Navigating the raging sea of Rules, requirements & recommendations

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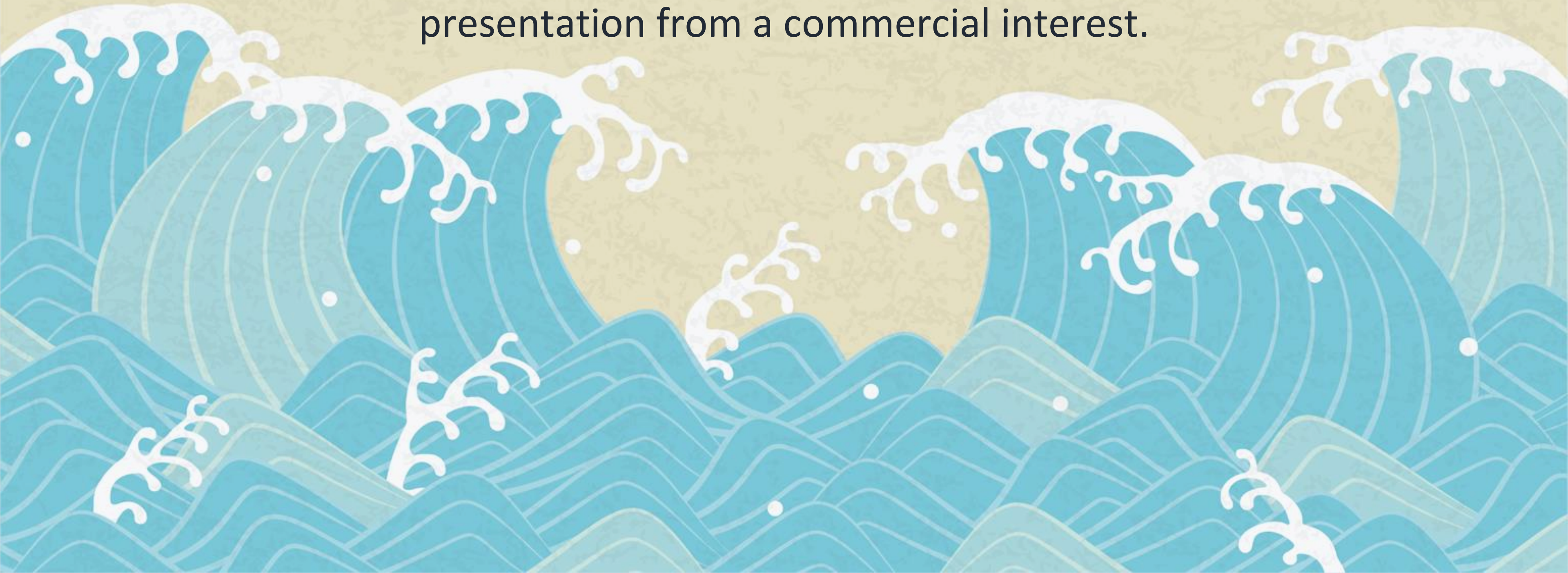
Project Firstline is a national collaborative led by the U.S. Centers for Disease Control and Prevention (CDC) to provide infection control training and education to frontline healthcare workers and public health personnel. National Association of County and City Health Officials (NACCHO) is proud to partner with Project Firstline to host the NACCHO Healthcare Infection Prevention and Control Summit (Summit), as supported through CDC Grant # 6NU38OT000306-03-05. CDC is an agency within the Department of Health and Human Services (HHS). This presentation is being hosted as part of the Summit; the contents of this presentation and Summit do not necessarily represent the policies of CDC or HHS and should not be considered an endorsement by the Federal Government.

Disclosure

Rebecca is employed by Diversey—A Solenis Company. The company pays her expenses to attend this meeting (salary) & create educational content but has given no input into this presentation from a commercial interest.

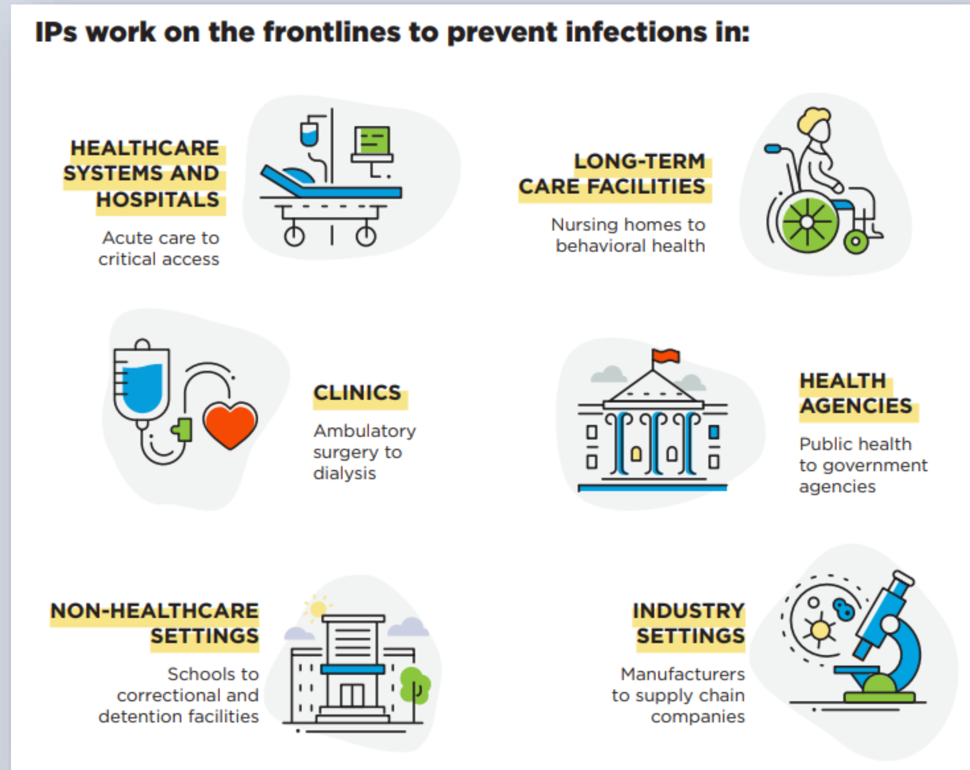


Objectives

- Describe the difference between regulations, guidelines, standards & recommendations.
- State three keywords that have an impact on infection prevention & control (IPC) programs' policies & procedures.
- Describe two scenarios as an IP when you have had to bend the rules (or haven't had a rule *to* bend!).

Infection Preventionists: Who Are We?

- Nursing
- Public health & epidemiology
- Microbiology/Lab
- Medicine
- Information technology
- Allied health professions, e.g., respiratory therapy, medical imaging, radiography, physical therapy (and beyond?)



https://apic.org/wp-content/uploads/2022/10/WhoAreIPs_Infographic.pdf

What brought you to IP?
For me, it was **pure circumstance (and a bit of luck & desperation)**.

