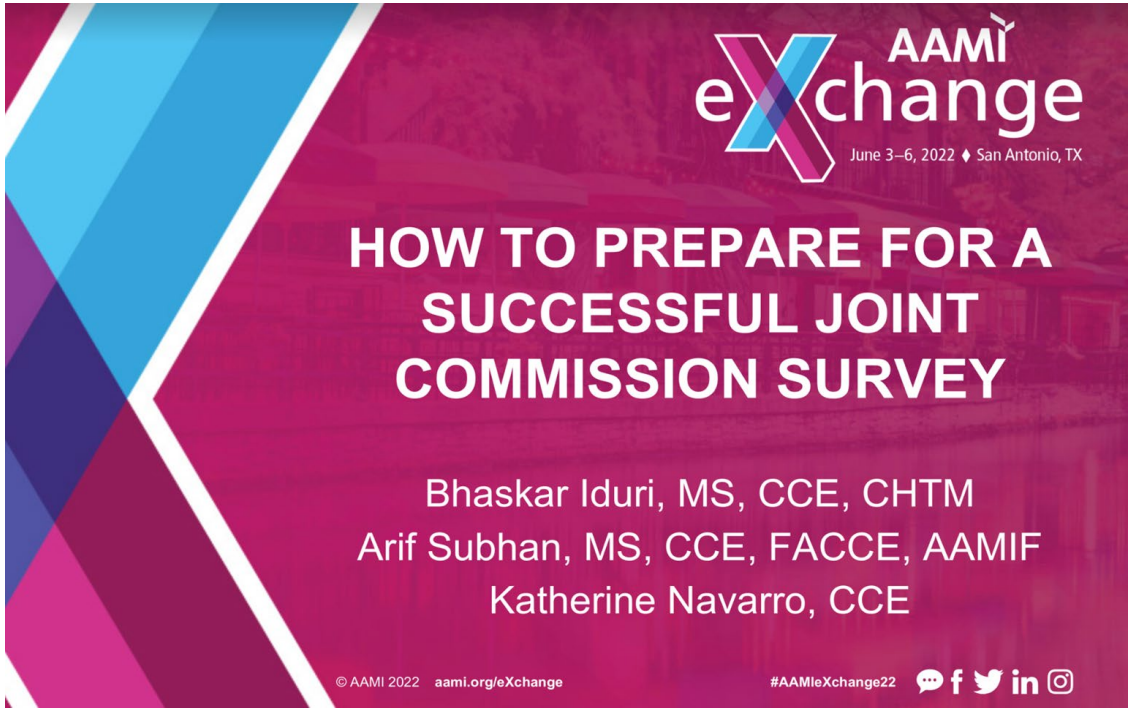

https://vimeo.com/720457602/49498e8860

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

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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. 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 and Det Norske Veritas (DNV)** 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

