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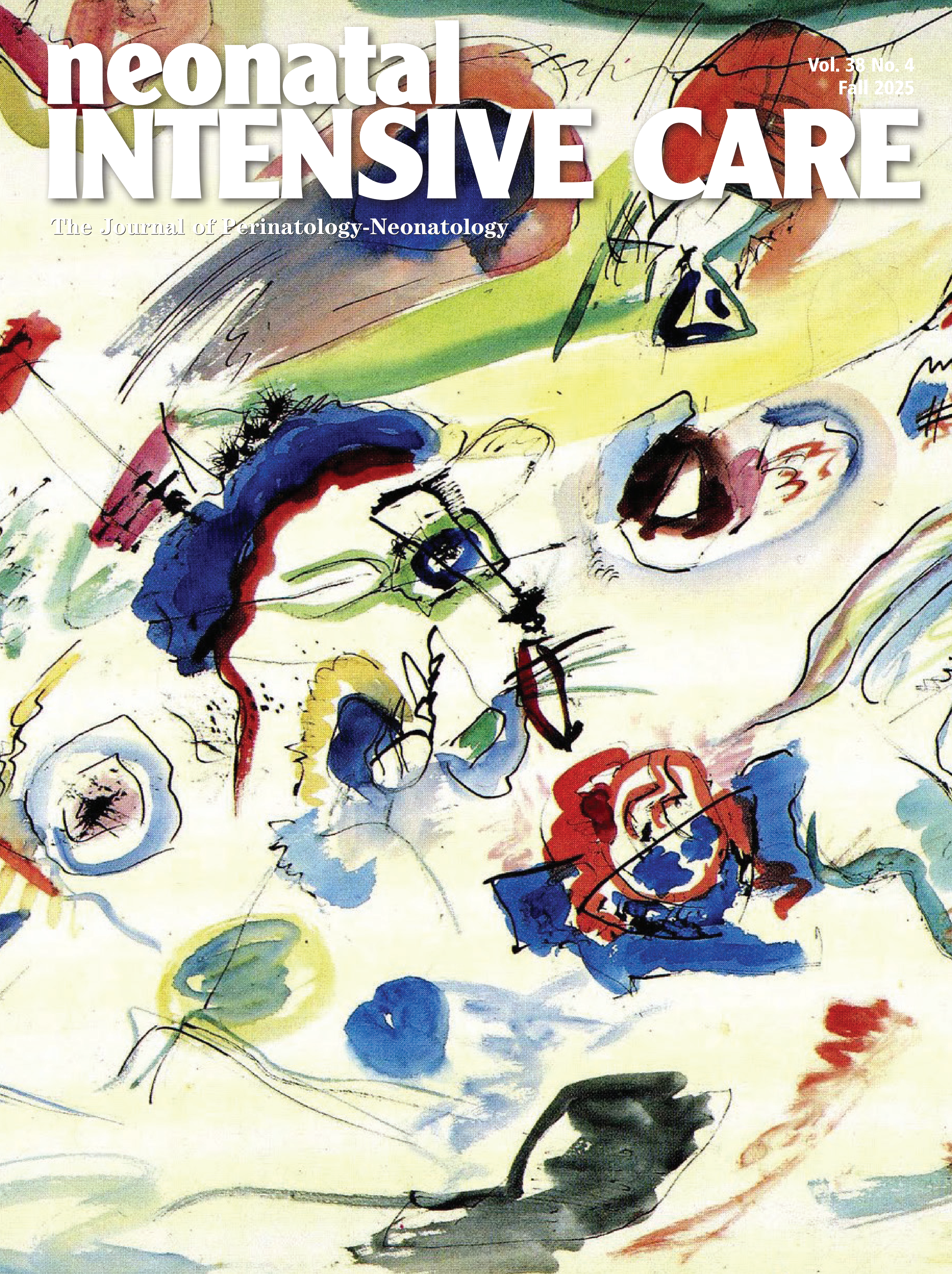

Evolving Approaches to Infection Prevention in Neonatal Intensive Care

Aligning medical equipment manufacturers' IFUs, hospital protocols and accreditation compliance with disinfectant agents to help reduce risks and help protect babies.