- ✓ Studied creative writing, English & Hispanic literature?!
- ✓ Worked in the ER as a unit clerk. (Underpaid, burned out, high stress)
- ✓ Had **no idea** what to do with my life. (Literature professor? Doctor? Nurse? Librarian?)
- ✓ Saw a job posting for an Infection Control Assistant & hit "apply." (Not a ton of options in healthcare, given the above.)

Me, the Infection Control Assistant, circa 2005

Infection Preventionists:
How Are We Today?

- Short answer = there's a lot we ***don't know.***

Increased alcohol use during COVID	
No	577 (62.6)
Yes	345 (37.4)
Burnout	
No	320 (34.8)
Yes	600 (65.2)
COVID impact on physical health	
No change	326 (35.2)
Better	44 (4.8)
Worse	555 (60.0)
COVID impact on mental health	
No change	219 (23.7)
Better	21 (2.3)
Worse	683 (74.0)

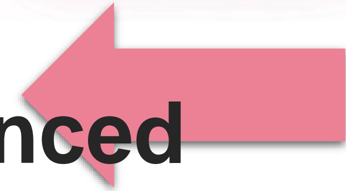
Mazurek Melnyk B et al. 2022. Associations among infection prevention professionals' mental/physical health, lifestyle behaviors, shift length, race, and workplace wellness support during COVID-19. Am J of Inf Control. Article in press. https://doi.org/10.1016/j.ajic.2022.04.004.

Me, March 12, 2020
The day the first COVID-19 case was suspected in our hospital.

Complex Factors Contributing to IP/AS Burnout & Moral Injury

Organizational	Professional	Societal	Personal
Departure of workforce (extra work among fewer people)	Pandemic roles & responsibilities are ill-defined. Constantly "on call" with poor work/life balance.	"Dyssynchrony" of IP guidance for community vs. healthcare settings	Potential moral injury when IP staff are asked to promote policies they deem suboptimal or based on incomplete data
Health systems are not structures to rapidly adopt IP strategies	Multiple responsibilities, for some, includes direct patient care	Response to new COVID-19 waves remains reactive with constant threats to funding	Potential moral injury & ethical dilemmas for AS staff involved in rationing limited COVID-19 therapeutics
Collateral damage: HAIs and AMR/MDROs	Suboptimal protected time for pandemic & usual responsibilities	Colleagues & social networks embrace a normalcy while IP/AS workforce are constantly preparing for future surges.	
IP/AS programs remain busy in surge & post-surge conditions Escalation & de-escalation of IP protocols	Work largely occurs behind the scenes. Undervaluation compared to other hospital colleagues. Leadership unaware of scope of daily efforts & contributions.		

READ THIS STAT



Also, more inexperienced IPs

Nori, P., Stevens, M., & Patel, P. (2022). Rising from the pandemic ashes: Reflections on burnout and resiliency from the infection prevention and antimicrobial stewardship workforce. Antimicrobial Stewardship & Healthcare Epidemiology, 2(1), E101. doi:10.1017/ash.2022.240

Infection Prevention: Is it an art or a science?

art[1]

/ärt/

See definitions in:

All | Art | Military

noun

1. the expression or application of human creative skill and imagination, typically in a visual form such as painting or sculpture, producing works to be appreciated primarily for their beauty or emotional power.
   "the art of the Renaissance"

   Similar: fine art | artwork | creative activity
2. the various branches of creative activity, such as painting, music, literature, and dance.
   "the visual arts"

sci·ence

/ˈsīəns/

noun

the intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment.
"the world of science and technology"

Similar: branch of knowledge | area of study | discipline | field

- a particular area of science.
  plural noun: **sciences**
  "veterinary science"
- a systematically organized body of knowledge on a particular subject.
  "the science of criminology"

Art vs. Science?

Art	Science
Abstract	Concrete
Subjective	Objective
Emotional	Rationale
Feelings & opinions	Data & facts
Conceptual	Theoretical

https://www.differencebetween.com/difference-between-science-and-vs-art/

Rules, Requirements & Recommendations

Regulation

- A rule or order issued by an executive authority or regulatory agency of a government and having the force of law.
  - A **rule** that we must follow
  - In healthcare, synonymous with **requirement**
- **Rules** that the government makes under an Act
  - Exist at the local, state & federal levels

https://www.merriam-webster.com/dictionary/regulation

Regulations in the Post-Pandemic US

- As the COVID-19 pandemic revealed, regulations are not always guided by evidence & best practice recommendations

Gov. Ron DeSantis: COVID-related mask mandates will never return to Florida

By Dani Medina | Published September 7, 2023 | Florida | FOX 35 Orlando |

https://www.fox35orlando.com/news/desantis-mask-mandates-florida-covid
https://www.flgov.com/wp-content/uploads/2023/05/medical-freedom.png

Code of Federal Regulations (CFR)

- The codification (arrangement) of the general and permanent rules and regulations (administrative law) published in the *Federal Register* by the executive departments and agencies of the federal government of the United States
- Divided into 50 titles, IP falls under Public Health

Title 42 :: Public Health
Title 43 :: Public Lands: Interior
Title 44 :: Emergency Management and Assistance
Title 45 :: Public Welfare
Title 46 :: Shipping
Title 47 :: Telecommunication
Title 48 :: Federal Acquisition Regulations System
Title 49 :: Transportation
Title 50 :: Wildlife and Fisheries

8/10/2022

▼ Title 42 - Public Health *(19 sections changed)*

Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter B - Medicare Program
Part 412 - Prospective Payment Systems for Inpatient Hospital Services
Subpart B - Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs
§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.
Subpart D - Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs
§ 412.60 DRG classification and weighting factors.
§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.
Subpart G - Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs
§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.
§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.
Subpart H - Payments to Hospitals Under the Prospective Payment Systems
§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.
Subpart I - Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs
Incentive Payments Under the Hospital Value-Based Purchasing Program - Incentive Payments Under the Hospital Value-Based Purchasing Program
§ 412.168 Special rule for FY 2022.
Subpart L - The Medicare Geographic Classification Review Board
Composition and Procedures - Composition and Procedures
§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.
Subpart O - Prospective Payment System for Long-Term Care Hospitals
§ 412.515 LTC-DRG weighting factors.
§ 412.525 Adjustments to the Federal prospective payment.
§ 412.529 Special payment provision for short-stay outliers.
Part 413 - Principles of Reasonable Cost Reimbursement; Payment for End-Stage Renal Disease Services; Prospectively Determined Payment Rates for Skilled Nursing Facilities; Payment for Acute Kidney Injury Dialysis
Subpart F - Specific Categories of Costs
§ 413.75 Direct GME payments: General requirements.
§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.
§ 413.99 xxx
Subchapter G - Standards and Certification
Part 482 - Conditions of Participation for Hospitals
Subpart C - Basic Hospital Functions

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

https://www.ecfr.gov/

Rulemaking

- Federal agencies are authorized by "enabling legislation" to promulgate regulations (rulemaking).
    - Dept Health & Human Services
        - Centers for Medicare & Medicaid
- In administrative law, **rulemaking** is the process that executive and independent agencies use to create, or *promulgate*, regulations.
- **It is the LAW!**

Regulation/Requirement: Example

Example statements within OSHA Bloodborne Pathogen Standard:

1910.1030(c)(1)(iii)Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

1910.1030(c)(1)(iv)The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure . . .

