

# Accelerating HTM's Standardization Journey

Prepare for Disruption

BY : Heidi Horn and Kurt Finke



# About the Speaker: Heidi Horn

➤ President of Heidi Horn HTM Consulting LLC

## Past Experience:

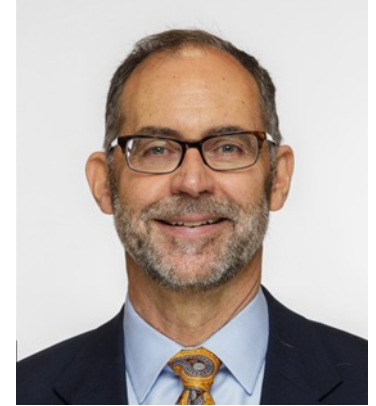
- VP of Healthcare Marketing Strategy/ VP of Healthcare Industry Solutions, Nuvolo – 4 years
- VP of healthcare technology management, SSM Health – 20 years
- **Association for the Advancement of Medical Instrumentation (AAMI) – 2005 to present**
  - Currently serve on AAMI's Board of Directors Executive Committee as Treasurer
  - Nominated to be AAMI's next Board Chair Elect (June 2024-June 2026)
  - Previous chair of AAMI's Technology Management Council (TMC)
  - Inaugural member of the AAMI Fellow program.
  - 2019 recipient of AAMI's "HTM Leadership Award"



**Heidi Horn, MA, AAMIF**  
**Heidi Horn HTM Consulting LLC**

# About the Speaker: Kurt Finke

- President of Finke Clinical Engineering LLC, providing HTM/Clinical Engineering consulting services to Federal Government and Private Sector healthcare delivery organizations, commercial businesses, and medical device manufacturers.
- Served with the U.S. Department of Veterans Affairs for 36 years, working as a biomedical/clinical engineer at several VA Medical Centers, Regional Offices, and culminating as Executive Director of VA's National Healthcare Technology Management Program.
- Received the VA Biomedical Engineer of the Year Award, the AAMI HTM Leadership Award, the ACCE Professional Achievement in Management Award. Mr. Finke currently serves on the AAMI Board of Directors as Vice-Chair for HTM and on the Executive Committee.
- Earned a Bachelor of Science in Engineering (BSE) degree in Biomedical Engineering from Tulane University and attained Certified Clinical Engineer (CCE). Mr. Finke is an AAMI Fellow.



**Kurt Finke BSE, CCE, AAMIF  
Finke Clinical Engineering LLC**

# Objectives of Session

- **Current State**

- Review the impact on the HTM industry caused by the lack of standards.
- Explain what standards are (and are not) and how they are different from regulations and guidelines.
- Provide an overview of what HTM standards and guidelines have been published or are in the works.

- **Future State**

- Describe the benefits (and disruption) on the HTM industry if more standards are created and adopted.
- Help accelerate standards adoption by educating the HTM industry on how equipment management standards can improve patient safety, equipment design and reliability, and the overall operations of HTM programs.

- **Encourage participation** in standards development, adoption, and transformation of the HTM industry

# Audience Quiz



In your HTM organization, do you:

Have adopted all the Work Order Type codes suggested by AAMI's CMMS Collaborative Guide.

OR

Use the same Work Order Type codes (plus some) you have used for decades.

Close the PM WO after searching for the device once and not locating it.

OR

Close the PM WO only after attempting to locate it two or more times.

Call your department Healthcare Technology Management (HTM)

OR

Call your department Clinical Engineering or Biomed

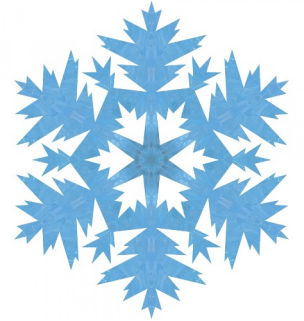
Use the formula of Severity x Probability to determine your equipment's' risk code.

OR

Use some other method to determine your equipment's' risk.

# Current State

- Very few standardized best practices have been adopted across the industry – each HTM organization customizes its own operating procedures. This results in:
  - Different CMMS nomenclature/codes (i.e. WO Type, Failure, Response, Equipment Description, etc.)
  - Different methods for determining technician staffing needs.
  - Different policies and procedures to be compliant with regulations.
  - Different metrics to measure performance.
- The list goes on-and-on. Every HTM organization is a snowflake.



