Guidance for Addressing Problems with the Manufacturer's Instructions for Use

A TOOLKIT FOR NON-CRITICAL DEVICES

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APIC®
Association for Professionals in Infection Control and Epidemiology

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The Association for Professionals in Infection Control and Epidemiology (APIC) is the leading professional association for infection preventionists (IPs) with more than 15,000 members. Our mission is to advance the science and practice of infection prevention and control. APIC advances its mission through patient safety, education, implementation science, competencies and certification, advocacy, and data standardization. Visit us at apic.org.

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DEFINITIONS AND TERMINOLOGY

Terminology	Definitions
Alternative recommendation	Recommendation that differs from guidance or instructions provided by the manufacturer within the manufacturer's instruction for use (MIFU) when the primary recommendation is unavailable or unsuitable. Alternative recommendations for cleaning and disinfection can include, but are not limited to, the use of a different disinfectant, optimizing the cleaning steps for a clear and followable process, and other strategies. These alternatives may not be validated by the manufacturer and should be based on scientific evidence and/or infection prevention principles.
Disinfection and sterilization levels	**Low-level disinfection:** This process destroys most vegetative vegetative bacteria, some viruses, and fungi, but does not reliably kill resistant microorganisms like mycobacteria or bacterial spores. It is suitable for non-critical devices that have contact with intact skin.[1] *Examples: Blood pressure cuffs, stethoscopes, and pulse oximeters.* **Intermediate-level disinfection:** This process destroys most vegetative bacteria and mycobacteria, most fungi, and viruses, but does not reliably kill bacterial spores. It is required for non-critical devices that have contact with patient skin but require a higher level of cleanliness than what is provided by low-level disinfection.[1] **High-level disinfection (HLD):** This process destroys all microorganisms, except for a small number of bacterial spores. It is appropriate for semi-critical devices that have contact with mucous membranes or non-intact skin.[1] *Examples: Gastro-intestinal endoscopes, cystoscopes, and endocavitary probes.* **Sterilization:** This process destroys all microbial life, including bacterial spores. It is necessary for critical devices that enter sterile tissue or the vascular system.[1] *Examples: Surgical instruments and trays, laparoscopes, and arthroscopes that enter sterile tissue.*
Infection prevention practices	Practices that aim to minimize the spread of infections, especially in the healthcare setting.
Manufacturer's instructions for use (MIFU)	MIFU refers to the instructions provided by the manufacturer for the proper use, cleaning, and disinfection of a device or equipment. These instructions are intended to ensure the device and equipment are used safely and effectively in healthcare settings.
Multidisciplinary team	A group of healthcare professionals from different departments and specialties who work collaboratively to coordinate actions with a shared purpose. Each member contributes their expertise to assess, evaluate, and comprehensively provide actions towards a common goal, to mitigate risk, and improve outcomes. Examples may include, but are not limited to, infection preventionists, nursing, nursing, materials management, supply chain, environmental services, quality, safety, risk management, regulatory, leadership, biomedical engineers, and other end users.
Risk assessment	A risk assessment is a systematic process of evaluating potential risks that could cause harm to individuals (e.g., patients, staff, visitors) or the healthcare facility. It involves identifying hazards, analyzing and evaluating the risks associated with those hazards, and determining appropriate ways to eliminate or control the risks.
Spaulding Classification	The Spaulding Classification is a system used to determine the level of disinfection or sterilization required for devices and equipment based on their intended use and risk of infection.[1] Devices are classified into three categories: **Non-critical:** Devices that have contact with intact skin on onlyly require low- to intermediate-level disinfection. **Semi-critical:** Devices that have contact with mucous membranes or non-intact skin require HLD. **Critical:** Devices that enter sterile tissues or the vascular system require sterilization.
Validation studies	A process used to systemically assess the accuracy, reliability, and overall quality of a method, tool, or data source. The aim of a study is to confirm the method(s), effectively measures what it's intended to measure, and provide trustworthy results for the intended purpose.