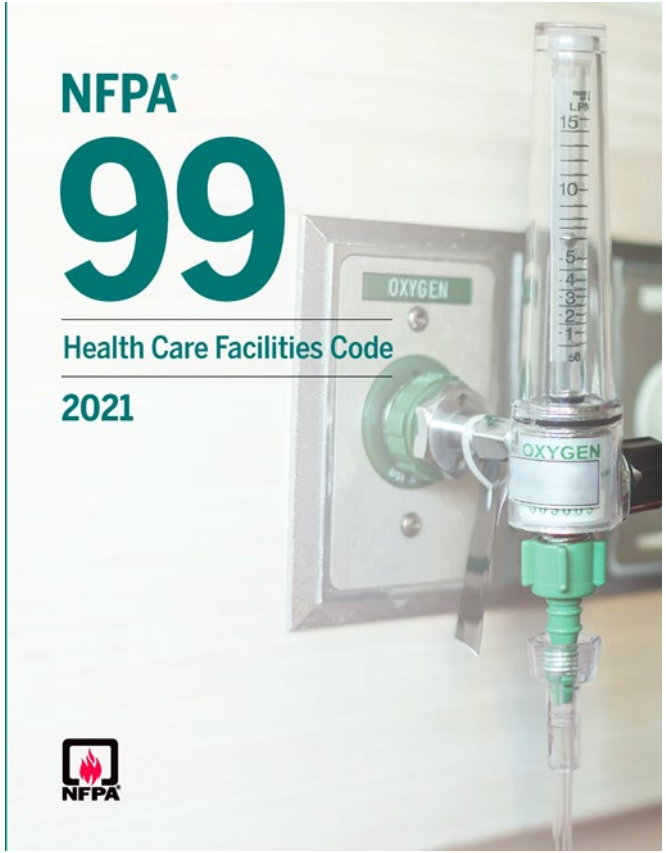
CMS-Approved Accrediting Organizations

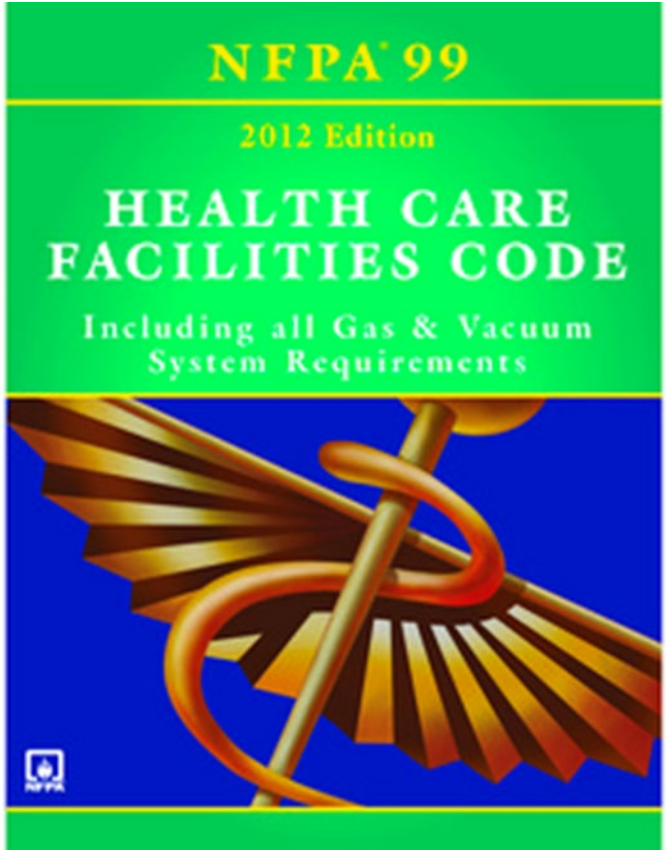
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- DNV – Healthcare (DNV)
- The Joint Commission (TJC)
- Other organizations

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 HTM professionals.


NFPA
99
Health Care Facilities Code
2021
OXYGEN
OXYGEN
NFPA


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

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

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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

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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)

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Food & Drug Administration (FDA)

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

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FDA's Role in Regulating Medical Devices

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Home Use Devices

- Home Use Devices Initiative
- Unique Considerations in the Home

FDA regulates the sale of medical device products (including diagnostic tests) in the U.S. and monitors the safety of all regulated medical products.

In the U.S., FDA regulates the sale of medical device products. Before a medical device can be legally sold in the U.S., the person or company that wants to sell the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use.

Content current as of:
08/31/2018

Regulated Product(s)
Medical Devices

https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices

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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

Safe Medical Devices Act (SMDA) of 1990

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.

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

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.

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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.

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

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.

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Medical Device 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

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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U.S. FOOD & DRUG ADMINISTRATION

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Blood & Blood Products

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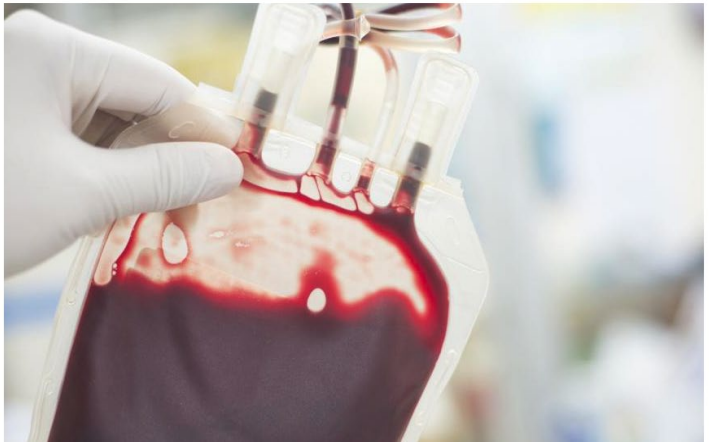

Content current as of:
07/12/2021

Regulated Product(s)
Biologics
Blood Products

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

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Blood Banks

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.

