HTM Standards 101

What are they and why should I care?

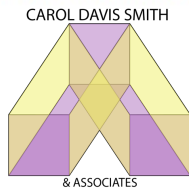Carol Davis-Smith, MS CCE   Matt Baretich, PhD CCE

MDEXPO

Las Vegas • April 7-9, 2024

Introctions

Carol Davis-Smith, President, Carol Davis-Smith & Associates, LLC

CAROL DAVIS SMITH

& ASSOCIATES

Matt Baretich, Baretich Engineering Inc.

Baretich Engineering

Matt

Badges?

We ain't got no badges.

We don't need no badges.

I don't have to show you any stinkin' badges!

Standards?

We ain't got no standards.

We don't need no standards.

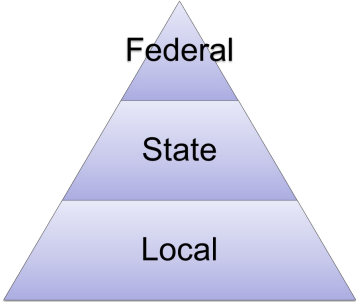I don't have to show you any stinkin' standards!

Carol

Standardization versus Standards

Civics 101

Government Structure

Federal
State
Local

U.S. Constitution
Laws
Code of Federal Regulations

State Constitution
Laws
Medicaid, Hospital licensure, Public safety, Workers' compensation

Regulations
Rent, Public safety, Zoning

Legislative
Senate & House of Representatives

Create bills (precursors to laws)
Authority to override veto
Define appropriations
Provide oversight

Executive
President & Vice President
Agencies

Set agenda
Propose budget
Issue executive orders
Sign bills into laws
Administer & execute laws
Make regulation & policy

Judicial
Supreme Court
Federal Courts

Interpret laws
Enforce laws
Set precedent

Legislative
Senate & House of Representatives
County Supervisors
City Councils

Executive
Governor
Mayor

Judicial
State & Municipal
Courts

Social Determinants of Health
Conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes

Food
Health Insurance
Employment

Housing
Healthcare
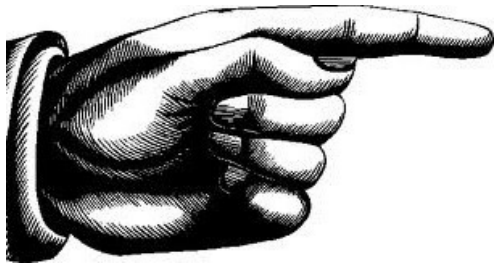Education

Civics 101

Government Structure
❖ Federal Government
❖ State & Local Governments

Types of compliance

Mandatory: what must be followed by law

Recommended: what should be followed to align with industry practice

Voluntary: What we might choose to follow as a best practice

Authority Having Jurisdiction (AHJ)

Civics 101

Government Structure
❖ Federal Government
❖ State & Local Governments

Types of compliance

Laws

Laws are rules that are:

❖ Mandatory

❖ Enforced by government (federal, state, local)

Health Insurance Portability and Accountability Act of 1996 (HIPAA) | CDC

Clinical Laboratory Improvement Amendments (CLIA) | CDC

Civics 101
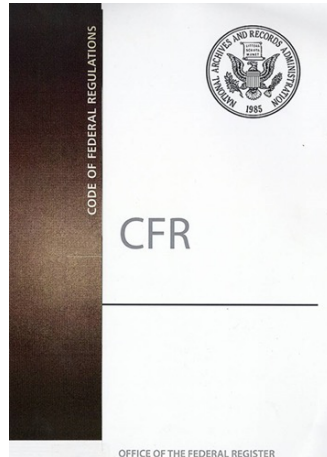
Government Structure
❖ Federal Government
❖ State & Local Governments

Types of compliance

Laws

Regulations, Policies & Directives

Regulations are rules that are:

❖ Mandatory

❖ Issued by agencies, boards, and commissions
- Federal – e.g., FDA, CMS
- State – e.g., Health Department