SECTION 1: BACKGROUND

Introduction

Manufacturer's instructions for use (MIFUs) refer to the information provided by the manufacturer to inform the user(s) about the intended purpose, proper use, and necessary precautions for medical devices and equipment. The Food and Drug Administration (FDA) requires manufacturers of medical devices and equipment to provide instructions for use that detail safe and effective use, including cleaning, disinfection, and storage.[2] Healthcare facilities are expected to adhere to these MIFUs to ensure safety and maintain compliance with the device and equipment.[4-5] This toolkit will guide infection preventionist (IPs) through a systematic process for addressing problems identified with MIFUs for non-critical devices and equipment that require low- and intermediate-level disinfection and a structure for how to conduct a risk assessment if needed.

In 2026, APIC met with stakeholders from accrediting organizations to further define a problematic MIFU for non-critical devices. Their consensus included:

- A multidisciplinary team of subject matter experts determines that the MIFU introduces unwarranted complexity that increases burden in the disinfection process without evidence to support the necessity
- The MIFU is not accessible or available to the organization for the specific intended clinical use
- The MIFU lacks cleaning and disinfection instructions for all FDA-approved uses of the device
- The MIFU contains contradictory or outdated information
- The MIFU requires products that are not commercially available to the organization
- The MIFU requires products that increase healthcare worker or patient safety risk
- The MIFU is not aligned with accepted infection prevention practices in accordance with evidence-based guidelines

Intended Use

The tool focuses on low- and intermediate-level disinfection and provides structured guidance to assist the IP in assessing whether an MIFU is evidence-based and complies with regulatory requirements.

The toolkit provides an algorithm, templates, and examples that can be used to:

- Assist IPs or a healthcare facility when reviewing the cleaning and disinfection instructions of a MIFU
- Facilitate an evaluation of potential risks from problematic MIFUs for the cleaning and disinfection of devices and equipment by identifying hazards, analyzing the associated risks, and proposing mitigation strategies
- Provide an example that uses the algorithm, risk assessment template, risk-benefit matrix, and other resources/tools
- Address problematic MIFUs by evaluating acceptable and/or alternative recommendations related to cleaning and disinfection, using a step-by-step process.
- Ensure the final recommendation(s) align with evidence-based guidelines (EBG), best practices, and regulatory requirements, which may vary by state
- Document processes and outcomes that may be presented for evaluation and reporting

Common Issues and Concerns Related to MIFUs

In 2023, APIC released a white paper titled *Modernizing Medical Device Instructions for Use: Infection Preventionists Speak Up for Patient Safety*. APIC surveyed 1,198 IPs who were currently practicing in United States healthcare facilities to identify the challenges associated with MIFUs.[3] The following is a summary of the findings from the survey included within the white paper:

- Not easily accessible, difficult to locate
- Complex and time-consuming processes
- Contradictory information
- Outdated information
- Lack of specificity and clarity
- Focused on product lifespan over preventing healthcare-associated infections

Evaluation of MIFUs

An essential element in reviewing MIFUs is an evaluation to ensure that the healthcare facility has the expertise, resources, and physical infrastructure needed for the device or equipment.[4] MIFU evaluation often falls within the value analysis, capital request process, or a similar process, where a multidisciplinary team guides the selection of a device or equipment before purchasing. An IP should be a primary participant within the multidisciplinary team in the review process to address the cleaning and disinfection aspects of the new device or equipment prior to the item being approved or purchased for the healthcare facility. Additionally, if a MIFU is updated after a device is purchased and is in use, a multidisciplinary team may need to conviene.