- 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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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 are 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.

FDA U.S. FOOD & DRUG ADMINISTRATION

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CFR - Code of Federal Regulations Title 21

FDA Home › Medical Devices › Databases

The information on this page is current as of Mar 29, 2022.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).

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See Related Information

[Code of Federal Regulations]
[Title 21, Volume 8]
[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)

- 1992 – **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.
- 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

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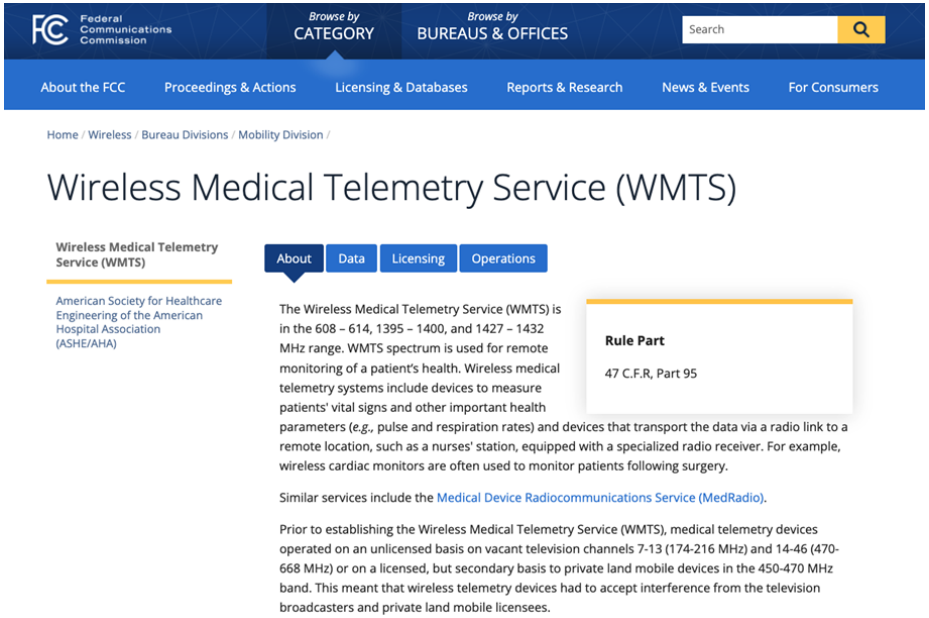
Federal Communications Commission (FCC)



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

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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)

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Federal Communications Commission (FCC)

- 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

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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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Occupational Safety and Health Administration (OSHA)

Mission

- 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

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UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety and Health Administration

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OSHA STANDARDS ENFORCEMENT TOPICS HELP AND RESOURCES NEWS SEARCH OSHA

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/

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U.S. Nuclear Regulatory Commission (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.

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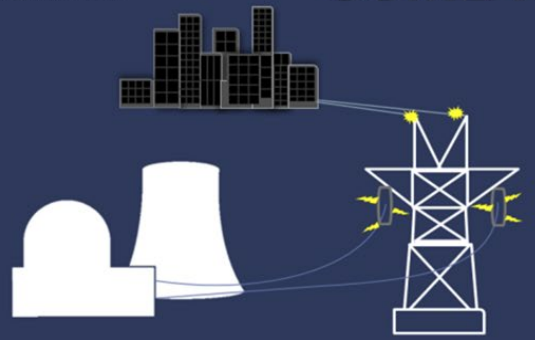
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

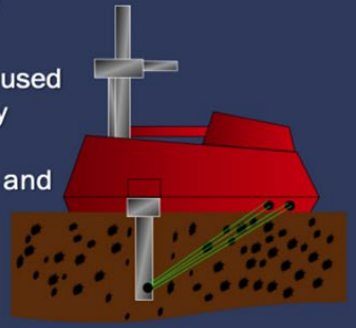
SOME NUCLEAR FACTS



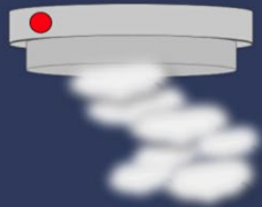
- Commercial nuclear power plants supply about 20 percent of electricity in the U.S.