❖ Explain how agencies plan to carry out (enforce) laws

❖ Published yearly in the Code of Federal Regulations eCFR :: Home

eCFR :: Title 21 of the CFR -- Food and Drugs
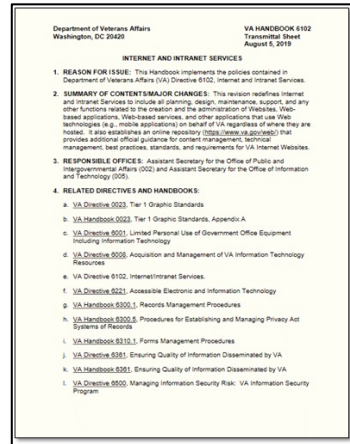Safe Medical Devices Act of 1990

Civics 101

Government Structure
- Federal Government
- State & Local Governments

Types of compliance

Laws

Regulations, Policies & Directives

Policies and Directives are instructions that are:

- ❖ Mandatory

- ❖ Issued by federal agencies, boards, and commissions

- ❖ Further explain how agencies plan to carry out (enforce) laws

- ❖ Published in the Federal Register and the within the department's manual

Centers for Medicare & Medicaid Services
Hospital Equipment Maintenance Requirements
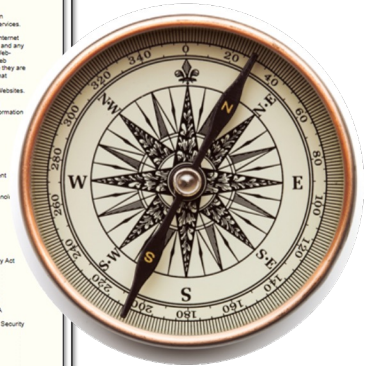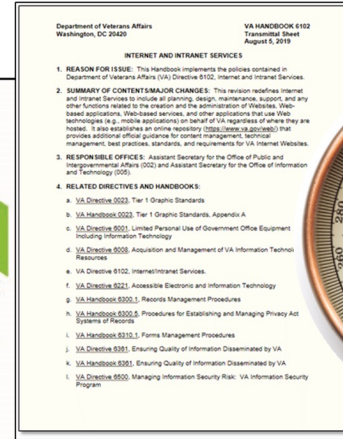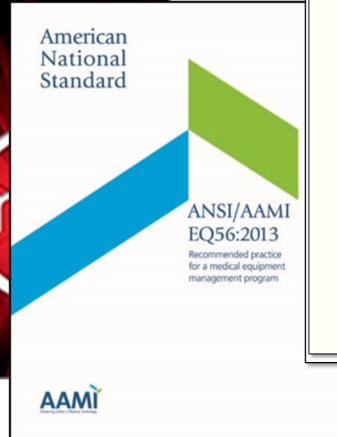**Memo #14-07-Hospital**

Civics 101

Government Structure
❖ Federal Government
❖ State & Local Governments

Types of compliance

Laws

Regulations, Policies &
Directives

Standards, Codes, Guidance,
& Best Practices

Matt

What are Standards?

- Consensus documents that provide requirements, specifications, guidelines, or characteristics to enrure fitness of materials, products, processes, and services

- Voluntary (unless adopted by an AHJ)

Store - ANSI/AAMI EQ56:2013 - AAMI Community
NFPA 110: Standard for Emergency and Standby Power Systems
2022 Accreditation Standards Books | Joint Commission Resources (jcrinc.com)

What are Codes?

- Standards written for enforcement

- Voluntary (until adopted by an AHJ)

NFPA 70®: National Electrical Code®
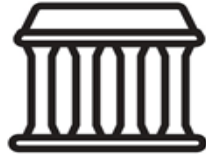NFPA 99: Health Care Facilities Code

What is a Guidance Document?

- Best practices or other practice guidelines

- Recommended but not required

- Voluntary (but worth considering)

Store - HTM Levels Guide, 3rd Edition (PDF) - AAMI Community
Store - Medical Equipment Servicing Guide (PDF) - AAMI Community
Store - AEM Program Guide - AAMI Community

A Common Path: Code/Standard ➔ Law

Non-government organizations create standards to meet or exceed federal regulations.