A multidisciplinary team can be beneficial to guide the selection and evaluation to ensure:

- Patient and staff safety
- MIFU compatibility with healthcare facility expertise, resources, and processes
- Assessment of material compatibility with existing products (e.g., cleaners and disinfectants) used by the healthcare facility, including the evaluation of additional products to support the device and equipment
- Confirmation of process(es) outlined by the manufacturer in the MIFU is validated by EBG and/or follows infection prevention principles
- Compliance related to regulatory requirements and EBG followed by the healthcare facility (see below for examples)

Examples of Regulatory Organizations, Evidence-Based Guidelines, and Expert Consensus Documents

Type	Examples
Regulatory organizations, or agencies, mandate activities by setting standards, ensuring compliance, and enforcing rules within specific sectors.	Centers for Medicare and Medicaid Services (CMS)
	Environmental Protection Agency (EPA)
	Federal Drug Administration (FDA)
	Occupational Safety & Health Administration (OSHA)
Evidence-based guidelines and practice standards are considerations and recommendations for clinical practice informed by a thorough review and ranking of the best scientific evidence available at the time of publication. When there is a lack of evidence on a topic, an expert consensus document can be utilized to help inform decision-making.	Association for the Advancement of Medical Instrumentation (AAMI)
	American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)
	Centers for Disease Control and Prevention (CDC)
	Facility Guidelines Institute (FGI)

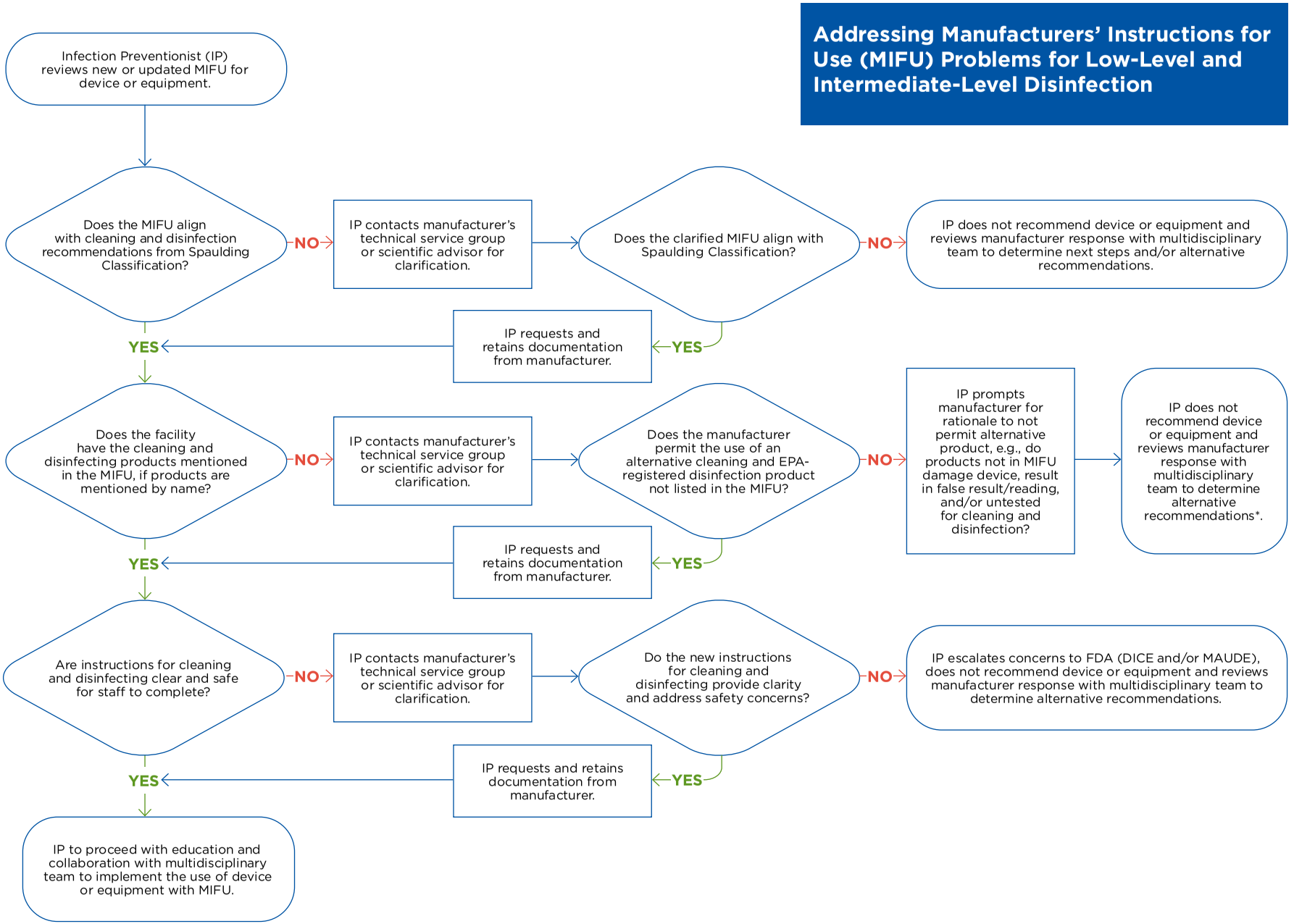
SECTION 2: GUIDANCE FOR ADDRESSING PROBLEMATIC MIFUs