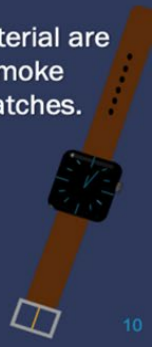
- Nuclear materials are used in medicine for cancer treatment and diagnosis.

- 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.





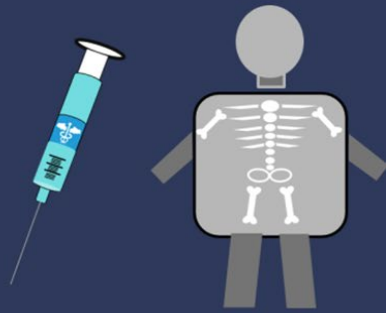
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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.



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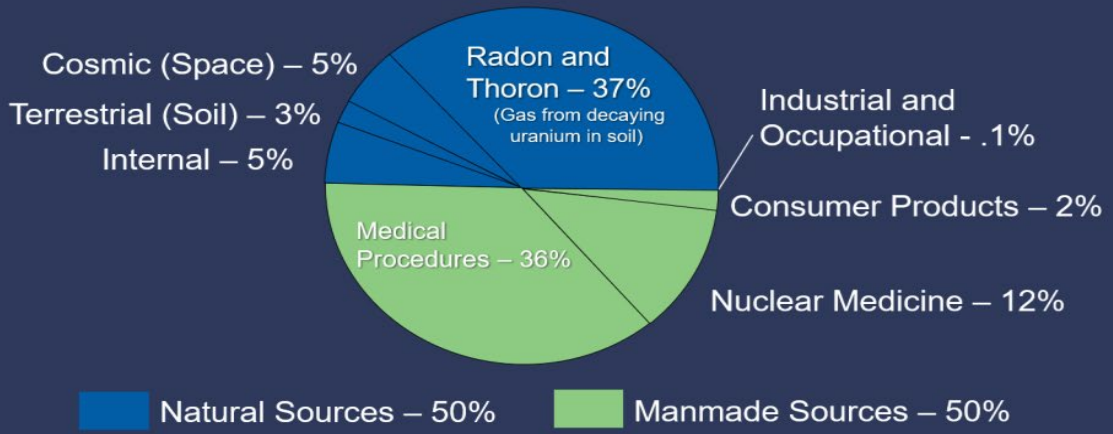
Protecting People and the Environment

SOME RADIATION FACTS

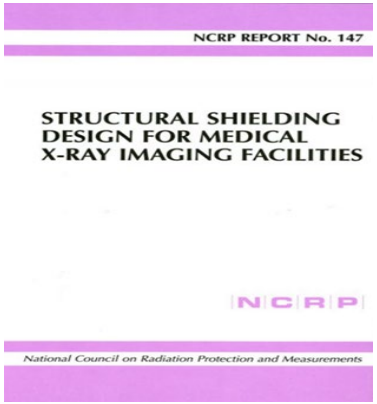
Sources of Radiation Exposure in the United States



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

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 - primary radiation

- **Primary radiation** – useful beam *"radiation emitted directly from the x-ray tube that is used for patient imaging."*

- **Primary barrier** is a wall, ceiling, floor or other structure that will intercept radiation emitted directly from the x-ray tube. It **attenuates the useful beam** to appropriate shielding design goals.