Standards are adopted by agencies as policy.

Policy is made into law.

NFPA 70 National Electrical Code 2020

Examples

- NFPA 70 National Electrical Code
- Adopted by states and other jurisdictions (law)

- NFPA 99 (2012)
- Adopted by CMS (and TJC et al.)

Alternatively: Law ➔ Code/Standard

The Legislative branch proposes law in the form of bills.

The Executive branch signs bills into law.

The Executive branch then carries out those laws through its agencies, which create regulations.

Non-government organizations create standards in line with regulations.

Example

Occupational Safety and Health Administration (OSHA 29 CFR)
- o   Part 1910 Occupational Safety and Health Standards
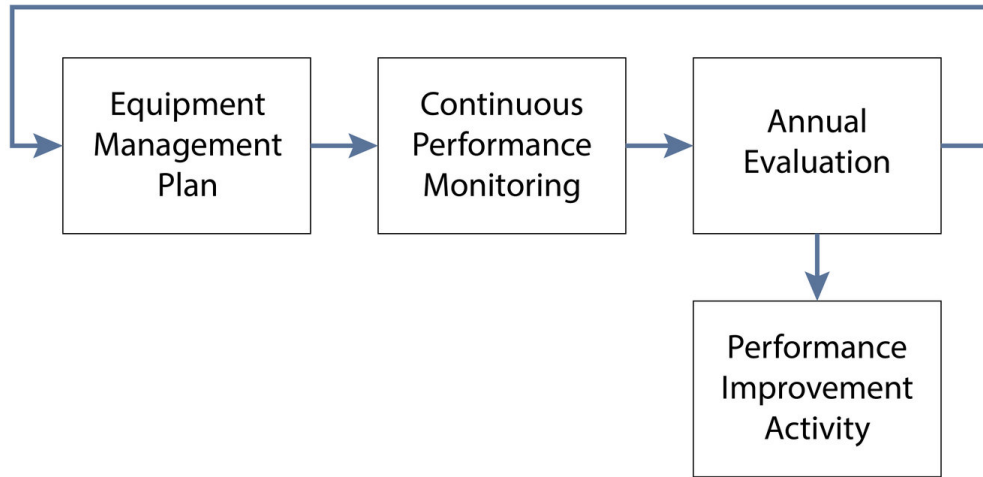- o   1910 Subpart S – Electrical

NFPA 70E Standard for Electrical Safety in the Workplace
- o   Electrical shock protection
- o   Arc flash protection
- o   Lockout-Tagout

Incorporating Standards into Your HTM Program

- Who are your AHJs?

- What are the requirements?

- Integrate the requirements into your HTM program

- Monitor compliance

- Review periodically

Medical Equipment Management Plan

- Objectives
- Scope
- Performance
- Effectiveness

AEM (Alternative Equipment Maintenance) Programs

2013   CMS issues an official letter allowing AEM

CMS provides details in its *State Operations Manual*

TJC includes AEM in its HAP accreditation standards

2018   AAMI publishes the *AEM Program Guide*

2023   AAMI begins work on an AEM standard (EQ103)

2024   TJC removes (almost) all AEM material from standards

CMS removes AEM material from *State Operations Manual*

NFPA 99 (2012) testing requirements

- Physical integrity of power cord assembly (visual inspection)

- Resistance between the appliance chassis and the ground pin: 0.50 Ω

NFPA 99 (2012) testing requirements

- Chassis leakage current (touch current):

  100 μA (ground wire intact)

  500 μA (ground wire open)

  Normal polarity only

NFPA 99 (2012) testing requirements

- Lead leakage current

  All leads together to ground <u>only</u>

  <u>100</u> µA (ground wire intact)

  <u>500</u> µA (ground wire open)

  Normal polarity <u>only</u>

10.5.2.1.2 All patient care related electrical equipment used in patient care areas shall be tested in accordance with 10.3.5.4 [chassis leakage] and 10.3.6 [lead leakage]

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… before being put into service
    for the first time

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… before being put into service
for the first time

… and after any repair or modification
that might have compromised
electrical safety.