Occupational Safety and Health Administration

OSHA | STANDARDS | ENFORCEMENT | TOPICS | HELP AND RESOURCES

By Standard Number › 1910.1030 - Bloodborne pathogens.

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Standard Number:** 1910.1030
- **Title:** Bloodborne pathogens.
- **Appendix:** A
- **GPO Source:** e-CFR

Guideline

- A CDC guideline is any document issued under agency authority that contains recommendations for clinical practice or public health policy, falling into one of three categories:
  - Interim
    - Expert opinion or indirect/emerging evidence, generally developed in response to emergencies or disasters
  - Standard
    - Evidence-based recs with systematic reviews of the lit
  - Updated
    - Replace or supplement previously published guideline

Carande-Kulis V, Elder RW, Koffman DM. Standards Required for the Development of CDC Evidence-Based Guidelines. MMWR Suppl 2022;71(Suppl-1):1–6. DOI: http://dx.doi.org/10.15585/mmwr.su7101a1.

Accessable version: https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html

Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30329

2003
Updated: July 2019

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Environmental Cleaning

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The Guideline for Environmental Cleaning was approved by the AORN Guidelines Advisory Board and became effective as of January 13, 2020. The recommendations in the guideline are intended to be ...

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Recommendations

1. Product Selection and Use
2. Cleaning Procedures

MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports December 30, 2005 / Vol. 54 / No. RR-17

Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Last update: July 2023

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee

Acknowledgement: The authors and HICPAC gratefully acknowledge Dr. Larry Strausbaugh for his many contributions and valued guidance in the preparation of this guideline.

Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

Recommendation

- Statement that describes a specific prevention, treatment, or policy action.
- Per CDC, also referred to as "good practice recommendations."
- Recommendations typically are found within the guidelines

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated May 8, 2023   Print

The recommendations in this guidance continue to apply after the expiration of the federal COVID-19 Public Health Emergency.

For healthcare personnel, see Isolation and work restriction guidance. For strategies to mitigate healthcare personnel staffing shortages, see Contingency and crisis management. For healthcare professionals advising people in non-healthcare settings about isolation for laboratory-confirmed COVID-19, see Ending Isolation and Precautions for People with COVID-19.

Carande-Kulis V, Elder RW, Koffman DM. Standards Required for the Development of CDC Evidence-Based Guidelines. MMWR Suppl 2022;71(Suppl-1):1–6. DOI: http://dx.doi.org/10.15585/mmwr.su7101a1.

HICPAC Recommendation Categories

Rank	Description
Category IA	Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB	Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
Category IC	Required by state or federal regulation, or representing an established association standard. (Note: Abbreviations for governing agencies and regulatory citations are listed, where appropriate. Recommendations from regulations adopted at state levels are also noted. Recommendations from AIA guidelines cite the appropriate sections of the standard).
Category II	Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.
Unresolved Issue	No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.

New Categorization Scheme for Recommendations [November 2018]
In November 2018, HICPAC voted to approve an updated recommendation scheme. The category **Recommendation** means that we are confident that the benefits of the recommended approach clearly exceed the harms (or, in the case of a negative recommendation, that the harms clearly exceed the benefits). In general, Recommendations should be supported by high- to moderate-quality evidence. In some circumstances, however, Recommendations may be made based on lesser evidence or even expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms or when then Recommendation is required by federal law. For more information, see November 2018 HICPAC Meeting Minutes [PDF - 126 pages] (http://www.cdc.gov/hicpac/pdf/2018-Nov-HICPAC-Meeting-508.pdf).

"In some circumstances, however, **Recommendations may be made based on lesser evidence or even expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms** or when then Recommendation is required by federal law."

https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html

Standard

- Document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. http://www.iso.org/iso/home/standards.htm
- Per CDC, standards consider the benefits & harms related to specific actions to address a disease, condition or risk factor.
  - Includes systematic reviews of the lit
- Per TJC, standards are "the basis of an objective evaluation process that can help healthcare orgs measure, assess & improve performance."
  - Chapter → Standard → Element(s) of Performance

- https://www.merriam-webster.com/dictionary/standard
- Carande-Kulis V, Elder RW, Koffman DM. Standards Required for the Development of CDC Evidence-Based Guidelines. MMWR Suppl 2022;71(Suppl-1):1–6. DOI: http://dx.doi.org/10.15585/mmwr.su7101a1.
- https://www.jointcommission.org/standards/about-our-standards/

American
National
Standard

ANSI/AAMI
ST91:2021
Flexible and semi-rigid
endoscope processing in
health care facilities

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Position Statements & Standards

Set the Standard with SGNA

New and Revised Requirements Addressing Antibiotic Stewardship for the Hospital and Critical Access Hospital Programs

Effective January 1, 2023, new and revised antibiotic stewardship requirements will apply to all Joint Commission–accredited hospitals and critical access hospitals. The 12 elements of performance (EPs) are included in the "Medication Management" (MM) chapter Standard MM.09.01.01) nd expand upon the current expectations for antibiotic stewardship programs in the hospital setting.

Prepublication Standards

- Revisions to the Environment of Care and Life Safety Chapters
- New and Revised Requirements Addressing Antibiotic Stewardship for the Hospital and Critical Access Hospital Programs
- New and Revised Requirements to Reduce Health Care Disparities
- New COVID-19 Staff Vaccination Standard
- New Requirements for the Advanced Certification in Perinatal Care