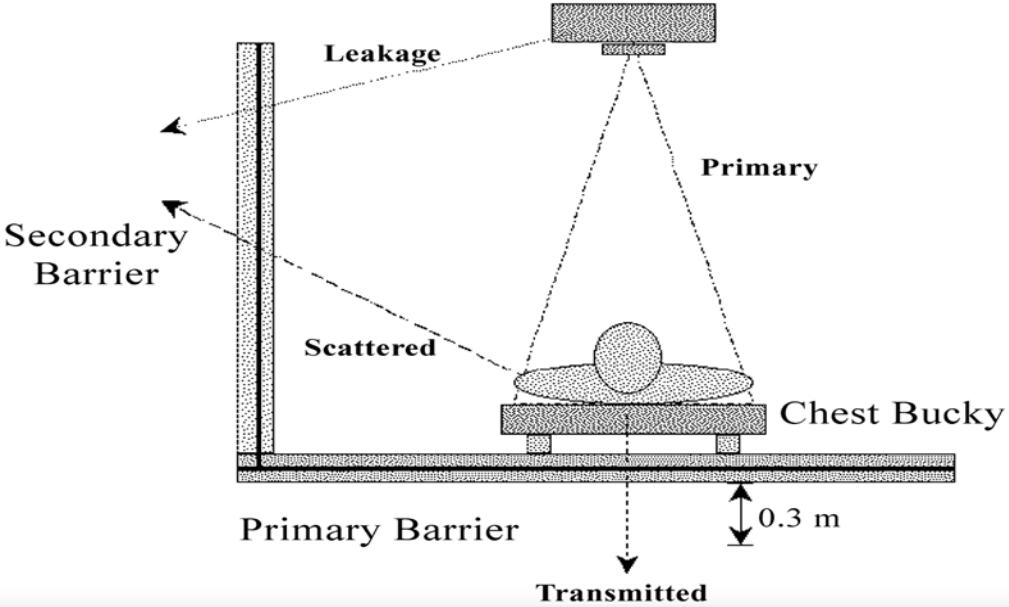


Figure 2.1 illustrates primary, scattered, leakage and transmitted radiation in a typical radiographic room.

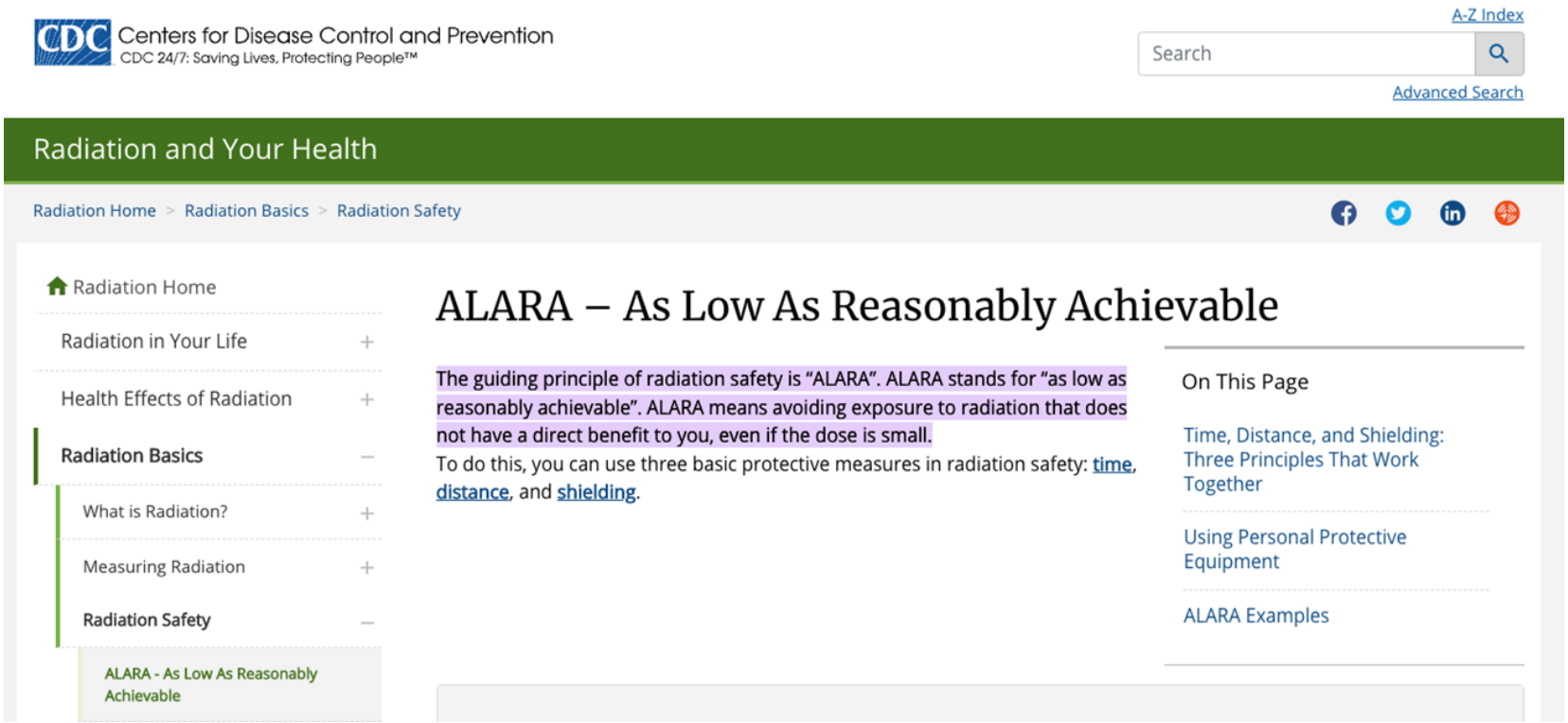
Medical x-ray imaging - secondary radiation

- **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.

