Washington State Biomedical Association

Risk and Liability in HTM

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Speaker Introductions

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How to talk about risk

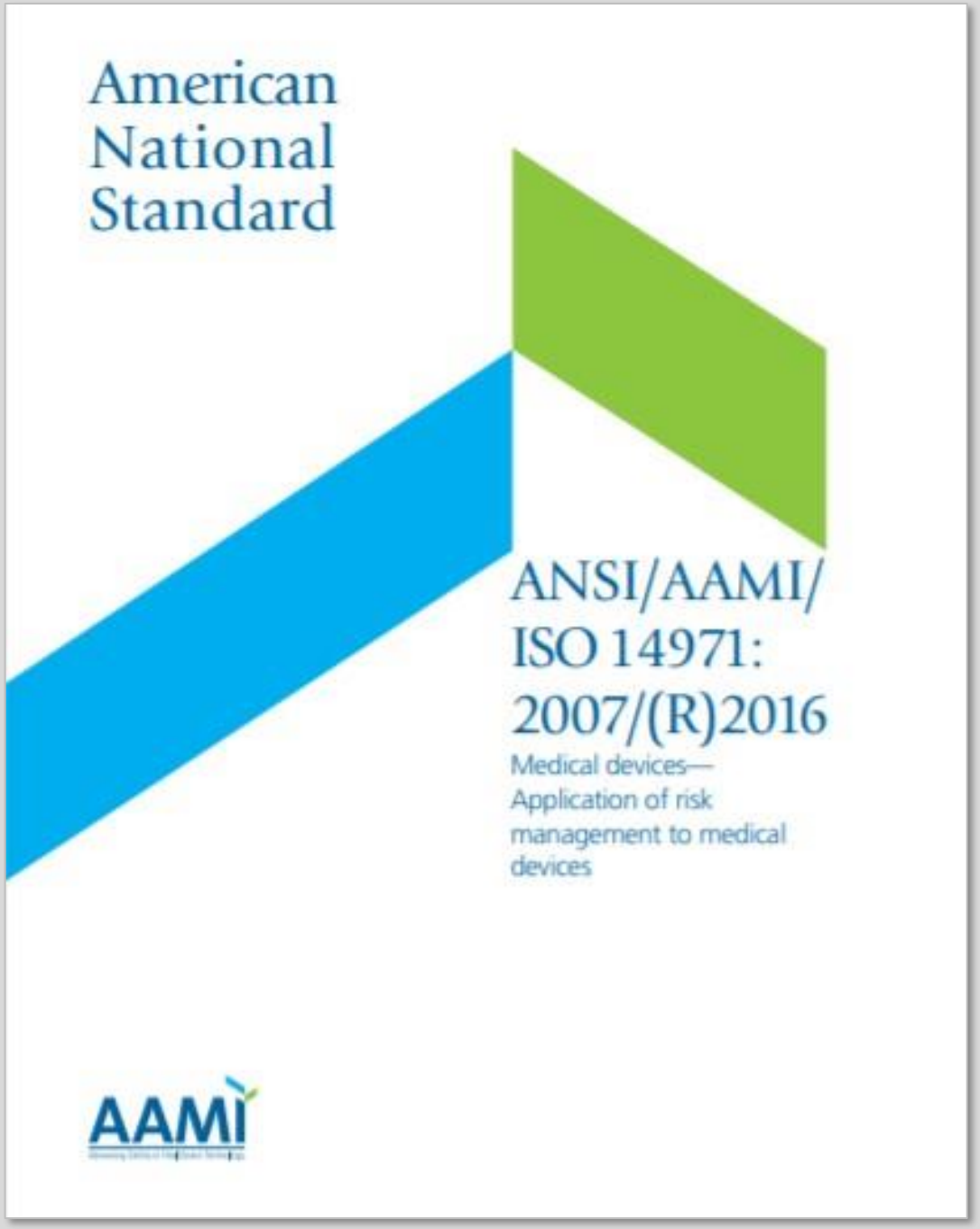
Fennigkoh-Smith ≠ Risk Assessment

Cat or SubCat Code:	For example: 18-823	BMET completes Green Sections	BME Asset Tag Req'd:	YES
UMDNS Description:	For Example: Ultrasonic Therapy Systems			
Evaluation Criteria: *Risk evaluation method based on World Health Organization guidelines.*			Scheduled Maintenance Req'd: ↓	
Equipment Function Therapeutic, Diagnostic, Analytical and Miscellaneous equipment categories are considered. *Note : This score in NOT based on equipment location (e.g. ICU) rather you are being asked whether the equipment's FUNCTION is Therapeutic, Diagnostic or Analytical regardless of it's physical location. For example a thermometer has a diagnostic score of 6, even though it may be located in a critical care area, while a defibrillator has a score of 10 even if located in a general ward.*		9	Scheduled Maintenance Required:	YES
Physical Risk Associated with Clinical Application Lists the potential patient or equipment risk during use.		3	Priority:	NORMAL