IPs may identify problems with MIFUs for devices or equipment during routine workflows (example: during environment of care rounds or a formal product evaluation process). IPs may also identify cleaning products or disinfection technologies not validated for devices or equipment. The following steps are recommended if a problem is identified within a MIFU:

1. Ensure the IP understands the intended use of the medical device and that it aligns with the Spaulding Classification which requires low- or intermediate-level disinfection
2. Contact the manufacturer's technical support department or scientific advisor[4]
    a. Reference the problem in the MIFU that needs clarification and/or resolution
    b. Request the following documentation with appropriate studies (e.g., validation studies, material compatibility studies, etc.):
        i. Evidence to support guidance in MIFU
        ii. Evidence related to the use of alternative products
        iii. Evidence to support compatibility of other products (e.g., cleaning and/or disinfecting products)
3. Retain all documentation from the manufacturer[4] (e.g., alternative recommendations on letterhead from the manufacturer)
4. Review regulatory requirements to outline current guidance and supporting documents related to alternative recommendations (e.g., AAMI, ASHRAE, CDC, CMS, EPA, FDA, FGI, OSHA)
5. If the manufacturer does not provide any alternatives, facilitate collaboration with a multidisciplinary team to determine next steps (i.e., not purchase the device, use the validated disinfectant, or complete a risk assessment and implement alternative recommendations)
6. If the problem is not resolved by the manufacturer, the team should escalate the inquiry to the FDA Division of Industry and Consumer Education (DICE)[6] or the Manufacturer and User Facility Device Experience (MAUDE)[7] database

Algorithm for Problematic MIFU

The following algorithm has been created based on the guidance for addressing MIFU problems. If the problem in the MIFU cannot be resolved, a multidisciplinary team may be necessary to conduct a risk assessment for the device or equipment to implement alternative recommendations.



Example: Problematic MIFU for Blood Pressure Cuff

The following example is provided as a guide and is intended for educational purposes only. The example is not inclusive of the entire MIFU assessment process; it is intended to serve as a reference for identifying potential problems related to MIFUs. See Appendix A for the template.

MIFU Problem Assessment Template	
Assessment date	1/1/2025
Describe the issue	"Brand X" blood pressure cuff: MIFU states to "clean with mild detergent." We need clarification by the manufacturer as to what they consider a "mild" detergent used to clean the device prior to disinfection.

Example: Problematic MIFU for Blood Pressure Cuff		
Assessment steps	**Details and instructions**	**Facility response**
Does MIFU align with the Spaulding Classification? *Note: Identify the intended use of the medical device with the multidisciplinary team.*	**YES:** Go to the next question. **NO:** IP does NOT recommend device or equipment and reviews manufacturer's response with multidisciplinary team to determine next steps and/or alternative recommendations.	**YES:** A blood pressure cuff is considered a non-critical device and requires cleaning prior to disinfection.
Does the healthcare facility have the cleaning and/ or disinfecting product mentioned in MIFU?	**YES:** Go to the next question. **NO:** IP to contact the manufacturer's technical department or scientific advisor for possible alternative cleaning and/or disinfecting products.	**UNKNOWN:** We do not know what the manufacturer considers a "mild" detergent to clean the device.
Are MIFUs clear and aligned with infection prevention principles?	**YES:** Go to the next question. **NO:** IP to contact the manufacturer's technical department or scientific advisor for clarity.	**NO:** Need clarification of what the manufacturer considers a "mild" detergent to be used to clean the device prior to disinfection. [The disinfectant is not in question. The healthcare facility has the appropriate EPA-registered disinfectant listed in MIFU to use after cleaning the device.]