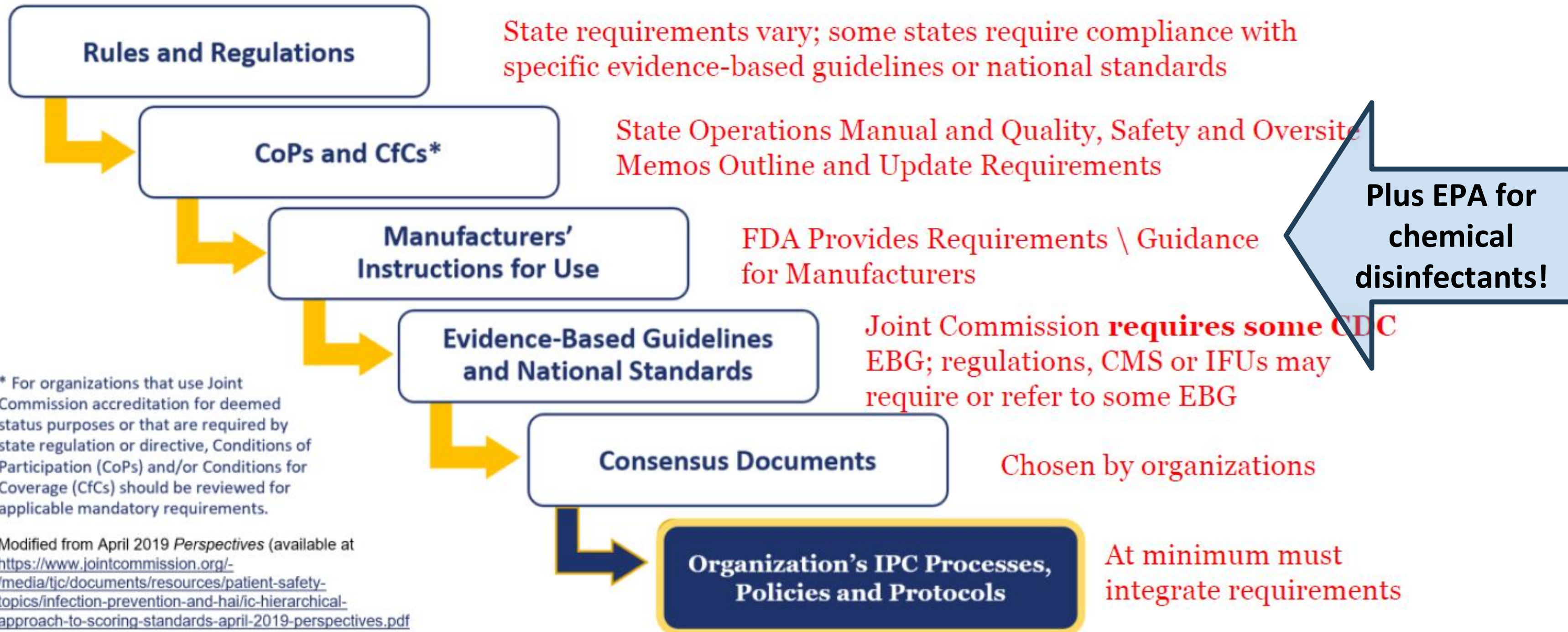
https://www.jointcommission.org/standards/prepublication-standards/new-and-revised-requirements-addressing-antibiotic-stewardship-for-hospital/

True or False:
The Joint Commission is a **rulemaking/ regulatory** organization.

False: No. TJC is an *accrediting organization*, **not a regulatory body.**

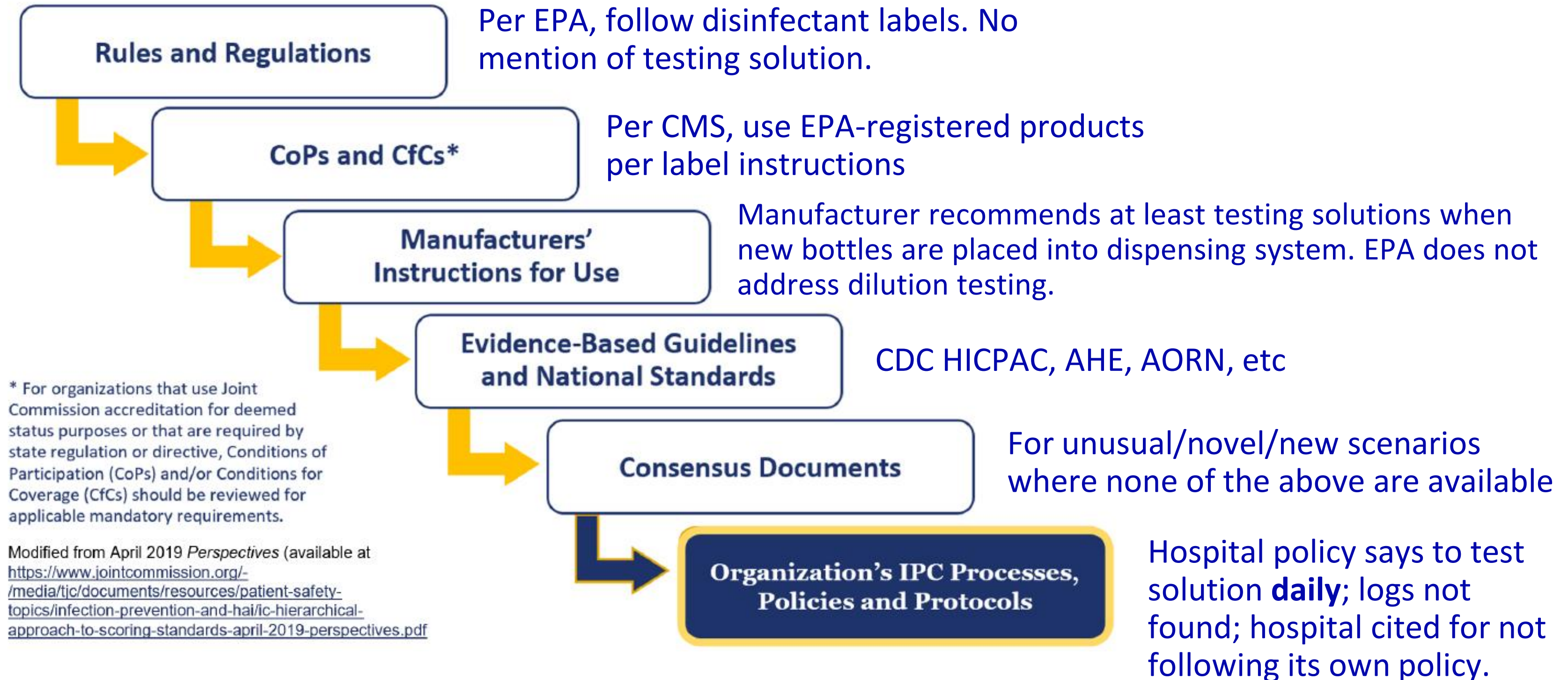
Joint Commission accreditation is *voluntary.* Other examples of accrediting organizations are AOA/HFAP & DNV.

https://www.jointcommission.org/about-us/facts-about-the-joint-commission/joint-commission-faqs/



Used with written permission from Sylvia Garica-Houchins, RN, MBA, CIC; Director of Infection Prevention & Control, The Joint Commission. Available online at https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/infection-prevention-and-hai/ic-hierarchical-approach-to-scoring-standards-april-2019-perspectives.pdf.

Applying the Hierarchy to Testing Dilutable Disinfectants



Crystal clear, right?