Anduin Anderle, RN and Kara L Nadeau

Infection prevention (IP) in neonatal intensive care units (NICU) is a critical aspect of patient safety, as newborns, particularly premature and medically fragile infants, are highly susceptible to healthcare-associated infections (HAIs).[1,2] Every object in the NICU, including medical equipment, can serve as a potential reservoir for harmful pathogens—necessitating rigorous cleaning and disinfection protocols.[3]

However, aligning infection prevention (IP) practices with accreditation requirements, manufacturers' instructions for use (IFU), disinfectant agent IFUs, and hospital protocols can present challenges for NICU clinicians, supply chain teams and value analysis professionals alike.

In this introductory article—part of a multi-part series—readers will learn:

- The unique disinfection needs of the NICU environment
- Common challenges in aligning disinfectant agents with accreditation and equipment manufacturer IFUs
- Key considerations for disinfectant selection ahead of accreditation inspections

Infection risks in the NICU

NICUs face unique challenges in infection prevention due to the vulnerability of fragile newborns.[4] Research has found hospitalized neonates are highly vulnerable to healthcare-associated infections (HAIs).[5] Nosocomial infections are relatively common and increase morbidity and mortality, particularly in the smallest and most fragile infants.[6]

HAIs can also impact NICU length of stay and costs, with the estimated cost of a single healthcare-acquired bloodstream infection (HA-BSI) in neonates ranging from $1,642 to $160,8045.[7,8] Furthermore, private and public insurers, including the Centers for Medicare & Medicaid Services (CMS) under its Hospital-Acquired Condition (HAC) Reduction Program, often do not reimburse hospitals for certain HAIs.[9]

About The Joint Commission (TJC)

The Joint Commission (TJC) accredits and certifies over 22,000 healthcare organizations and programs in the US, including both acute and non-acute facilities. Its accreditation process provides an objective evaluation that helps organizations improve performance and deliver safe, high-quality care.

Accreditation is granted following an unannounced, on-site survey by trained surveyors. These surveyors assess compliance with TJC standards by reviewing patient records, observing care, and speaking with staff and patients to trace the patient care experience.

Because NICUs present high risk for HAIs, frequent cleaning of the environment is critical, including disinfection of surfaces, which can serve as reservoirs of potential pathogens.[10] Research has shown "Generally, all objects and equipment used in the NICU environment constitute a reservoir for microbial transmission."[11]

Equipment disinfection responsibilities

Both medical equipment manufacturers and end user hospitals can bear responsibility for effective cleaning and disinfection of reusable medical equipment used in NICUs and other patient care areas.[12,13]

Medical equipment manufacturers

The US Food and Drug Administration (FDA) regulates manufacturers of medical equipment used in hospitals and other care settings. An element of this oversight is guidance to manufacturers of reusable devices that they "should consider device designs that facilitate easy and effective cleaning, as well as any necessary disinfection or sterilization by the users."[14]

The FDA requires manufacturers to include in their equipment instructions for use (IFU), recommended "cleaning agents or classes of agents that were used during the cleaning validation studies, that have been demonstrated to be compatible with the device and are effective in cleaning the device."[15] The IFU "should address both cleaning and disinfection if both are intended and should be clear regarding the difference between cleaning and disinfection, and the products used for each step."[16]

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>
> – APIC letter to TJC, May 19, 2025

Additionally, the manufacturer of the disinfection product specified in the equipment manufacturer's IFU must include in its own IFU instructions to help ensure efficacy and/or confirmation that cleaning, disinfection or sterilization cycles are successful.[17]

Hospitals

Hospitals accredited by The Joint Commission (TJC) must demonstrate compliance with equipment and disinfectant manufacturers' IFUs during TJC accreditation surveys.[18] Surveyors evaluate whether medical equipment disinfection practices—including agent type, dilution, contact time, and temperature—adhere to manufacturer guidelines.[19]