Example: Problematic MIFU for Blood Pressure Cuff		
Assessment steps	**Details and instructions**	**Facility response**
Contact the manufacturer if recommended above These questions are designed to support the multidisciplinary team's evaluation and should be raised with the manufacturer as part of a comprehensive discussion. *Note: If the MIFU states "other EPA-registered wipes may be used for cleaning and/or disinfecting," they may have not been validated by the manufacturer. Therefore, an alternative EPA-registered disinfectant could affect the performance of the product or damage the product. Discuss these risks with the multidisciplinary team.* *Note: Ensure all fine print in the MIFU has been reviewed by the IP and ask clarifying questions.*	Questions to consider asking when speaking to the manufacturer: • What cleaning product/ disinfectant validation studies were done? (i.e., what active ingredients were used in the validation studies?) • Were alternative cleaning product/ disinfectant validation studies done that are not mentioned in the MIFU? • Why was a specific brand of a cleaning product/ disinfectant mentioned in the MIFU and not the active ingredient(s)? • Could the same active ingredient(s) and concentration of the cleaning product disinfectant be used on the device or equipment safely? • Have other cleaning/disinfecting products been validated for use on the device or equipment?	
After Contact with the Manufacturer, is Additional Clarification and/or Alternative Recommendations Provided?	**YES:** IP to retain documentation and healthcare facility to proceed with product implementation plan (i.e., education). **NO:** • IP should escalate concerns to FDA's DICE or MAUDE. • IP does NOT recommend device or equipment and reviews manufacturer response with multidisciplinary team to determine next steps and/or alternative recommendations. • Recommend discussion with multidisciplinary team to determine next steps, which may include conducting a risk assessment.	**YES:** • The manufacturer states "mild" detergent is any dish detergent that contains only surfactants that dissolve dirt and grease, without added ingredients like builders, bleach, or ammonia. • Following clarification from the manufacturer on what is defined as a "mild" detergent, use the "mild" detergent to clean the blood pressure cuff prior to disinfection with an EPA-registered disinfectant per MIFU.
Discuss MIFU problem **review with multidisciplinary team** These questions are designed to support a thorough review and should be considered before making a final recommendation.	Questions to discuss with team: • Does the device or equipment's intended use include high risk of exposure to bloodborne pathogens? • If alternative disinfectants haven't been validated, is there a risk they could damage the device or equipment? • What type of damage might occur to the device or equipment? • Could a damaged device or equipment harm the patient? • Would using an alternative disinfectant void the warranty?	

Example: Problematic MIFU for Blood Pressure Cuff		
Assessment steps	**Details and instructions**	**Facility response**
Multidisciplinary team	Names of staff and roles present for discussion.	1. Name, Hospital Epidemiologist/ Medical Director 2. Name, Director of Infection Prevention & Control 3. Name, Chief Nursing Officer 4. Name, Chief Safety Officer 5. Name, Chief Medical Officer 6. Name, Materials Management 7. Name, Risk Management 8. Name, Regulatory 9. Name, Nurse Manager 10. Name, Health Technology Management or Biomedical Engineering
Final recommendation(s)	• The manufacturer has provided documentation for defining "mild" detergent as a dish detergent that could be used on the device. • Retain manufacturer documentation approving the use of the cleaning and disinfectant product.	
Communication plan	• Immediate training and education for all staff who utilize "Brand X" blood pressure cuffs for proper cleaning and disinfection of the device between each use. • IP reported to department managers on 2/5/2026. • IP reported to leadership on 3/1/2026.	
References and guidance	• Manufacturer's correspondence with date received. • Current dish detergent ingredients. • MIFU of disinfectant wipe.	