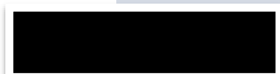
Rules, Regs & Recs: Key Takeaways

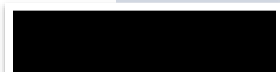
- There is a great deal of overlap between recommendations, guidelines, standards, best practices, etc.
- **BUT . . . the law (regulation) is the law.**
    - New IPs may struggle with what is a rule versus *interpretations of* rules.
- Accreditation standards & your facility policies can be more strict/detailed, but not less than rules & regulations.
    - You will be held to versions referenced in your policies!
    - Don’t just update a policy without understanding updates to guideline versions

Words matter. A lot.

A review of common concepts & words that impact Infection Prevention & Control

must 1 of 4 **verb**





Rules
Regulations
Requirements

2 : be compelled by physical necessity to

one *must* eat to live

: be required by immediate or future need or purpose to

we *must* hurry to catch the bus

3 a : be obliged to : be compelled by social considerations to

I *must* say you're looking well

b : be required by law, custom, or moral conscience (see CONSCIENCE sense 1) to

we *must* obey the rules

https://www.merriam-webster.com/dictionary/must

shall verb

3 **a** → used to express a command or exhortation

you shall go

b → used in laws, regulations, or directives to express what is mandatory

it shall be unlawful to carry firearms

- Is used to express a requirement, i.e. a provision that the user is obliged to satisfy in order to comply with the standard
- Most litigated word in English language
- Sometimes means “may”
- Discouraged from use per PlainLanguage.gov given ongoing multiple interpretations
  - https://www.faa.gov/about/initiatives/plain_language/articles/mandatory/

Canadian Standards Association Standard Z314.15-10

https://www.merriam-webster.com/dictionary/shall

should auxiliary verb

shəd, ˈshu̇d

4 → used in auxiliary function to express what is probable or expected

with an early start, they *should* be here by noon

5 → used in auxiliary function to express a request in a polite manner or to soften direct statement

Typically used to express a recommendation or that which is ***advised but not required.***

https://www.merriam-webster.com/dictionary/should

may 1 of 3 auxiliary verb

1 a → used to indicate possibility or probability

you *may* be right

things you *may* need

→ sometimes used interchangeably with *can*

one of those slipups that *may* happen from time to time

– Jessica Mitford

→ sometimes used where *might* would be expected

you *may* think from a little distance that the country was solid woods

– Robert Frost

b : have permission to

you *may* go now

: be free to

a rug on which children *may* sprawl

– C. E. Silberman

→ used nearly interchangeably with *can*

https://www.merriam-webster.com/dictionary/may

can 1 of 5 verb (1)

kən, ˈkan also ˈken; *dialectal* ˈkin

1 **a** : be physically or mentally able to

He *can* lift 200 pounds.

b : know how to

She *can* read.

c → used to indicate possibility

Do you think he *can* still be alive?

Those things *can* happen.

→ sometimes used interchangeably with *may*

https://www.merriam-webster.com/dictionary/can

Document-Specific Definitions Help!

The following verbal forms are used within AAMI documents to distinguish requirements [illegible] other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Do our facility policies clearly define what each of these words mean?

Association for the Advancement of Medical Instrumentation. 2021. ST91: Flexible and semi-rigid endoscope processing in healthcare facilities. Arlington, VA. Available for purchase at www.aami.org.

ENHANCED CONTACT	A. Standard Precautions apply. B. Perform HH per policy. Soap and water is required if there is direct contact with feces, or an area where fecal contamination is likely. In outbreaks of Hepatitis A, norovirus and/or *C. difficile* infection, perform hand hygiene with soap and water preferentially. C. Gloves and gown required for contact with patient and/or environment. Donning of PPE occurs within facility defined entrance or zone or anteroom. PPE should be worn regardless of whether patient is in the room at the time, if contact with the environment is anticipated. D. Remove all PPE before leaving the room. Perform HH immediately after removing PPE. E. Dedicated or single use disposable equipment is preferred. If patient equipment is not dedicated or single patient use, it must be cleaned and disinfected per policy and instructions for use (IFU.) Sporicidal agents (example bleach) must be used, unless contraindicated. Transportation and Ambulation Guidelines:

Let’s navigate some rules!

APIC Text: Basic Principles of Infection Prevention Practice

Hand Hygiene

Transmission-Based Precautions

Aseptic Technique

Standard Precautions

Cleaning Disinfection & Sterilization

Reprocessing Single Use Devices

Antimicrobial Stewardship Programs

What is Our Guiding Principle in Infection Prevention & Control?

constant 2 of 2 **noun**

: something invariable or unchanging: such as

a : a number that has a fixed value in a given situation or universally or that is characteristic of some substance or instrument

b : a number that is assumed not to change value in a given mathematical discussion

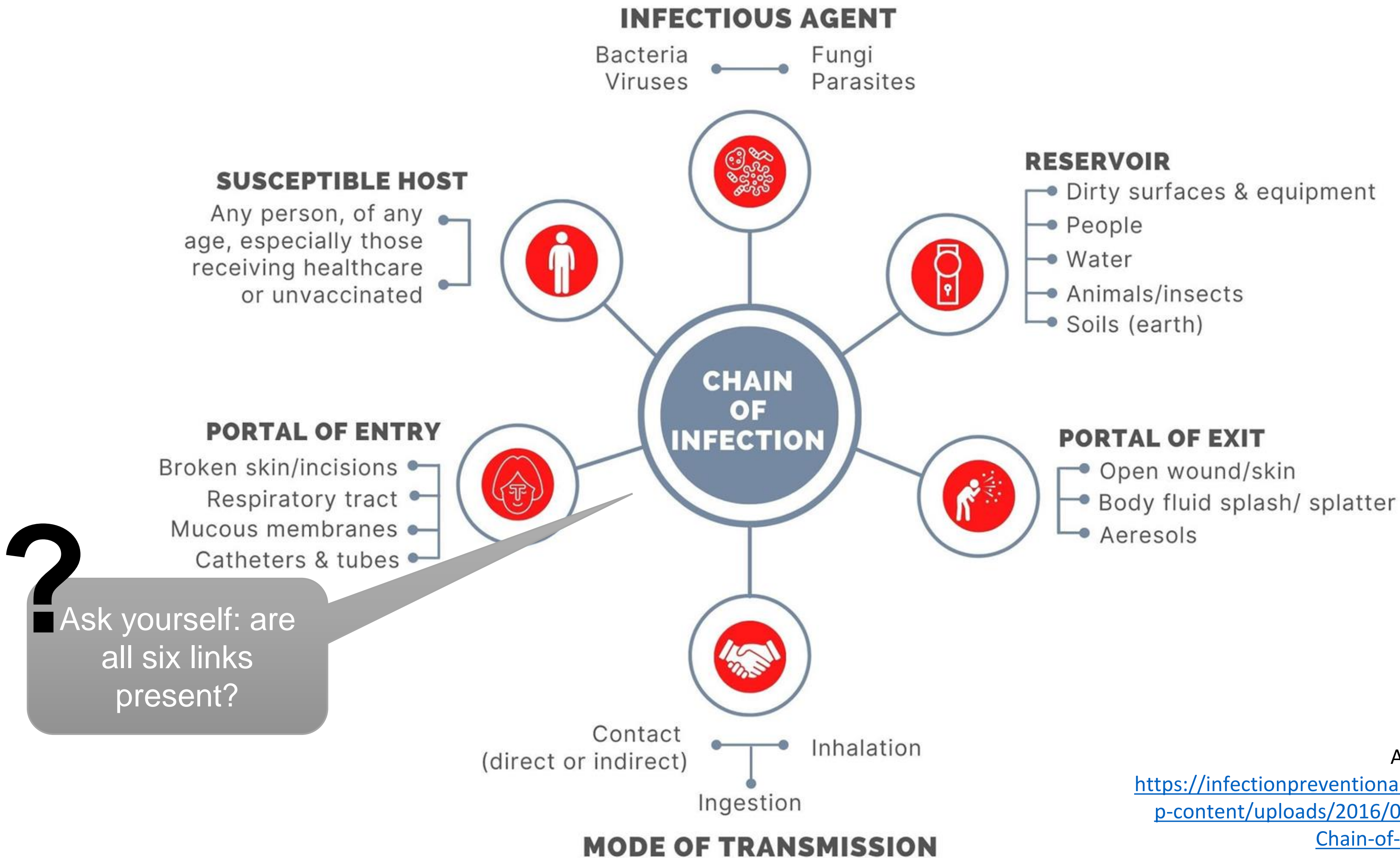
c : a term in logic with a fixed designation