10.5.2.1.2 All patient care related electrical equipment used in patient care areas shall be tested in accordance with **10.3.5.4** [chassis leakage] and **10.3.6** [lead leakage]

... before being put into service
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   that might have compromised
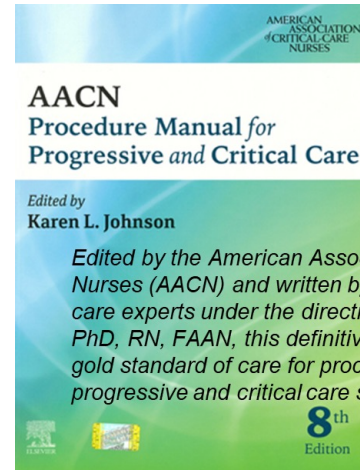   electrical safety.

"That's all folks!"

Carol

Elevating Your HTM Program with **Clinical** Standards

American Association of Critical-Care Nurses (AACN)

Association of periOperative Registered Nurses (AORN)

AMERICAN ASSOCIATION of CRITICAL-CARE NURSES

AACN
Procedure Manual *for* Progressive *and* Critical Care

Edited by
Karen L. Johnson

Edited by the American Association of Critical-Care Nurses (AACN) and written by more than 100 critical care experts under the direction of Karen L. Johnson, PhD, RN, FAAN, this definitive reference represents the gold standard of care for procedures performed in progressive and critical care settings.
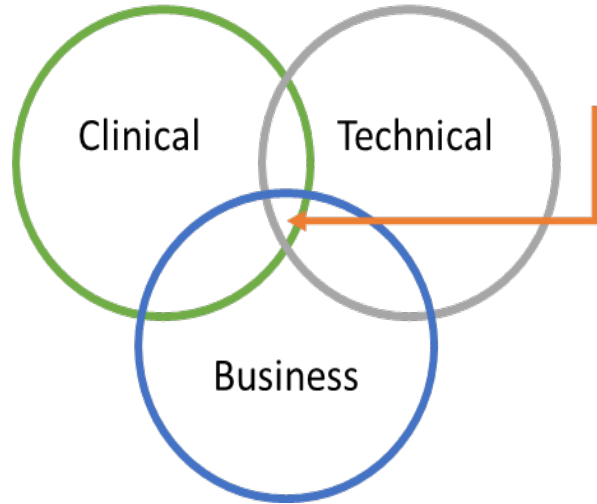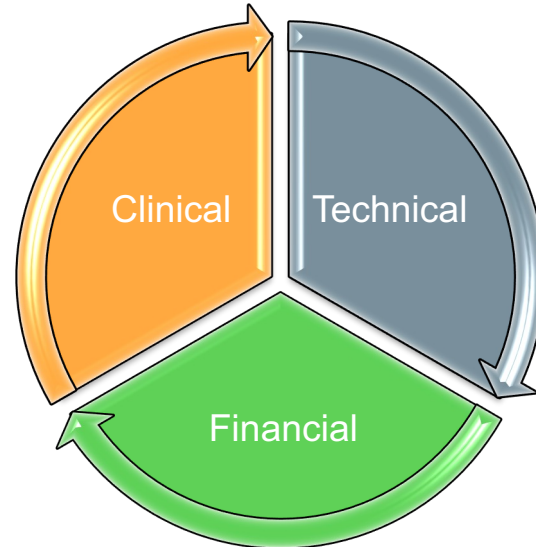
8th Edition

AORN's *Guidelines for Perioperative Practice* are the gold-standard in evidence-based recommendations to deliver safe perioperative patient care and achieve workplace safety.

Strategic Technology Forecasting

Clinical

Technical

Business

Optimized balance between Clinical, Technical, & Business considerations

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Clinical

Technical

Financial

Strategic Technology Forecasting
Start with the technical ...