To maintain accreditation status, hospitals must undergo an on-site survey at least every three years.[20] A survey includes an "objective evaluation" of "organizational compliance to performance standards," including equipment disinfection practices.[2,22]

IFU compliance challenges and complexities

Hospitals face significant barriers in achieving IFU compliance due to:[23]

- A wide array of medical equipment with varying disinfectant requirements
- Pressure to standardize products for cost, storage, and usability
- Disinfectants specified in IFUs becoming unavailable, recalled, or unsafe for staff
- Newer disinfectants (e.g., broad-spectrum wipes) lacking validation in equipment IFUs

Push for supply standardization

Faced with increased pressures to reduce the risk for HAIs alongside cost pressures to standardize supply purchases for greater cost savings, hospitals report challenges adhering to use of medical equipment manufacturers specified disinfectant agents.[24]

Given the broad range of medical equipment used across patient care units in hospitals, including NICUs, the procurement and effective use of IFU specified disinfectant agents for each individual piece of equipment can present complexities and costs that can be burdensome for most healthcare organizations to manage.[25]

Supply chain professionals, value analysis committees, and clinicians striving for supply standardization and the associated stocking, storage, usability and cost benefits, many struggle with the compliance challenges presented by accreditation requirements around IFU adherence.[26]

How Often Should My Hospital Reprocess Medical Equipment?

In its IFU, a medical equipment manufacturer will specify how often its product should be reprocessed – components dissembled, disinfected (and sometimes sterilized) and reassembled for patient use.

Frequency and steps for adequate reprocessing will be defined in your device IFU. Frequency can vary between product types and manufacturer recommendations.

Disinfectants entering–and exiting–the market

Additionally, the COVID-19 pandemic spurred the development of many new broad-spectrum disinfectants that medical equipment manufacturers have not tested with their products.[27] It may not be feasible for equipment manufacturers to test and validate every new disinfectant agent and update their IFUs accordingly.[28]

Common types of disinfectants include:[29,30]

- Reconstituted agents
- Wipes
- UV light

Adding to hospital challenges in disinfectant procurement and use aligned with equipment manufacturers' IFUs, the disinfectant agent the manufacturer has specified in its IFU could be subsequently taken off the market due to adverse events or a recall.[31] For example, one commonly used and approved agent is involved in a class action lawsuit due to reports of side effects such as skin burns, asthma and respiratory issues among healthcare workers.[32]

Different components, different disinfection methods

Adding to the complexity, a piece of medical equipment might be comprised of multiple components that each require different disinfection agents and processes, as specified in the manufacturer's IFU. Depending on the agent/process, disinfection could be performed by any number of healthcare stakeholders, including environmental services (EVS) staff members, bedside clinicians or sterile processing (SP) technicians.

For example, a NICU incubator's manufacturer might specify that surface cleaning can be performed with disinfectant wipes, something commonly available and easily used in clinical units. On the other hand, the incubator's reservoir for its humidification system might require a washer/disinfector machine cycle, with this mode of reprocessing handled by SP technicians in their department.

Performing a risk assessment

"Hospitals should assess the risks associated with equipment that does not align with standardized disinfectants," according to Vizient. "This assessment should focus on the following three key factors to determine the appropriate compliance approach and ensure patient safety."[33]

1. Determine whether the equipment comes into direct contact with a patient. Devices involved in direct patient care pose a higher risk and require stricter compliance measures.
2. Evaluate the prevalence of these items within the facility. If a device or piece of equipment is widely used or exists in large quantities, ensuring compliance becomes a higher priority.

