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?)

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.)
Infection Preventionists: How Are We Today?

• Short answer = there’s a lot we don’t know.

## Complex Factors Contributing to IP/AS Burnout & Moral Injury

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

**Also, more inexperienced IPs**

Infection Prevention: Is it an art or a science?

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

**science**
- 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"
- 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?

<table>
<thead>
<tr>
<th>Art</th>
<th>Science</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>Concrete</td>
</tr>
<tr>
<td>Subjective</td>
<td>Objective</td>
</tr>
<tr>
<td>Emotional</td>
<td>Rationale</td>
</tr>
<tr>
<td>Feelings &amp; opinions</td>
<td>Data &amp; facts</td>
</tr>
<tr>
<td>Conceptual</td>
<td>Theoretical</td>
</tr>
</tbody>
</table>

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
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

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 . . .
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

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

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

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

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

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

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
**HICPAC Recommendation Categories**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
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<tbody>
<tr>
<td>Category IA</td>
<td>Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.</td>
</tr>
<tr>
<td>Category IB</td>
<td>Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.</td>
</tr>
<tr>
<td>Category IC</td>
<td>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).</td>
</tr>
<tr>
<td>Category II</td>
<td>Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.</td>
</tr>
<tr>
<td>Unresolved Issue</td>
<td>No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.</td>
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</table>

"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."


**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](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

- 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](http://dx.doi.org/10.15585/mmwr.su7101a1).
- [https://www.jointcommission.org/standards/about-our-standards/](https://www.jointcommission.org/standards/about-our-standards/)
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 and expand upon the current expectations for antibiotic stewardship programs in the hospital setting.

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.

Hierarchical Approach to Infection Control Issues

State requirements vary; some states require compliance with specific evidence-based guidelines or national standards

State Operations Manual and Quality, Safety and Oversight Memos Outline and Update Requirements

FDA Provides Requirements \ Guidance for Manufacturers

Joint Commission requires some CDC EBG; regulations, CMS or IFUs may require or refer to some EBG

Chosen by organizations

At minimum must integrate requirements

* For organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, Conditions of Participation (CoPs) and/or Conditions for Coverage (CfCs) should be reviewed for applicable mandatory requirements.


Applying the Hierarchy to Testing Dilutable Disinfectants

Per EPA, follow disinfectant labels. No mention of testing solution.

Per CMS, use EPA-registered products per label instructions

Manufacturer recommends at least testing solutions when new bottles are placed into dispensing system. EPA does not address dilution testing.

CDC HICPAC, AHE, AORN, etc

For unusual/novel/new scenarios where none of the above are available

Hospital policy says to test solution daily; logs not found; hospital cited for not following its own policy.
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 (verb)

2  : be compelled by physical necessity to
    one must eat to live
    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
• 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/](https://www.faa.gov/about/initiatives/plain_language/articles/mandatory/)

Canadian Standards Association Standard Z314.15-10
[https://www.merriam-webster.com/dictionary/shall](https://www.merriam-webster.com/dictionary/shall)
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*

- 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*
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
The following verbal forms are used within AAMI documents to distinguish requirements from 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.”

Document-Specific Definitions Help!

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

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!
What is Our Guiding Principle in Infection Prevention & Control?

const\texttt{ant} \ 2 \text{ of } 2 \quad \text{noun}

: something invariable or unchanging: such as

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

\text{b} : a number that is assumed not to change value in a given mathematical discussion

\text{c} : a term in logic with a fixed designation

\text{d} : something or someone that is reliably present or available

\begin{quote}
My parents put in me in piano lessons when I was really young, so music has always been a \textit{constant} in my life.
- Mélát
\end{quote}

\begin{quote}
He's my \textit{constant} for when I seek guidance both on a professional and personal front.
- Gautam Mehra
\end{quote}

https://www.merriam-webster.com/dictionary/constant
Ask yourself: are all six links present?

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

- **Long-Range**
  - 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.


Tonometer tip courtesy of presenter
Manufacturers’ IFUs: Problem Solving

- 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


• 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*
Prevent most transmission from floor with hand hygiene & disinfection with List P product.
Infection Prevention: Is it an art or a science?

**art**
- 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"

**science**
- 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"
- a particular area of science.
- a systematically organized body of knowledge on a particular subject. "the science of criminology"
The Old Me (Cynical, Burned Out)

cha·os
/ˈkɑːəs/

See definitions in:
All  Physics  Mythology

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

Similar:
disorder  disarray  disorganization  confusion  mayhem  bedlam

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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