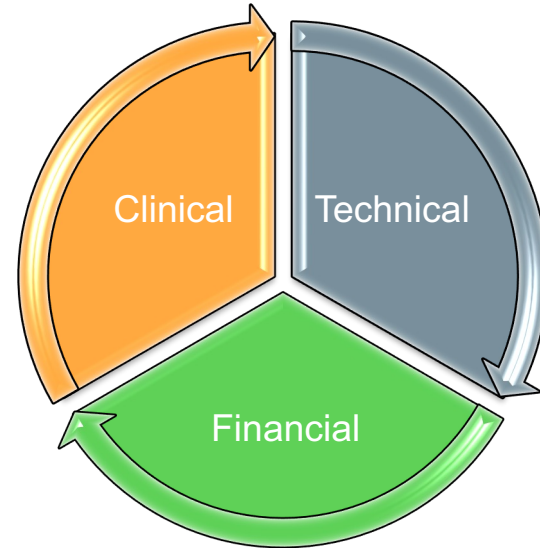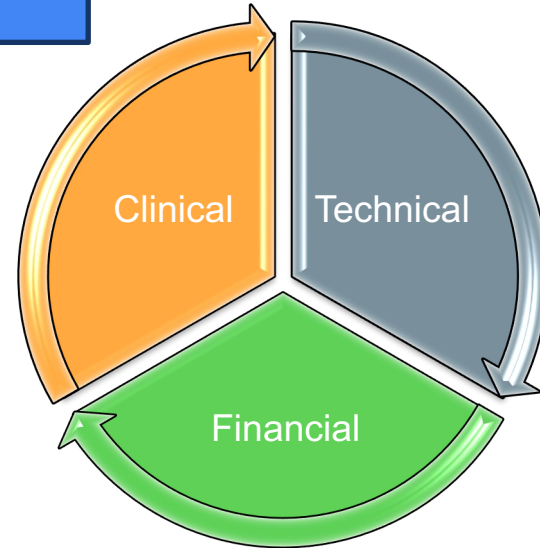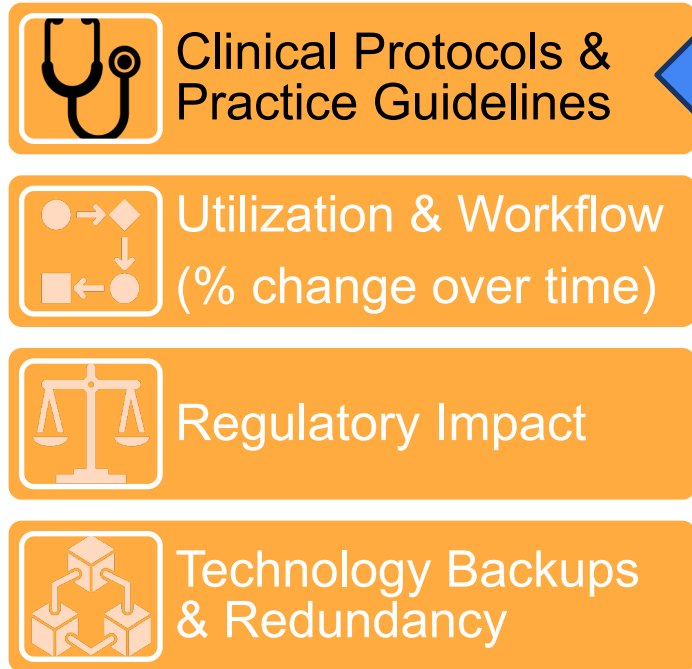|	
🏭	End of Manufacture (EOM)
🔧	End of Service/Parts (EOS)
💾	Obsolete Operating System
⌛	Maintenance History (% change over time)

Strategic Technology Forecasting
... then move beyond to the clinical

TOO MUCH INFO

THANK YOU FOR YOUR "ATTENTION"

DOES ANYONE HAVE ANY "QUESTIONS?"

makeameme.org

Thank You

Enjoy MD Expo – Las Vegas!

MD EXPO
Las Vegas • April 7-9, 2024

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Discovering the Possibilities