3. Lastly, determine how closely the available disinfectant aligns with IFU requirements.

APIC calls for changes in TJC's assessment of IFU compliance

A letter from the Association for Professionals in Infection Control & Epidemiology (APIC) CEO Devin Jopp, EdD to TJC president and CEO Johnathan B. Perlin, dated May 19, 2025, highlights challenges faced by hospitals when TJC assesses IFU compliance during surveys. Jopp referenced APIC member surveys and focus groups, which found:[34]

- 42% of participants indicated that their facility had been cited by a surveyor for failure to follow an IFU (including both regulatory and accrediting surveys)
- 54% percent of those who had been cited reported not being able to successfully challenge the citation by providing evidence for their practice
- 84% of respondents indicated that they had reached out to a manufacturer for clarification on an IFU in the past, and eight percent went as far as reaching out to the FDA directly

Jopp goes onto provide APIC's recommended modifications to TJC's approach, which include: [35]

- A differentiation be made between simple non-compliance with policy or stated practice and a commonly used approach where a facility has conducted a risk assessment and determined that an alternative cleaning, disinfection, and/or sterilization method is appropriate.
- IFU-related findings no longer be assessed under the "Infection Prevention and Control" chapter of the TJC standards and instead be housed under either "Environment of Care" or "Leadership" as the "burden of reconciling IFUs falls to the Infection Prevention and Control department, rather than the team that owns, operates, and maintains the equipment."

The letter concludes, "While we understand that adherence to strict cleaning, disinfection, and sterilization practices is essential for patient safety, we also understand that the current IFU process is inherentlyflawed."[36]

Aligning effective NICU infection prevention practices with industry requirements

Many NICU clinicians, IP practitioners and other hospital stakeholders are aligned in their commitment to protect tiny and fragile newborns from the risks of contracting HAIs. Despite this, they still may face the challenge of adhering to disinfectant agents specified in medical equipment manufacturer's IFUs.

When a hospital that has standardized on a disinfectant agent that is not specified in the manufacturer's IFU or switched to a new agent that has come to market, or the disinfectant specified in the IFU is unavailable or questionably safe for workers to use, NICU and IP teams can be left scrambling to comply with TJC requirements.[37,38]

> "APIC recommends that some degree of flexibility be given to facilities to determine safe, effective alternatives when compliance with the manufacturer's IFUs is not feasible or does not meet infection prevention standards."
>
> – APIC letter to TJC, May 19, 2025

4 Key Questions to Ask About Your Hospital's Chosen Disinfectant Agent Ahead of a JACHO Inspection

1. Is it efficacious in neutralizing microorganisms of concern in the NICU environment?
2. Does it not prematurely erode or compromise medical equipment surfaces and components?
3. Is it used according to the disinfectant's IFU, including specified "wet time"?
4. Does it follow the medical equipment manufacturer's recommendations for rinsing parts following the specific "wet time" to maintain component integrity?

According to TJC's Environmental Cleaning Assessment, it is essential for organizations to follow manufacturer's IFUs for proper use of cleaning and disinfecting products, including aspects such as dilution, contact time, material compatibility, storage, shelf-life, safe use and disposal.[39]

When information from manufacturers is limited regarding the selection and use of agents for specific microorganisms, environmental surfaces, or equipment, TJC advises that "cleaning and disinfecting policies should be guided by the best available evidence and careful consideration of the risks and benefits of the available options."[40]

Preparing for an accreditation survey with proactive testing and validation

Ahead of an accreditation survey, hospital NICU teams in collaboration with IP practitioners and environmental service (EVS) staff members should conduct testing to demonstrate their chosen disinfectant agent:[41]

- Is efficacious in neutralizing microorganisms of concern in the NICU environment
- Does not prematurely erode or compromise medical equipment surfaces and components
- In used according to the disinfectant's IFU, including specified "wet time" (which is included in every disinfectant agent's IFU)
- Follows device manufacturers' cleaning instructions avoiding skipping steps such as wiping residual disinfectant from device after recommended "wet time"

A proactive approach to testing and compliance positions NICU teams for success and ultimately can contribute to greater safety for NICU babies.