Scheduled Maintenance Requirement Describes the level and frequency of "***scheduled maintenance***" required as noted by the Manufacturer or through experience.		3	Frequency:	1/YEAR
Equipment History Any information available regarding service history that should be considered *(repair frequency, patient incidents, device alerts)*		0		

"I'm not sure when or how the "risk" modifier became associated with what was intended to be a method for determining which medical device types to include in a PM program."

— Heroes of HTM: Larry Fennigkoh

24x7 Magazine, 2020


American
National
Standard
ANSI/AAMI/
ISO 14971:
2007/(R)2016
Medical devices—
Application of risk
management to medical
devices
AAMI

Risk = Severity x Probability

		Severity (Consequence)			
		1 Negligible	2 Marginal	3 Critical	4 Catastrophic
Probability	4 Probable	4	8	12	16
	3 Occasional	3	6	9	12
	2 Remote	2	4	6	8
	1 Improbable	1	2	3	4

Level of analysis: Medical equipment type

- Otoscope/ophthalmoscope
- Infusion pump

Level of analysis: Failure modes

- Infusion pump
  - Battery failure
  - Inaccurate flow fate
  - Upstream occlusion pressure sensor

Level of analysis: PM^{AEM} procedures

- Infusion pump flow rate testing
  - Test less often than PM^{OEM}
  - Test at fewer settings than PM^{OEM}
  - Do not test