d : something or someone that is reliably present or available

> My parents put in me in piano lessons when I was really young, so music has always been a *constant* in my life.
> \- Mélat

> He's my *constant* for when I seek guidance both on a professional and personal front.
> \- Gautam Mehra

https://www.merriam-webster.com/dictionary/constant



Adapted from https://infectionpreventionandyou.org/wp-content/uploads/2016/09/Break-the-Chain-of-Infection.pdf

Scenario #1

The IP team learns a piece of **portable medical equipment** (PME) does not list any of the facility-approved disinfectant wipes in the manufacturer’s instructions for use (MIFUs).

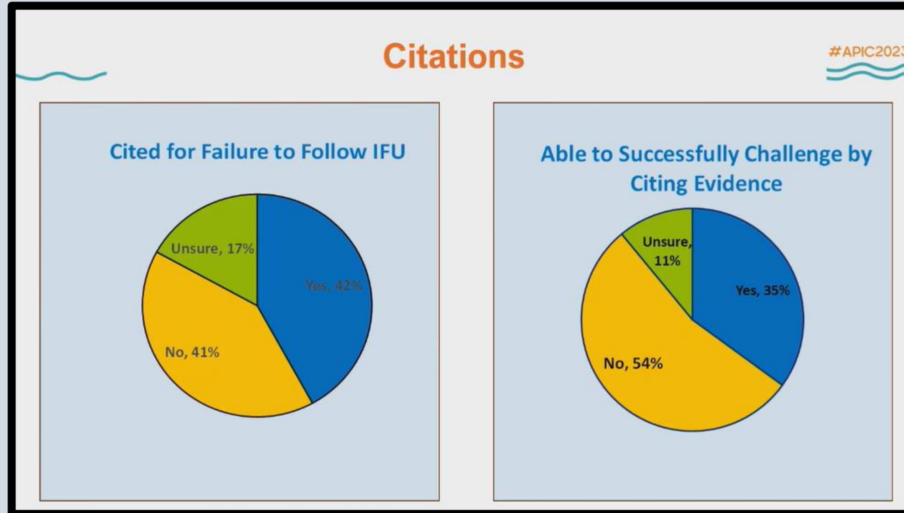
Manufacturers’ IFUs: Rules, Regs, Requirements

- Manufacturer's instructions for use
  - Equipment = FDA
  - Disinfectant = EPA
  - Notably, IFUs & labels (disinfectants) are **the Law**
    - ***Unless*** Spaulding criteria not met & risk to patient is identified

Manufacturers' IFUs: Can We Bend?

Can you utilize an evidence-based risk assessment?

- The answer: Maybe? (Tomlinson et al 2023)
- Include **risk mitigation** in your documentation!



Tiers of our Advocacy Plan

- **Provide clarity in the law or regulation: require standardized labels for cleaning disinfection and sterilization that take infection prevention and control into account and are updated regularly.**

Mid-Range

- **Work with partner organizations to develop a guidance that addresses some of the major issues.**

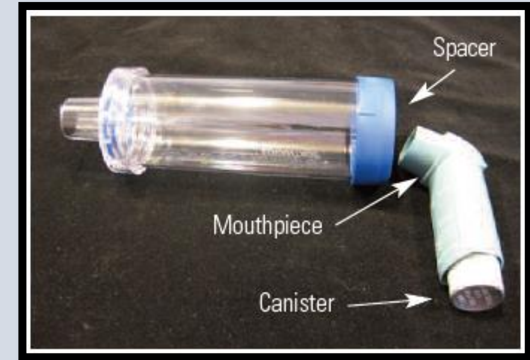
Short Range

- **Provide tools that help IPs navigate the process, share information about problematic IFUs with the FDA, and share information from manufacturers with other IPs.**

Tomlinson et al 2023

Manufacturers' IFUs

- Contentious issue for **disinfectant suppliers**
  - Newer disinfectants are not included in MIFUs
- Contentious issue for **equipment manufacturers**
  - May have found "a" (literally ONE) disinfectant that works, no regulation supporting chemistry/product diversity
  - May not have tested a true disinfectant (soap & water, isopropyl alcohol)
- MOST contentious for **INFECTION PREVENTIONISTS!**
  - IPs are caught in the middle, spending hours looking for answers.



https://www.ismp.org/resources/revisiting-need-mdi-common-canister-protocols-during-covid-19-pandemic