Conclusion

Effective infection prevention in the NICU requires a careful balance between compliance with regulatory and accreditation standards and the practical realities of hospital operations. Medical equipment manufacturers' FDA IFU recommendations can create challenges for hospitals striving for standardization and cost efficiency. Those healthcare organizations that take proactive measures, such as conducting efficacy and compatibility testing, can help bridge the gap.

Hospitals can implement evidence-based disinfection practices that help protect vulnerable newborns and staff while maintaining compliance with accreditations requirements. Ultimately, a well-coordinated approach to IP can help reduce the risk of HAIs, promote patient and staff safety in compliance with accreditation requirements, and reduce reprocessing time, staff resources and costs.

References

1 Johnson J, Akinboyo IC, Schaffzin JK. Infection Prevention in the Neonatal Intensive Care Unit. Clin Perinatol. 2021 Jun;48(2):413-429. doi: 10.1016/j.clp.2021.03.011. PMID: 34030822; PMCID: PMC8162277.

2 Marty D, Sorum K, Smith K, Nicoski P, Sayyed BA, Amin S. Nosocomial Infections in the Neonatal Intensive Care Unit. Neoreviews. 2024 May 1;25(5):e254-e264. doi: 10.1542/neo.25-5-e254. PMID: 38688885.

3 Chiguer M, Maleb A, Amrani R, Abda N, Alami Z. Assessment of surface cleaning and disinfection in neonatal intensive care unit. Heliyon. 2019 Dec 5;5(12):e02966. doi: 10.1016/j.heliyon.2019.e02966. PMID: 31872128; PMCID: PMC6911881.

4 Johnson J, Akinboyo IC, Schaffzin JK. Infection Prevention in the Neonatal Intensive Care Unit. Clin Perinatol. 2021 Jun;48(2):413-429. doi: 10.1016/j.clp.2021.03.011. PMID: 34030822; PMCID: PMC8162277.

5 Johnson J, Akinboyo IC, Schaffzin JK. Infection Prevention in the Neonatal Intensive Care Unit. Clin Perinatol. 2021 Jun;48(2):413-429. doi: 10.1016/j.clp.2021.03.011. PMID: 34030822; PMCID: PMC8162277.

6 Marty D, Sorum K, Smith K, Nicoski P, Sayyed BA, Amin S. Nosocomial Infections in the Neonatal Intensive Care Unit. Neoreviews. 2024 May 1;25(5):e254-e264. doi: 10.1542/neo.25-5-e254. PMID: 38688885.

7 Johnson J, Quach C. Outbreaks in the neonatal ICU: a review of the literature. Curr Opin Infect Dis. 2017 Aug;30(4):395-403. doi: 10.1097/QCO.0000000000000383. PMID: 28582313; PMCID: PMC8020806.

8 Karagiannidou S, Triantafyllou C, Zaoutis TE, Papaevangelou V, Maniadakis N, Kourlaba G. Length of stay, cost, and mortality of healthcare-acquired bloodstream infections in children and neonates: A systematic review and meta-analysis. *Infection Control & Hospital Epidemiology*. 2020;41(3):342-354. doi:10.1017/ice.2019.353

9 Hospital-Acquired Condition Reduction Program, CMS, https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/hospital-acquired-condition-reduction-program-hacrp

10 Hospital-Acquired Condition Reduction Program, CMS, https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/hospital-acquired-condition-reduction-program-hacrp

11 Chiguer M, Maleb A, Amrani R, Abda N, Alami Z. Assessment of surface cleaning and disinfection in neonatal intensive care unit. Heliyon. 2019 Dec 5;5(12):e02966. doi: 10.1016/j.heliyon.2019.e02966. PMID: 31872128; PMCID: PMC6911881.