You can’t do that because

“so and so” says you can’t

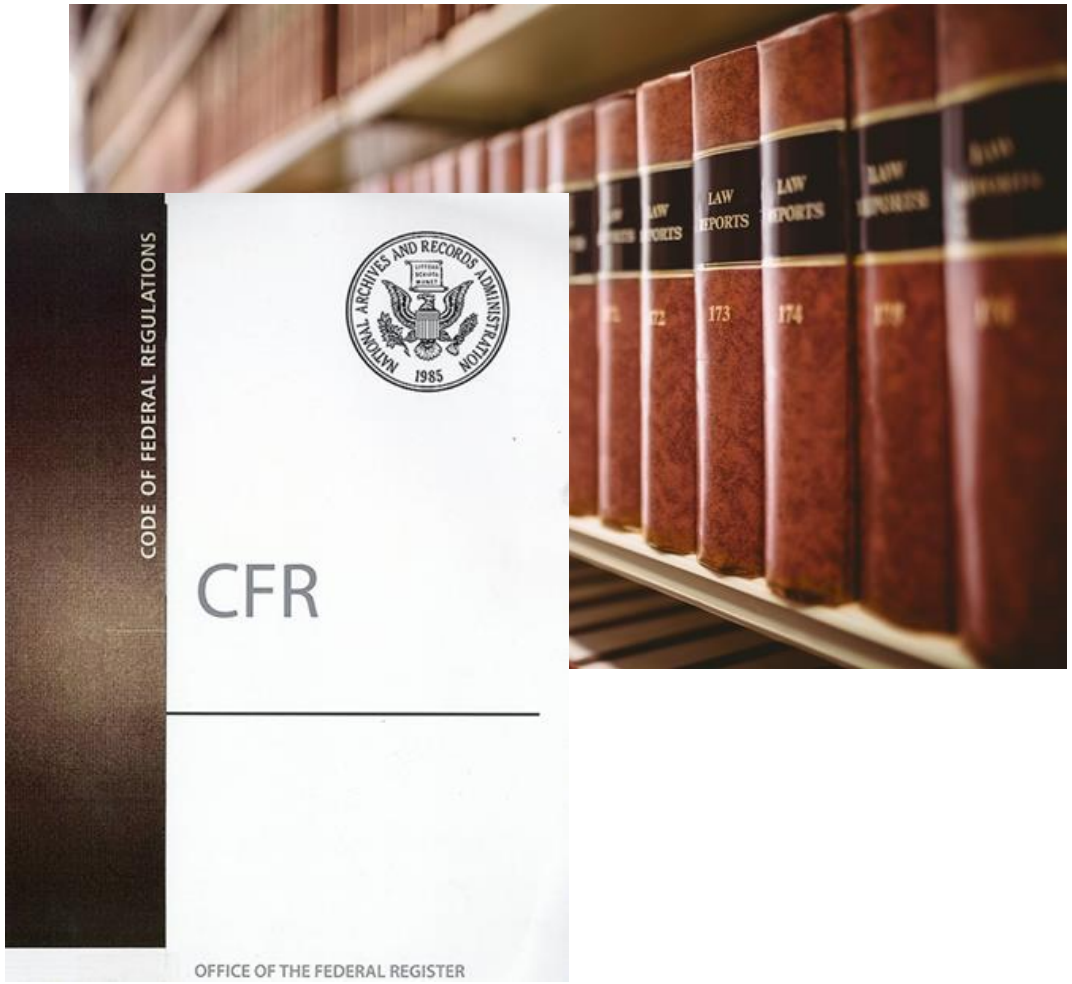
Types of Compliance

- **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)

Someone you must, or have chosen to, pay attention to

Laws & Regulations



Laws & Regulations are rules that are:

- Mandatory
- Laws are enacted by the Legislative and Executive branches of government and enforced by the Judiciary branch
- Regulations are issued by government agencies, boards, and commissions
  - Federal – e.g., FDA, CMS
  - State – e.g., Health Department
- Regulations explain how to carry out (enforce) laws
- Federal Regulations are published yearly in the Code of Federal Regulations eCFR :: Home

HTM-relevant Federal Laws & Regulations

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

Health Insurance Portability and Accountability Act of 1996 (HIPAA) | CDC
HIPAA Home | HHS.gov

Clinical Laboratory Improvement Amendments (CLIA)

CDC

Clinical Laboratory Improvement Amendments (CLIA) | CDC

CFR Title 21 – Food and Drug Administration

FDA

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

CFR Title 29 Part 1910 – Occupational Safety & Health Standards

OSHA®

eCFR :: 29 CFR Part 1910 -- Occupational Safety and Health Standards
Each State/Territory has its own State Plan

Centers for Medicare & Medicaid Services

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Hospital Equipment Maintenance Requirements
Memo #14-07-Hospital