Tonometer tip courtesy of presenter

Manufacturers' IFUs: Problem Solving

Compatibility For Original Equipment Manufacturers

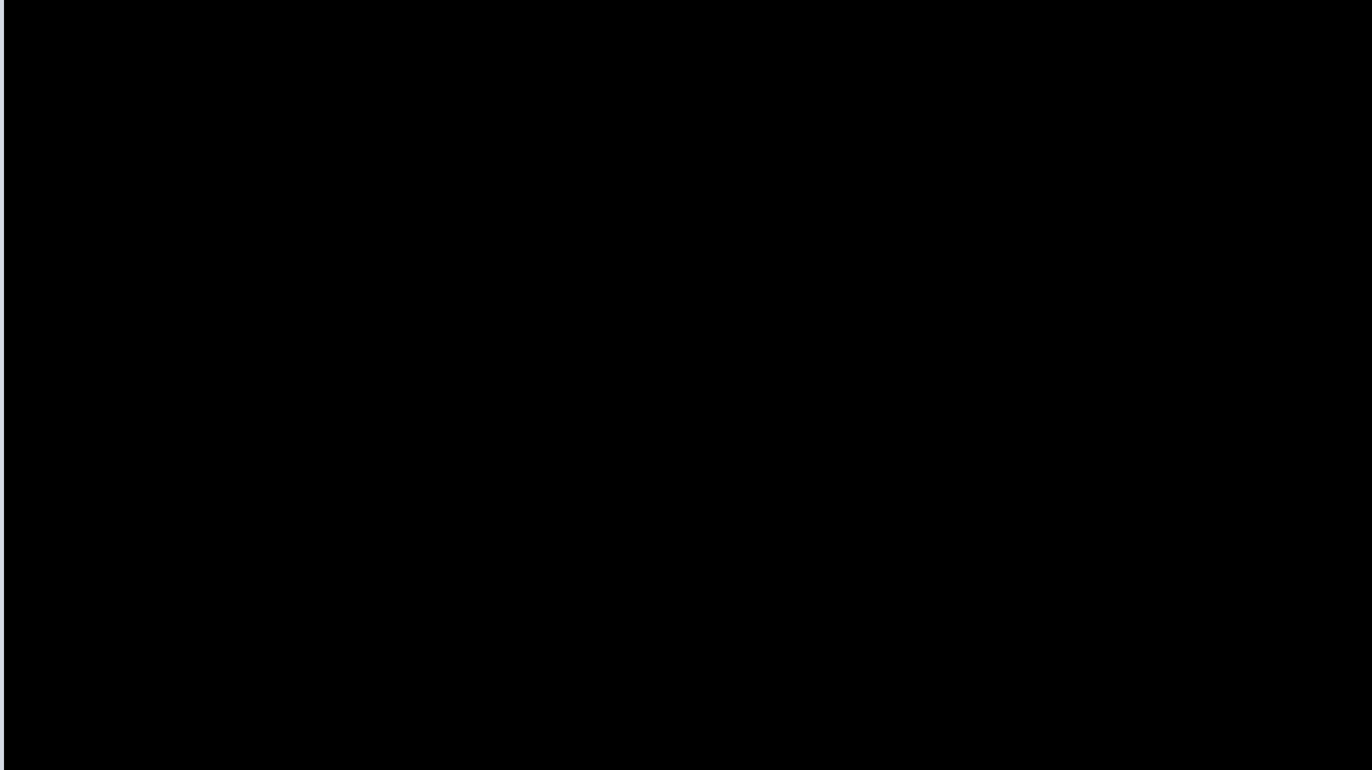
Follow Up Requested *(Required)*

- ☐ Request Samples for Product Testing
- ☐ Request Product Testing at Diversey Lab
- ☐ Material Compatibility by Chemical
- ☐ IFU Process recommendation to extend asset life
- ☐ Other

- Check if your **disinfectant supplier** has a **compatibility specialist/expert** that works with instrument components or provides our solutions to manufacturers!
- Per TJC at APIC 2022:
  - FDA expects you to communicate with device manufacturer *first*
  - If solution cannot be reached, use FDA's DICE to communicate IFU issues

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice

Manufacturers' IFUs: Upstream Resolution



https://youtu.be/vpJ4h8sxOJg

Pennsylvania Coalition to Advance Respect

Patching the Bridge Upstream

Leverage the power of economics *before* purchasing agreements whenever possible.

Scenario #2

Surveyor tells the IP that floor **should** be disinfected in rooms of patients with suspected/confirmed *Candida auris*.

Floor Disinfection: Rules & Recommendations

AORN Guidelines for Perioperative Practice: Environmental Cleaning

- **4.2.4:** Clean and **disinfect** the floor with a mop after each surgical or invasive procedure **when visibly soiled** or **potentially soiled** by blood or body fluids (e.g., splash, splatter, dropped item). [**Recommendation**]
- **4.4.2:** Clean and **disinfect** the entire floor, including areas under the OR bed and mobile equipment, using either a wet vacuum or mop." [**Recommendation**]

CDC Environmental Infection Control Guidelines

- E.I.I. After the last surgical procedure of the day or night, wet vacuum or mop operating room floors with a single-use mop and an EPA-registered hospital **disinfectant**. (Category IB Recommendation)
- E.II.A.: Promptly clean and decontaminate spills of blood or other potentially infectious materials. (**OSHA: 29 CFR 1910.1030 §d.4.ii.A**) (IB, IC)

Floor Disinfection: Rules & Recommendations

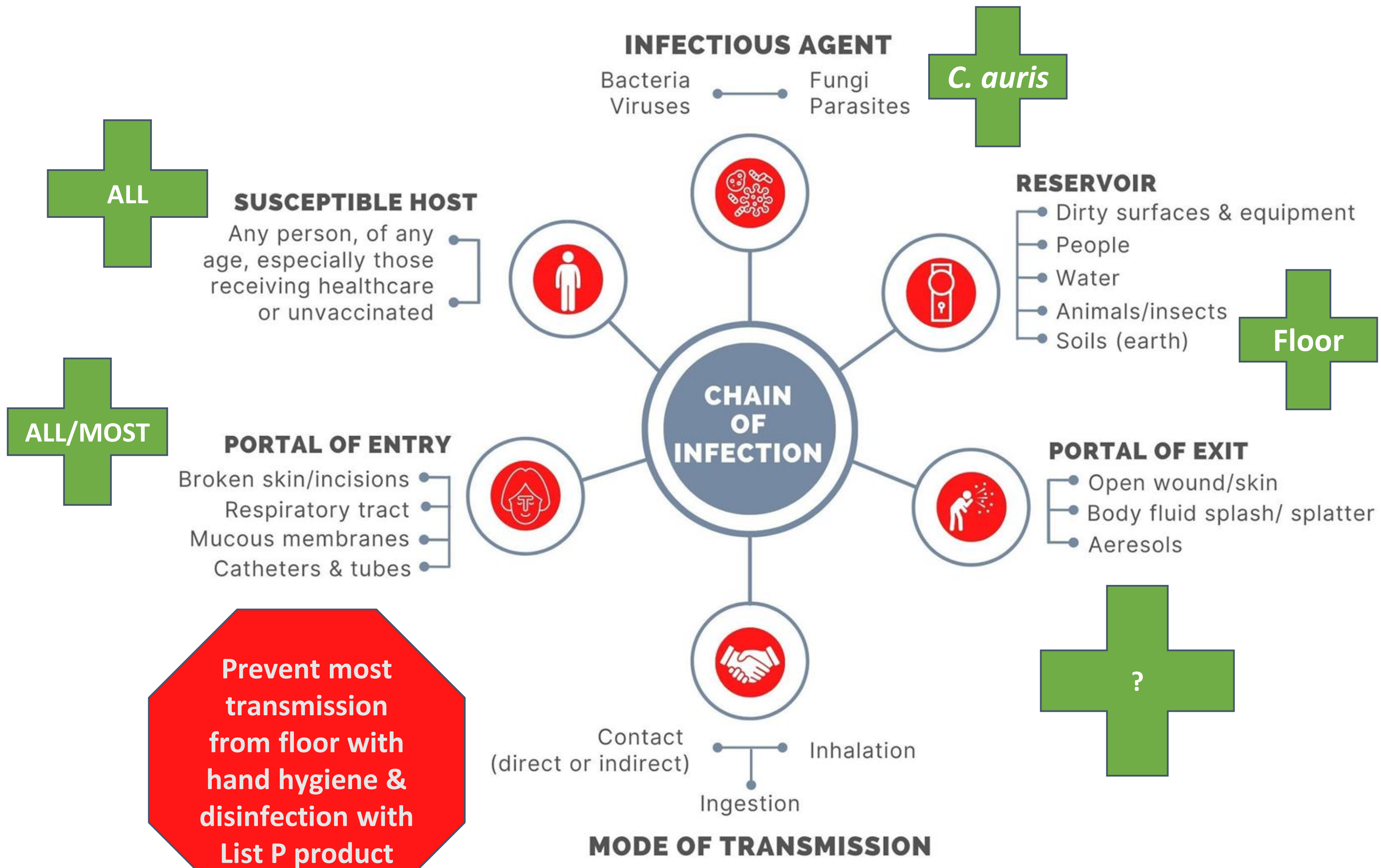
CDC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)