SECTION 3: CONDUCTING A RISK ASSESSMENT

Guidance on Conducting a Risk Assessment

Note: If the problem in the MIFU cannot be resolved, a multidisciplinary team may be necessary to conduct a risk assessment for the device or equipment to implement alternative recommendations.

The risk assessment can assist IPs in addressing problems in MIFUs related to noncritical device or equipment cleaning and disinfection. The tool focuses on low- and intermediate-level disinfection and provides structured guidance to ensure the cleaning and disinfection instructions in the MIFU are evidence-based and comply with regulatory requirements. The objective is to systematically assess risks in problematic MIFUs, identify hazards, analyze associated risks if the MIFU is followed/not followed, and propose strategies for risk reduction. IPs may conduct a risk assessment to support an organized method of evaluating and mitigating risk and provide evidence-based recommendations for maintaining safety and ensuring the delivery of quality care.

Components of the Risk Assessment

The following steps can be used to conduct a risk assessment. This is not intended to be an exhaustive list, and other steps may be included based on the needs of the healthcare facility.

1. **Definition of Problem:** Clearly describe the issue or problem in the MIFU. Define the scope, impact and likelihood of harm.
2. **Definition of Terminology:** Provide definitions for all terms (e.g., low-level disinfection).
3. **Identification of Healthcare Facility:** Specify the type of healthcare facility where the assessment is conducted.
4. **Identification of Key Participants:** Identify the key participants impacted by the problem that is relevant to the healthcare facility and/or concern for the MIFU. Include relevant end-users, quality assurance and performance improvement (QAPI) committee individuals and relevant governing bodies.
5. **Propose Alternative Recommendations:** Propose clearly defined alternative recommendations for cleaning and disinfection of the device or equipment.
6. **Evidence:** Provide evidence (peer-reviewed literature, evidence-based guidelines, and/or an expert consensus document) to support and negate alternative recommendations. Retain this documentation.
7. **Regulatory Requirements:** Cite regulatory requirements (local, tribal/territorial, state and/or federal) supporting the current and alternative recommendations.
8. **Risk Summary:** Summarize the risks and benefits associated with the current MIFU and alternative recommendations.
9. **Risk Mitigation Strategies:** List the actions implemented to reduce risk and enhance safety for the alternative recommendations. Include the validation processes, audit procedures undertaken, the frequency of audits, and summarize, available outcomes and trend metrics. The results of monitoring/auditing should be reported to a person or committee with appropriate authority.
10. **Final Recommendation:** State the rationale for the decision, including feedback from key participants and evidence-based practices. (see risk assessment summary template).
11. **Approval process:** A clear approval process for the risk assessment that includes appropriate collaborators and governing body approval is outlined and utilized.
12. **Review cycle:** The review cycle of the risk assessment is clearly defined.

Risk Assessment Process

Use the following steps to conduct a risk assessment:

1. Review the MIFU for the device or equipment (e.g., patient mattress), including cleaning guidance and disinfectant requirements.
2. Evaluate the disinfectant(s) in the MIFU and verify it is in alignment with Spaulding Criteria for intended use and registered with the EPA[8]
3. Review the MIFU of the disinfectant(s) and their compatibility with device and equipment materials
4. Assess the feasibility and impact of the cleaning and disinfection instructions provided in the MIFU
5. Perform a multidisciplinary review by interviewing and collaborating with representatives from relevant healthcare facility departments, including the end-user of the device, environmental services, biomedical teams, risk management, and/or legal counsel, if applicable
6. Evaluate the regulatory requirements and EBGs to ensure safety for patients and staff
7. Provide a written summary of the key steps, consult with the key participants which are outlined in the risk assessment, and secure their approval

Example: Risk Assessment of "Brand X" Blood Pressure Cuff

The following example is provided as a guide and is intended for educational purposes only. The examples are not inclusive of the entire problem and risk assessment processes; it is intended to serve as a reference for identifying potential risks related to MIFUs. See Appendix B for the template.