# So What?

The impact of a lack of standards on the HTM industry:

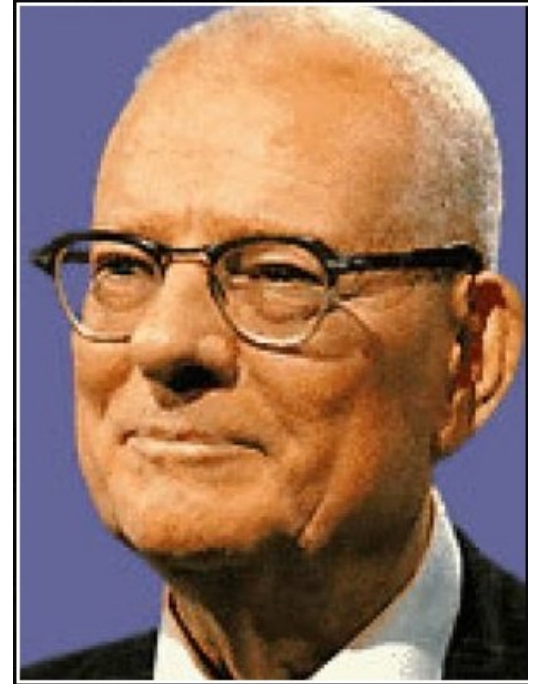
- It takes more time for everyone to “reinvent the wheel” versus adopting a proven standard.
- Varying levels of performance.
- Increased costs.
- More difficult to manage customized processes.
- Difficult to benchmark and compare performance against other HTM departments.
- Makes it more difficult to share solutions to common problems impacting the HTM industry.



# William Edwards Deming – economist

## Father of the Third-Wave of the Industrial Revolution

- “Uncontrolled variation is the enemy of quality”
- “Two basic rules of life are: 1) Change is inevitable. 2) Everybody resists change.”
- “Put a good person in a bad system and the bad system wins, no contest.”





# What Standards Are Not



# What are Standards?

**Standards / Codes** are typically:

- ✓ Developed within a *standards development organization* (SDO)
- ✓ Promote standardization of products, supplies, policies, and procedures.
- ✓ Spell out expected performance and technical specifications regarding processes/services and products
  - **Standards:** norms or requirements including uniform criteria, methods, processes and practices
  - **Codes:** minimum public safety rules, specifications or systematic procedures for design, fabrication, installation and inspection methods