Standards & Codes

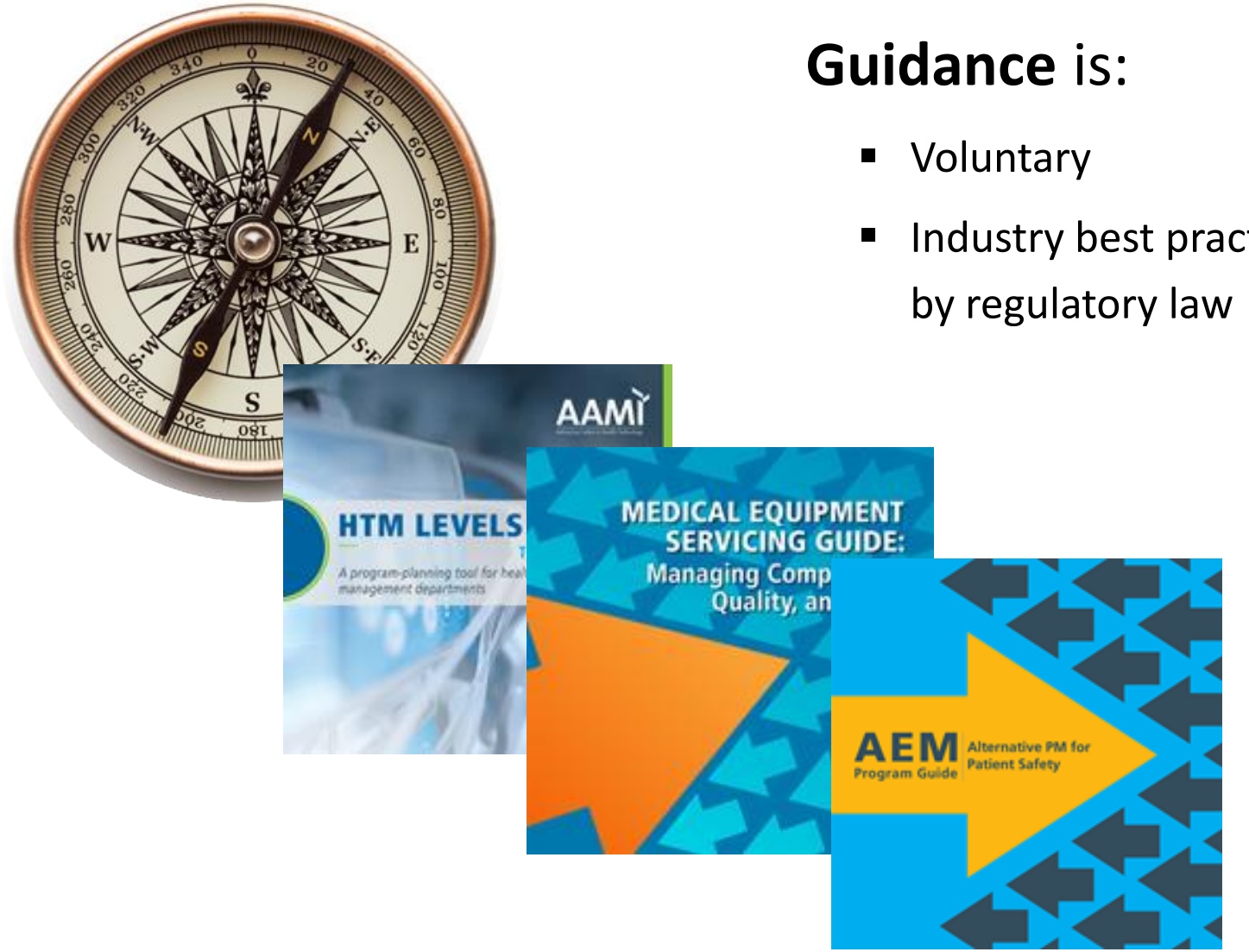
Standards are:

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

Codes are:

- Mandatory or Voluntary
- Non-government published standards adopted for a specific subset of work and within a particular jurisdiction
  - Not to be confused with the United States Code

Guidance



Guidance is:

- Voluntary
- Industry best practices that are often followed but not backed by regulatory law

“You Can’t Do That” Game Time

1. The use of non-OEM parts violates the medical device’s FDA clearance (“approval”).

   False. *The FDA does not regulate the sourcing of parts by healthcare delivery organizations. The FDA does monitor the OEM’s supply chain through the Quality Management Systems requirements.*

   The potentially bigger *risk is not having a parts management program to ensure quality and financial integrity.*

“You Can’t Do That” Game Time

2. An AEM schedule and/or procedure may be defined for ultrasound machines if the servicer has sufficient historical data to support the change.

   False. *The Centers for Medicare & Medicaid (CMS) requires all medical imaging modalities to adhere to OEM specified scheduled maintenance schedule and procedures.*

“You Can’t Do That” Game Time

3. The FDA regulates healthcare delivery organizations.

   False. *The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.*

   FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

   NOTE – *The FDA may request documentation – e.g., recall remediation documentation – from a health care delivery organization as a means of monitoring the OEM’s quality performance.*

“You Can’t Do That” Game Time

4. The Joint Commission regulates healthcare delivery organizations.

   False. *The Joint Commission (TJC) is* ***a deeming authority*** *recognized and approved by the Centers for Medicare & Medicaid (CMS) to conduct accreditation surveys and issue accreditation decisions.*

   The mission of CMS *is to ensure effective, up-to-date health care coverage and promote quality care for people with Medicare. The agency ensures its contractors and State agencies properly administer Medicare. It also serves the Medicare Program by:*

   - *Establishing policy for the payment of providers*
   - *Conducting research of health care management and treatment*
   - *Assessing the quality of health care facilities and services*

   Other examples of CMS deeming authorities include:

   - *DNV NIAHO/ISO program*
   - *American Osteopathic Association’s Healthcare Facilities Accreditation Program (HFAP)*
   - *Accreditation Association for Ambulatory Health Care (AAAHC)*