12 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

13 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

14 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

15 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

16 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

17 Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants - Guidance for Industry and FDA Reviewers, FDA, January 2000, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level#_Toc472478077

18 TJC Environmental Assessment Checklist, Published in The Joint Commission Big Book of Checklists for Infection Prevention and Control, Joint Commission Resources, 2020., File Name: 04 02 Environmental Cleaning Assessment

19 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, FDA, March 17, 2015, https://www.fda.gov/media/80265/download

20 History of The Joint Commission, https://www.jointcommission.org/who-we-are/facts-about-the-joint-commission/history-of-the-joint-commission/

21 The Accreditation Standards, The Joint Commission, https://www.jointcommission.org/what-we-offer/accreditation/become-accredited/learn-the-process/#:~:text=In%20the%20Joint%20Commission%20accreditation%20process%2C%20we%20evaluate,well%20as%20relevant%20standards%20from%20CMS%20and%20OSHA.

22 TJC Environmental Assessment Checklist, Published in The Joint Commission Big Book of Checklists for Infection Prevention and Control, Joint Commission Resources, 2020., File Name: 04 02 Environmental Cleaning Assessment

23 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/

24 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/

25 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/

26 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/

27 Disinfectant Use and Coronavirus (COVID-19), U.S. Environmental Protection Agency (EPA), https://www.epa.gov/coronavirus-and-disinfectants/disinfectant-use-and-coronavirus-covid-19

28 Disinfectant Use and Coronavirus (COVID-19), U.S. Environmental Protection Agency (EPA), https://www.epa.gov/coronavirus-and-disinfectants/disinfectant-use-and-coronavirus-covid-19

29 Rutala, W. A., & Weber, D. J. (2018). *Surface disinfection: Treatment time (wipes/sprays) versus contact time (liquids)*. Statewide Program for Infection Control and Epidemiology (SPICE), University of North Carolina. Retrieved from https://spice.unc.edu

30 Wall, M. (2024). *Sterile Processing 101: Cleaning, Disinfection, and Sterilization*. Los Angeles County Department of Public Health. Retrieved from http://www.publichealth.lacounty.gov

31 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/

32 Five workers sue Sutter Health for cleanser 'corrosive' to

eyes, skin, respiratory tract, The Sacramento Bee, January 19, 2022, https://www.sacbee.com/news/local/health-and-medicine/article257472368.html#storylink=cpy
33 Four steps to balance disinfectant standardization with medical equipment IFU compliance, Vizient, April 10, 2025, https://www.vizientinc.com/insights/all/2025/four-steps-to-balance-disinfectant-standardization-with-medical-equipment-ifu-compliance
34 APIC Letter to The Joint Commission on Instructions for Use (IFUs), May 19, 2025, https://apic.org/wp-content/uploads/2025/05/05-19-2025-Letter-to-TJC-Regarding-IFUs.pdf
35 APIC Letter to The Joint Commission on Instructions for Use (IFUs), May 19, 2025, https://apic.org/wp-content/uploads/2025/05/05-19-2025-Letter-to-TJC-Regarding-IFUs.pdf
36 APIC Letter to The Joint Commission on Instructions for Use (IFUs), May 19, 2025, https://apic.org/wp-content/uploads/2025/05/05-19-2025-Letter-to-TJC-Regarding-IFUs.pdf
37 APIC Letter to The Joint Commission on Instructions for Use (IFUs), May 19, 2025, https://apic.org/wp-content/uploads/2025/05/05-19-2025-Letter-to-TJC-Regarding-IFUs.pdf
38 Modernizing Medical Device Instructions for Use (IFUs), APIC, https://apic.org/modernizing-medical-device-instructions-for-use-ifus/
39 TJC Environmental Assessment Checklist, Published in The Joint Commission Big Book of Checklists for Infection Prevention and Control, Joint Commission Resources, 2020., File Name: 04 02 Environmental Cleaning Assessment
40 TJC Environmental Assessment Checklist, Published in The Joint Commission Big Book of Checklists for Infection Prevention and Control, Joint Commission Resources, 2020., File Name: 04 02 Environmental Cleaning Assessment
41 TJC Environmental Assessment Checklist, Published in The Joint Commission Big Book of Checklists for Infection Prevention and Control, Joint Commission Resources, 2020., File Name: 04 02 Environmental Cleaning Assessment