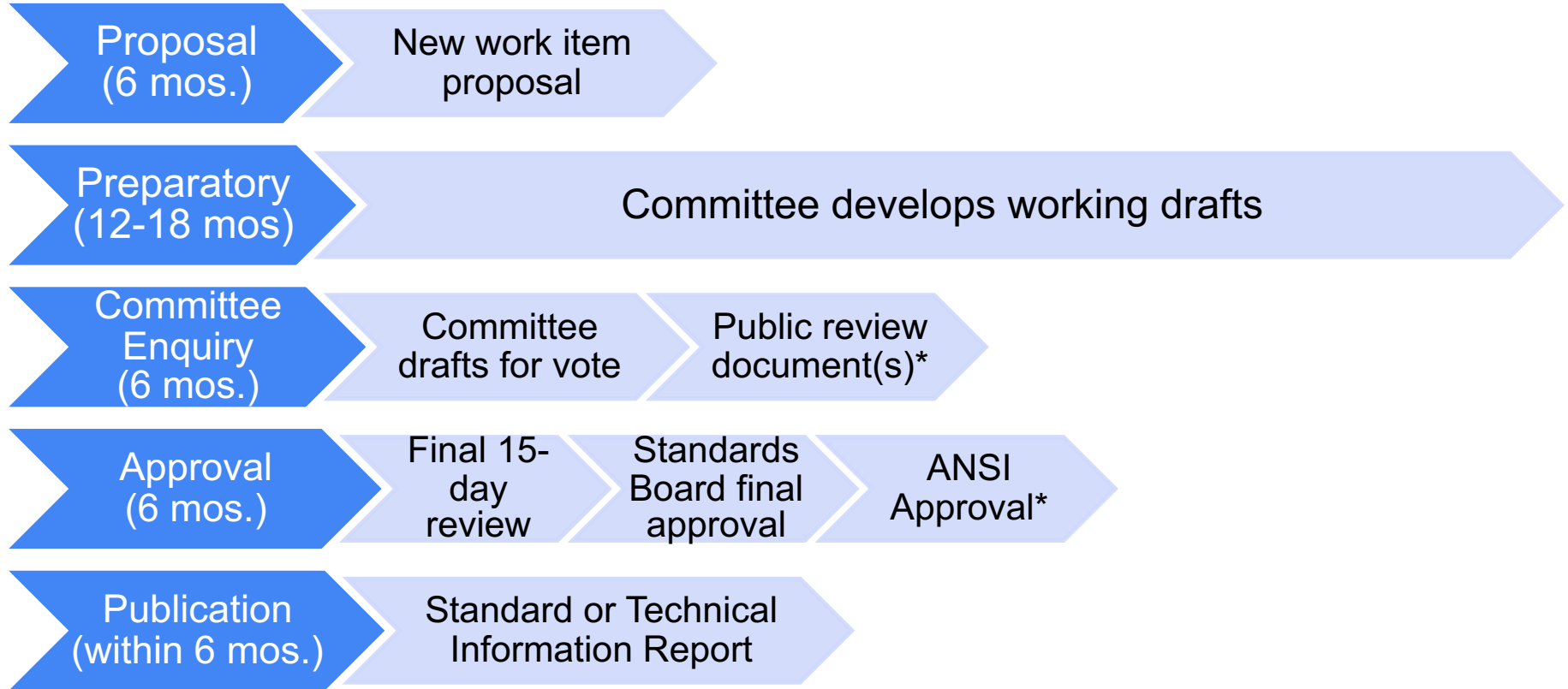


# What are Standards?

- ✓ **Consensus documents** developed by relevant stakeholders (e.g., manufacturers, regulators, ‘users’ or the consumers, subject matter experts) in a particular industry or discipline
- ✓ Voluntary (i.e., do not have force of law) ... unless they have been formally adopted by *authorities having jurisdiction* (CMS) ... e.g., federal, state, local authorities ... and referenced (by standards organization name, standard number and release date) in a regulation as a requirement.
- ✓ Reviewed periodically (e.g., every 5 years) with new or revised versions produced when indicated



# Standards Development Process



\* For standards proposed for publication as American National Standards only.

# Standards in Action

What color is used for **Oxygen** in hospitals?



What color is used for **Medical Air**?



What about **Medical Vacuum**?



# Standards in Action

What do you use the **DICOM** standard for?

**ISO 12052:** Digital Imaging and Communication in Medicine (DICOM)



Is **THE** international standard for medical images and related information. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.

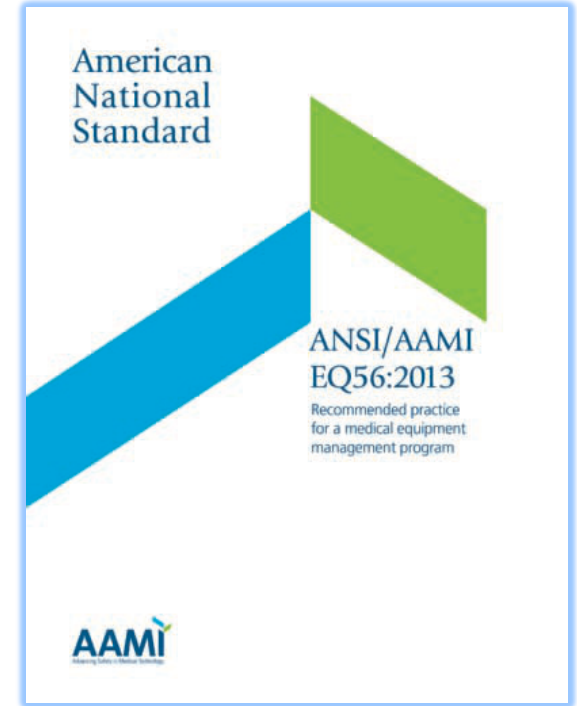
Discovering the Possibilities

# Standards in Action

## ANSI/AAMI EQ56

- What is it?
- How do you use it?
- Does it drive your HTM Practice?

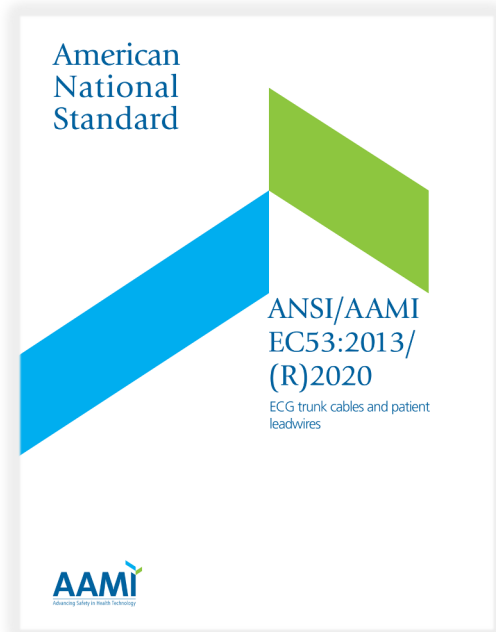
Applies to any entity responsible for the management of medical equipment used as part of the routine care of patients, including health care organizations as a whole, divisions and departments within health care organizations, and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations.