“You Can’t Do That” Game Time

5. The FDA prohibits use of medical devices that have reached “end of life.”

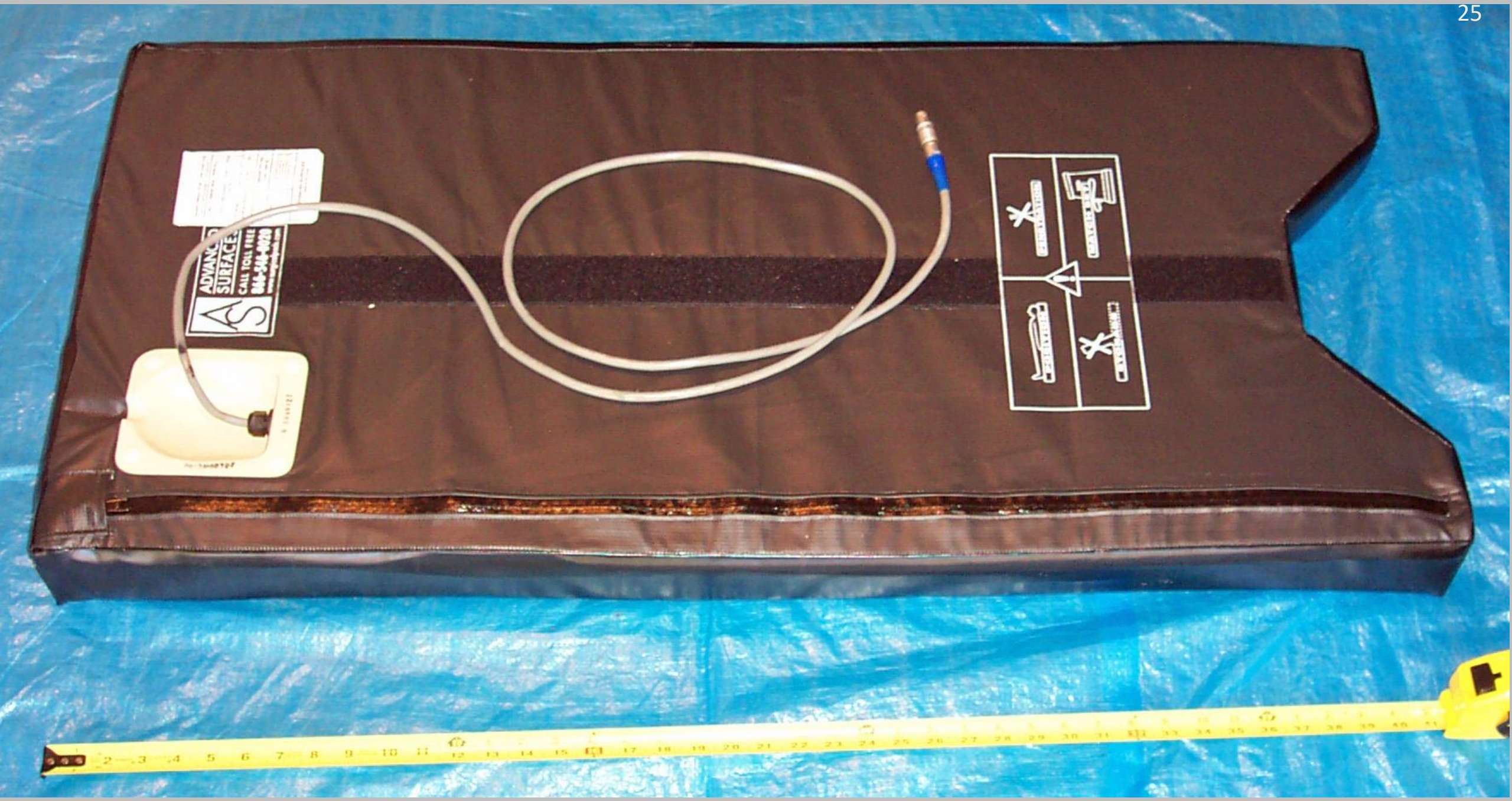
   False. *The FDA does not define “end of life” status of a medical device. This is a term inconsistently defined by original equipment manufacturers (OEMs), healthcare delivery organizations (HDOs), and 3rd-party service organizations.*

   The FDA may revoke a medical device’s clearance (“approval”) status and require the OEM to remove the product from the marketplace.