- **IV.F. Care of the Environment:**
- IV.F.2.Clean and disinfect surfaces that are likely to be contaminated with pathogens, including those that are in close proximity to the patient (e.g., bed rails, over bed tables) and frequently-touched surfaces in the patient care environment (e.g., door knobs, surfaces in and surrounding toilets in patients' rooms) on a more frequent schedule compared to that for other surfaces (e.g., horizontal surfaces in waiting rooms) [Category IB]
- **NO SPECIFIC MENTION OF FLOOR DISINFECTION**

Floor Disinfection:

- **Should ≠ must!** There is no rule to bend (unless stated in YOUR policy)!
- No requirement, recommendation or best practice guidance to date states *C. auris* or *C. diff* floors “should” or “must” be disinfected
- The surveyor may not fully understand the logistical challenges:

    - Floors are re-contaminated almost immediately
    - Sporicides create **pungent**, sometimes **irritating**/triggering odors
    - Difficult to truly achieve full **contact time**
    - Disinfecting one floor means disinfecting ALL floors (shadow EVS!)
    - **Damage** to the floor (creating stickiness that can **attract** more pathogens)
    - Quats are not effective against *C. auris*



Adapted from https://... entionandyou.org/wp-content/uploads/2016/09/Break-the-Chain-of-Infection.pdf

Infection Prevention:
Is it an art or a science?

art[1]

/ärt/

See definitions in:

All | Art | Military

noun

1. the expression or application of human creative skill and imagination, typically in a visual form such as painting or sculpture, producing works to be appreciated primarily for their beauty or emotional power.
   "the art of the Renaissance"

   Similar: fine art | artwork | creative activity

2. the various branches of creative activity, such as painting, music, literature, and dance.
   "the visual arts"

sci·ence

/ˈsīəns/

noun

the intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment.
"the world of science and technology"

Similar: branch of knowledge | area of study | discipline | field

- a particular area of science.
  plural noun: **sciences**
  "veterinary science"
- a systematically organized body of knowledge on a particular subject.
  "the science of criminology"

The Old Me (Cynical, Burned Out)

/ˈkāˌäs/

See definitions in:

All | Physics | Mythology

noun

complete disorder and confusion.
"snow caused chaos in the region"

Similar: disorder | disarray | disorganization | confusion | mayhem | bedlam

- PHYSICS
  behavior so unpredictable as to appear random, owing to great sensitivity to small changes in conditions.
- the formless matter supposed to have existed before the creation of the universe.

The New Me: It's Both!

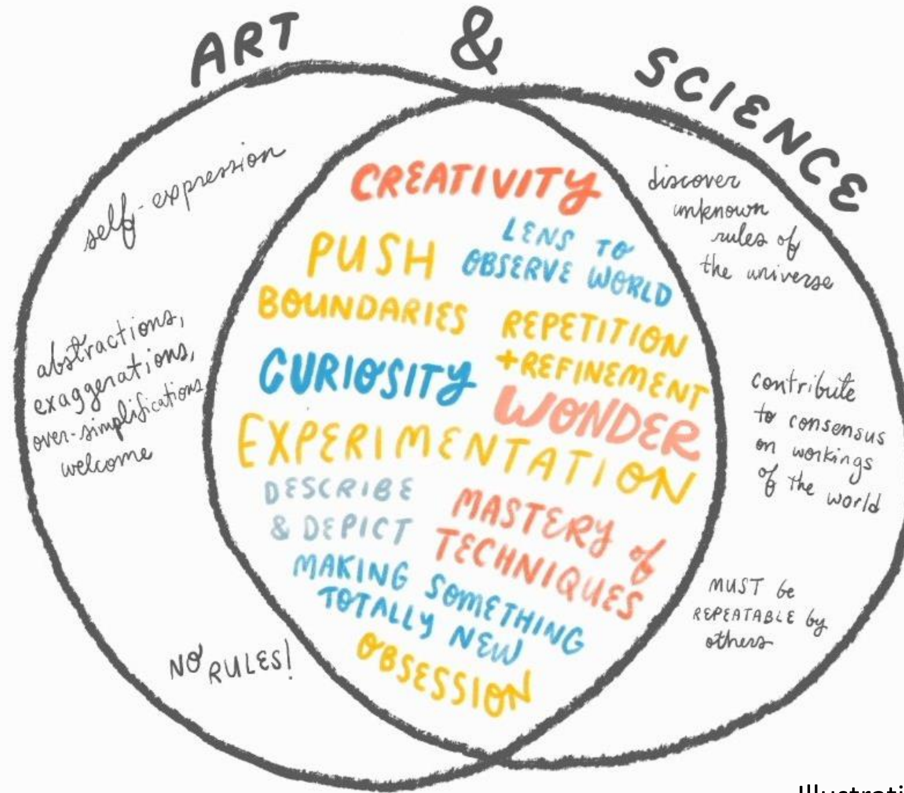


Illustration courtesy of Dr Cristine Liu on X
https://twitter.com/christineliuart/status/1223673670649823233

Summary

- What do you think?
    - Art, science, chaos or all of the above?
- Words matter. Remember the implications of words during your next policy review!
- In the face of chaos, unpredictability & surveys, look to your **guiding light**:
    - The **chain of transmission**, plus the **APIC Text**
    - **Don't be afraid of challenging surveyors & asking for sources/references!**

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