# Standards in Action

## ANSI/AAMI EC53

ECG Trunk Cables and Lead Wires



Covers safety and performance requirements for disposable and reusable lead wires as well as the cables used for surface electrocardiographic (ECG) monitoring in cardiac monitors.



# Standards: Ever Evolving

- Published standards are periodically **Reaffirmed or Revised**
  - **REAFFIRMATION:** ANSI/AAMI EQ93:2019, *Medical equipment management – Vocabulary used in medical equipment programs*
  - **REVISION:** AAMI EQ56, *Recommended practice for a medical equipment management program* (via AAMI EQ-WG01, HTM Program Management working group)
- Need for **New** Standards Emerge
  - **NEW:** AAMI EQ110, *Guidance for health care technology management education programs* (via AAMI EQ-WG05, HTM Education Programs working group)
  - **NEW:** Health Sector Coordinating Council (HSCC) published HIC-MaLTS *Health Industry Cybersecurity – Managing Legacy Technology Security*
- New Standards initially can be difficult to adopt; **they disrupt legacy operations**. But once adopted, you'll think, "**How did we ever operate without this Standard?!**"

# Future State

How might Standards benefit the HTM Industry? Envision what a future (e.g. 2040) could look like...

- Example of U.S. Department of Veterans Affairs' journey to reduce variation of HTM practices:
  - 172 Hospitals; 400+ Outpatient Clinics; >1 Million Medical Devices/Systems
  - Standardized across all HTM Teams:
    - Scope of Services
    - Nomenclature System
    - Data Definitions / Work Types
    - Workforce Classification
    - Staffing Guidelines
    - Competencies / Professional Development



# Future State (cont.)

Standardization across VA HTM organization *DROVE improvements*, such as:

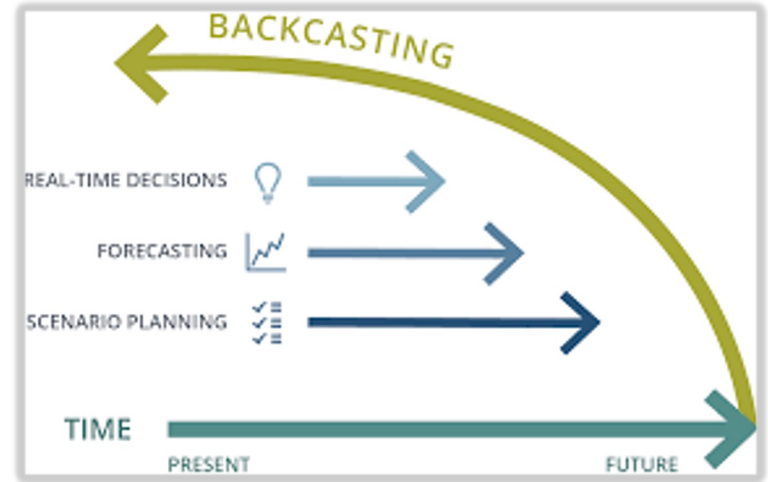
- Equipment **Safety** Alert remediation
- Enterprise-wide **data analysis**
- **Cybersecurity** Risk Management
- Higher caliber (**knowledgeable**) **HTM workers**
- **Increased staffing** levels (significantly!)
- Program Performance Monitoring and **Continuous Improvement**
- Medical Technology **Strategic Planning** and Refresh
- Greater Executive Leadership (**C-Suite**) **engagement** and support
- More **clearly defined HTM responsibilities** and core functions

# Future State (cont.)

**Backcasting:** a strategic planning process that starts with defining a highly desirable future and then reverse-engineering actions that must be taken in the present to achieve that future.

Let's brainstorm a future vision!

- Think without constraints.
- Put aside potential impact on current practice.
- Consider your pain points.



# Change Maker: YOU!

- YOU can influence change
- YOU can lead adoption and implementation in your organization
- YOU have subject matter expertise to help design/develop standards
- YOU have the dedication that it takes
- YOU can choose where and what to engage with, based upon YOUR passions: AAMI Technical, AAMI EQ management, IHE, HSCC, NFPA, IEEE, etc.

***Standards can, and do, improve quality and performance!***

A hand holding a yellow pencil points to the letter 'Q' on a blackboard. The text 'Q & A' is written in a light gray, casual font. Another hand is visible on the right side of the blackboard, holding the edge of the board. The background is white.

Q & A

# Contact Information

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