   CMS will likely refuse to reimburse HDOs for healthcare services delivered with medical devices that do not have FDA clearance (“approval”).

Investigation of medical device-related incidents

Use Error ≠ User Error


ADVANCED SURFACES
CALL TOLL FREE


POWER
ON
Standby
COOL HEAT
PAD
Temperature
DEGREE C
DEGREE F
Temperature
Setpoint
36°C – 96.8°F Low Temp
37°C – 98.6°F Medium Temp
38°C –100.4°F Med-High Temp
39°C –102.2°F High Temp
System Monitor
STANLEY
Life Guard


1
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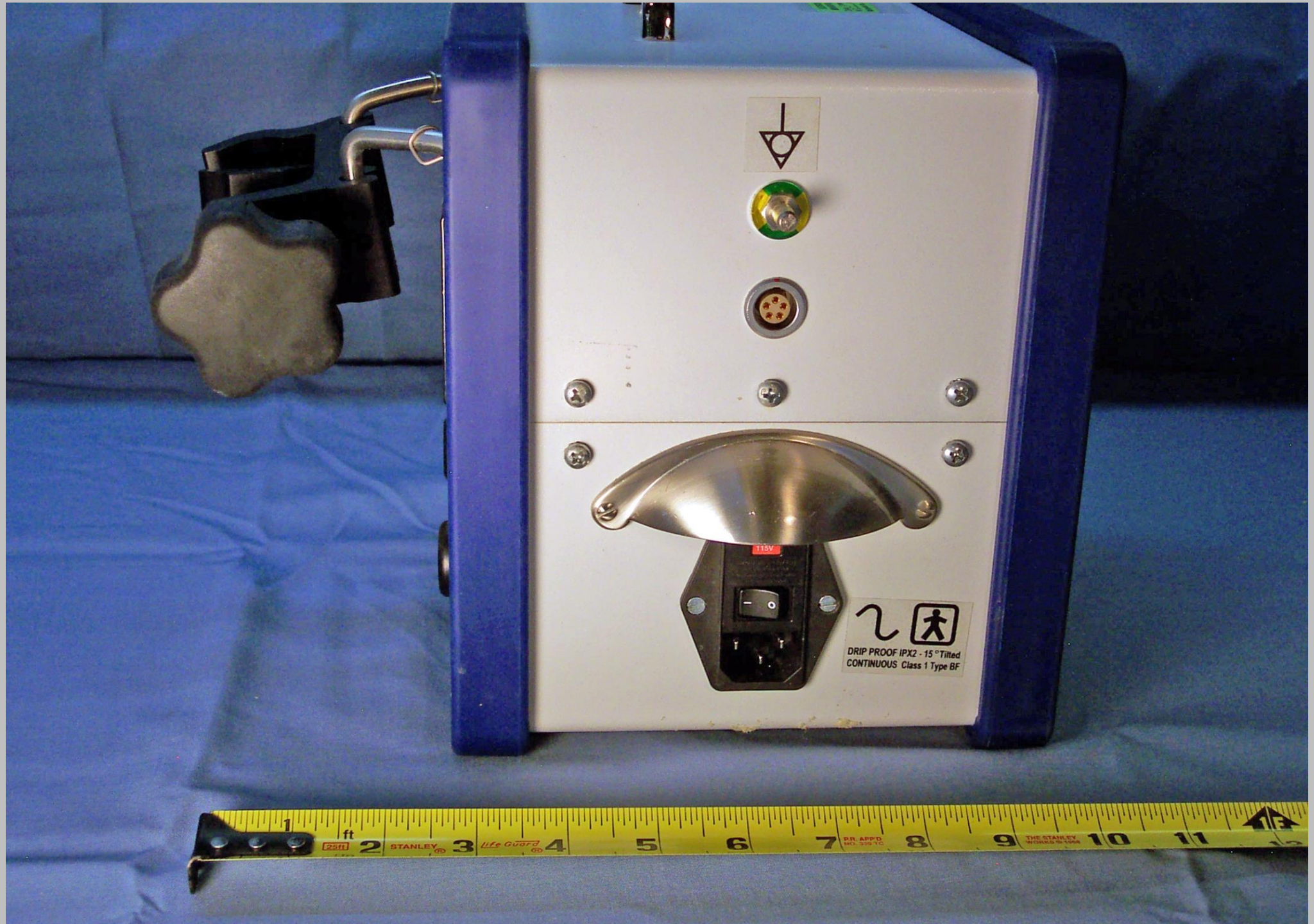

115V
DRIP PROOF IPX2 - 15°Tilted
CONTINUOUS Class 1 Type BF
STANLEY
Life Guard


WARNING
Possible fire hazard when used with oxygen administering equipment of other than a nasal mask or 1/2 bed tent type. Oxygen tent should not extend below mattress support level.
DANGER
EXPLOSIVE HAZARD Do not use in the presence of flammable anesthetics.
STANLEY
Life Guard

What if you get a subpoena to testify?