- **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.

Factors Affecting Radiation Exposure

- **Dose (amount) of radiation** produced by the source
- **Distance** between the exposed person and the source of the radiation
- Amount of **time** that an individual spends in the irradiated area
- Amount of **protective shielding** between the individual and the radiation source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CDC 24/7: Saving Lives, Protecting People™
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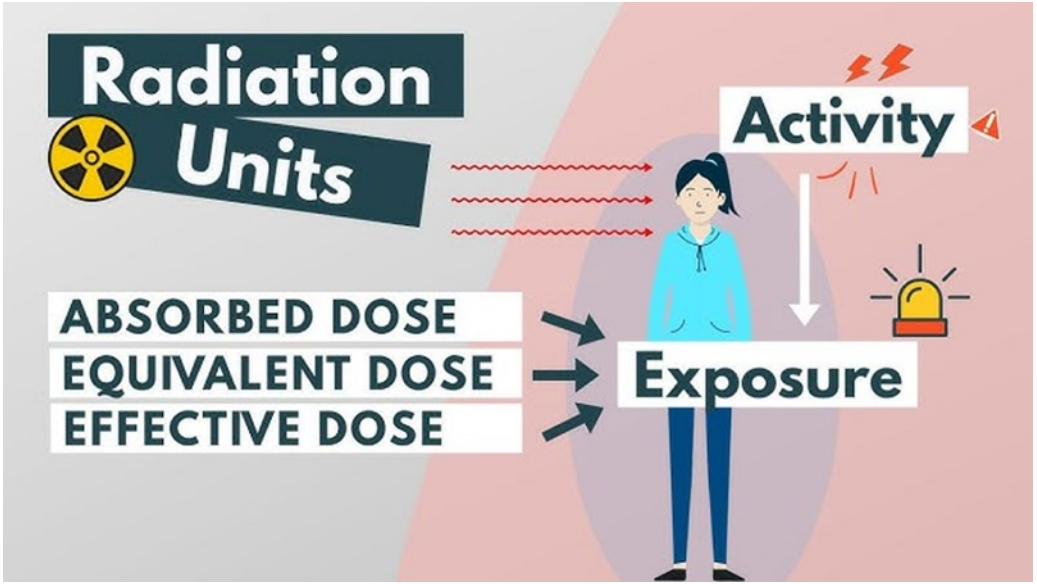
Radiation Basics
What is Radiation?
Measuring Radiation
Radiation Safety
ALARA - As Low As Reasonably Achievable
ALARA – As Low As Reasonably Achievable
The guiding principle of radiation safety is "ALARA". ALARA stands for "as low as reasonably achievable". ALARA means avoiding exposure to radiation that does not have a direct benefit to you, even if the dose is small.
To do this, you can use three basic protective measures in radiation safety: time, distance, and shielding.
On This Page
Time, Distance, and Shielding: Three Principles That Work Together
Using Personal Protective Equipment
ALARA Examples