Example: Risk Assessment of "Brand X" Blood Pressure Cuff	
Risk Assessment Template	
Assessment date	04/22/2024
Describe the issue Include likelihood of harm, scope/impact (see Appendix C)	"Brand X" blood pressure cuff: MIFU states to "clean with mild detergent." Infection prevention is concerned with how "mild detergent" is defined and wants to ensure an EPA-registered disinfectant is used to disinfect "Brand X" blood pressure cuff to reduce the risk of infection. The current MIFU excludes a disinfection product and only includes a cleaning product. **Scope/Impact:** Widespread - blood pressure cuffs are used multiple times a day in all patient care units as well as in ambulatory settings. **Likelihood to harm:** Medium risk - blood pressure cuffs can be used for patients on transmission-based precautions. Improper cleaning of blood pressure cuffs can lead to cross-contamination between patients. (see Appendix C for more information)
Proposed recommendation	Use an EPA-registered disinfectant that is healthcare facility-approved as opposed to a mild detergent to assure the device is safe for reuse.
Key participant	• End-users and infection prevention • Quality assurance and performance improvement (QAPI) committee • Governing body (or similar group)
Definitions	**Cleaning:** The removal of foreign material (e.g., dirt, organic matter) is a critical step that must always precede disinfection and sterilization. **Detergent:** A chemical with surfactants that helps water remove dirt, grease, and stains, which is used for cleaning on various surfaces and materials (e.g., clothes, dishes, and surfaces). **Disinfectant:** Chemical or physical agents used to destroy or inactivate microorganisms on surfaces or objects.

Example: Risk Assessment of "Brand X" Blood Pressure Cuff		
Risk Assessment Template		
Evidence	**Arguments FOR the proposed recommendation:** (i.e., follow the MIFU as written)	**Arguments AGAINST the proposed recommendation:** (i.e., follow the MIFU as written)
	Current MIFU lacks guidance to comply with regulatory and licensing bodies: • According to CDC, blood pressure cuffs are considered non-critical items and should be cleaned and disinfected with an EPA-registered disinfectant. • OSHA requires that blood pressure cuffs or other medical equipment contaminated with blood or other potentially infectious materials are properly cleaned and decontaminated with an appropriate disinfectant. • CMS requires that healthcare facilities have an IPC program that includes proper disinfection of medical equipment, consistent with national standards.	The current MIFU does not include the use of a healthcare facility-approved disinfectant
	The Infection Prevention Program promotes the safety of patients, staff, and facilities through the use of EPA-registered disinfectants to prevent contamination and control the spread of infections	The current MIFU does not include the use of EPA-registered disinfectant
	Blood pressure cuffs are used on intact skin and require low- and intermediate-level disinfection according to Spaulding classification.	An EPA-registered disinfectant could damage the blood pressure cuff.
Reports of sentinel events or safety alerts, if applicable	None	
Risk mitigation strategies Include audit process, frequency and reporting governance	• IP will monitor infection rates for unusual trends • Audits of the disinfection process of blood pressure cuffs will be done for 3 months with a goal of >90% and reported to the infection prevention committee. • End users will be educated to assess blood pressure cuff for damage prior to use	
Final recommendation(s) Include approval process and governing body for the final recommendation/risk assessment	• Infection prevention, in conjunction with a multidisciplinary team, RECOMMENDS using a specified healthcare facility-approved, EPA-registered disinfectant as an alternative recommendation • Healthcare facility is IN SUPPORT of using an alternative disinfectant validated by the manufacturer	
Communication plan for recommendation	• Use of healthcare-specific facility-approved disinfectant between use for shared patient care items is included in the policies and procedures.	

Example: Risk Assessment of "Brand X" Blood Pressure Cuff	
Risk Assessment Template	
Cite references and guidance documents used for assessment	• Risk Benefit Matrix could be used if no alternatives were provided by manufacturer (see Appendix C for more information) • Manufacturer's information related to "mild detergent" (e.g., definition, alternatives, validation studies) • Centers for Disease Control and Prevention. (2003). Guidelines for environmental infection control in healthcare facilities. MMWR, 52 (No. RR-10), 1-44. https://www.cdc.gov/infection-control/hcp/environmental-control/index.html
Timeframe for reassessment	• Re-assess in 3 years or if MIFU is updated, whichever occurs first.. • Determine a timeframe that is appropriate for the device or equipment
Key participant(s) responsible for follow-up, if applicable	Infection prevention

APPENDICES

Appendix A: Problematic MIFU Template

IPs may use the following template when problems are identified in MIFUs for devices or equipment that need further clarification from the manufacturer. This template will guide the IP in evaluating the problem and communicating with the manufacturer. If the manufacturer is unable to provide clarification or alternative recommendations, consider conducting a risk assessment.