- Most cases are settled before trial
- Tell the truth
- Don’t speculate

Professional judgment

Professional Judgement

Professional Judgement ***shall be defined as*** *judgement that is informed by professional knowledge of curriculum expectations, context, evidence of learning, methods of instruction and assessment, and the criteria and standards that indicate success in student learning. In professional practice, judgement involves a purposeful and systematic thinking process that evolves in terms of accuracy and insight with ongoing reflection and self-correction.*

Exercising professional judgement ***means the application of*** *professional knowledge and experience in defining objectives, solving problems, establishing guidelines, reviewing the work of others, interpreting results and providing and assessing advice or recommendations, and other matters that have an element of latitude or decision-making.*

https://www.lawinsider.com/dictionary/professional-judgement

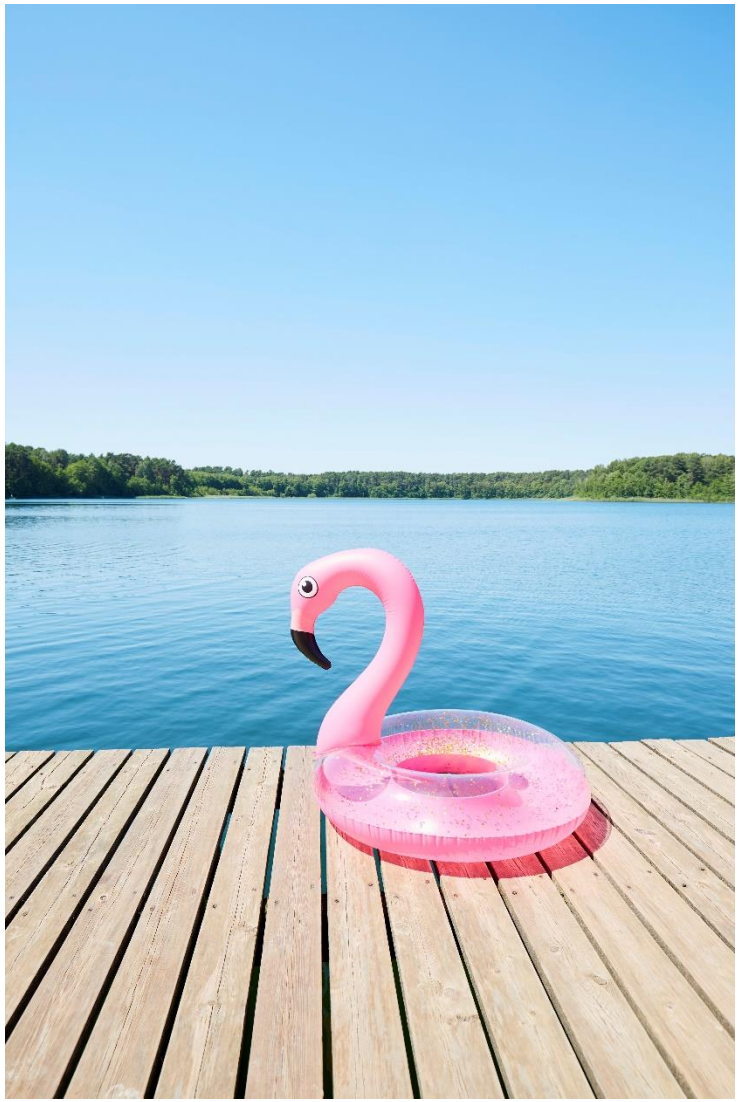
Professional Judgement

Understand your limits

- Education
- Experience
- Credentials

Stay safe

- Comply with policies and regulations
- Use data for decision-making
- Conduct risk assessments
- Document



Q&A: What keeps you up at night?