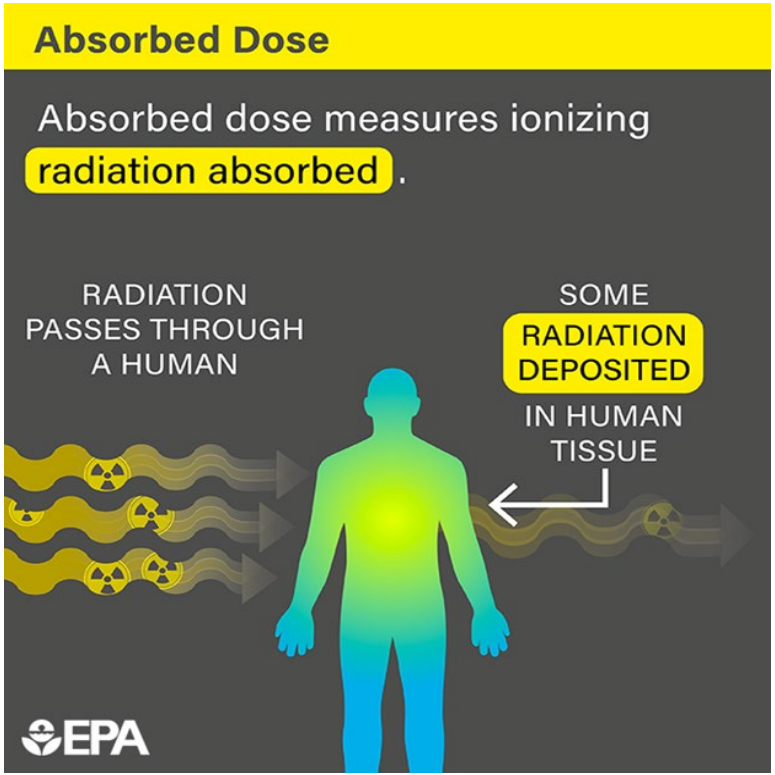


Measuring Radiation Exposure: What is a Sievert? - YouTube

Absorbed Dose

- **Amount of energy deposited per unit mass in an object or person.**

- The units for absorbed dose are gray (**Gy, international unit**) and rad (**rad, U.S. unit**).



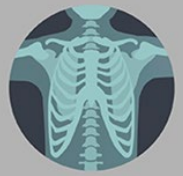
https://www.epa.gov/system/files/documents/2022-05/radiation_units_PDF.pdf

Using Absorbed Dose

Common Use	Measuring dose from medical equipment
Units	Gray (Gy), Rad (rad)

Examples

Dose to the lens of eyes from a brain CT scan
≈60 mGy or 6 rad



Dose to the thyroid from a chest CT scan
≈10 mGy or 1 rad

EPA

https://www.epa.gov/system/files/documents/2022-05/radiation_units_PDF.pdf

Effective Dose

- Takes the **absorbed dose** and adjusts it for **radiation type** and relative **organ sensitivity**. The result is an **indicator for the potential for long-term health effects** (i.e., cancer and hereditary effects) from an exposure.
- It is used to set **regulatory limits** that protect against long-term health effects in a population.
- Allows experts to **compare anticipated health effects** from different exposure situations.

https://www.epa.gov/system/files/documents/2022-05/radiation_units_PDF.pdf

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.

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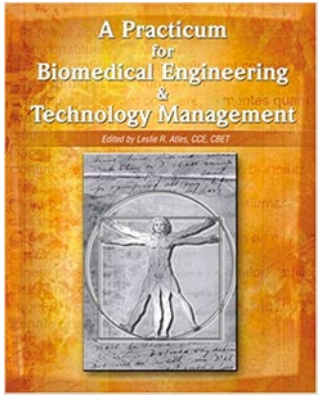
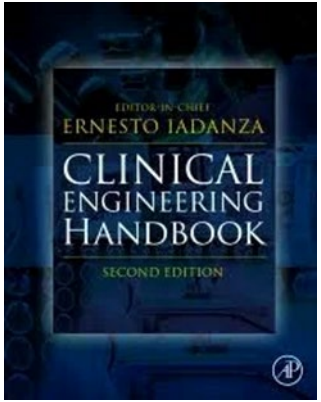
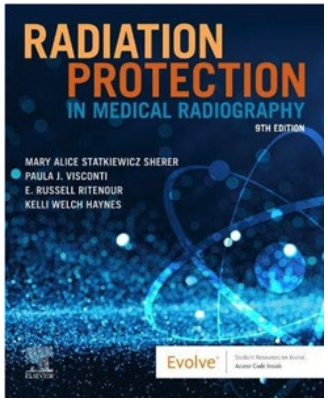
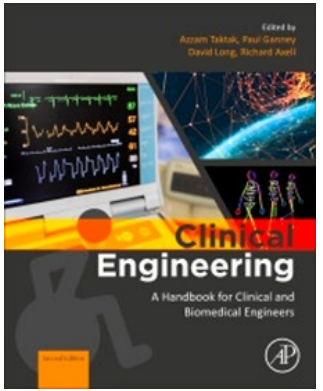
Resources









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Thank You!