Problematic MIFU Assessment Template	
Assessment date	
Describe the issue	

Appendix A: Problematic MIFU Template		
Assessment steps	**Details and instructions**	**Facility response**
Does MIFU align with the Spaulding Classification? *Note: Identify the intended use of the medical device with the multidisciplinary team.*	**YES:** Go to the next question. **NO:** IP does NOT recommend device or equipment and reviews manufacturer's response with multidisciplinary team to determine next steps and/or alternative recommendations.	
Does the healthcare facility have the cleaning and/ or disinfecting product mentioned in MIFU?	**YES:** Go to the next question. **NO:** IP to contact the manufacturer's technical department or scientific advisor for possible alternative cleaning and/or disinfecting products.	
Are MIFUs clear and aligned with infection prevention principles?	**YES:** Go to the next question. **NO:** IP to contact the manufacturer's technical department or scientific advisor for clarity.	

Appendix A: Problematic MIFU Template		
Assessment steps	**Details and instructions**	**Facility response**
Contact the manufacturer if recommended above These questions are designed to support the multidisciplinary team's evaluation and should be raised with the manufacturer as part of a comprehensive discussion. *Note: If the MIFU states "other EPA-registered wipes may be used for cleaning and/or disinfecting," they may have not been validated by the manufacturer. Therefore, an alternative EPA-registered disinfectant could affect the performance of the product or damage the product. Discuss these risks with the multidisciplinary team.* *Note: Ensure all fine print in the MIFU has been reviewed by the IP and ask clarifying questions.*	Questions to consider asking when speaking to the manufacturer: • What cleaning product /disinfectant validation studies were done? (i.e., what active ingredients were used in the validation studies?) • Were alternative cleaning product/ disinfectant validation studies done that are not mentioned in the MIFU? • Why was a specific brand of a cleaning product /disinfectant mentioned in the MIFU and not the active ingredient(s)? • Could the same active ingredient(s) and concentration of the cleaning product disinfectant be used on the device or equipment safely? • Have other cleaning/disinfecting products been validated for use on the device or equipment? .	
After Contact with the Manufacturer, is Additional Clarification and/or Alternative Recommendations Provided?	**YES:** IP to retain documentation and healthcare facility to proceed with product implementation plan (i.e., education). **NO:** • IP may escalate concerns to FDA's DICE or MAUDE. • IP does NOT recommend device or equipment and reviews manufacturer response with multidisciplinary team to determine next steps and/or alternative recommendations. • Recommend discussion with multidisciplinary team to determine next steps, which may include conducting a risk assessment.	
Discuss MIFU problem **review with multidisciplinary team** These questions are designed to support a thorough review and should be considered before making a final recommendation.	Questions to discuss with team: • Does the device or equipment's intended use include high risk of exposure to bloodborne pathogens? • If alternative cleaning product disinfectants haven't been validated, is there a risk they could damage the device? • What type of damage might occur to the device? • Could a damaged device or equipment harm the patient? • Would using an alternative cleaning product disinfectant void the warranty?	

Appendix A: Problematic MIFU Template		
Assessment steps	**Details and instructions**	**Facility response**
Multidisciplinary team	Names of staff and roles present for discussion.	
Final recommendation(s) Include approval process and governing body for the final recommendation/risk assessment		
Communication plan		
References and guidance		

Appendix B: Risk Assessment Template

IPs may use the following template when conducting a risk assessment with a multidisciplinary team. The risk assessment can assist IPs in addressing problematic MIFUs related to device or equipment cleaning and disinfection.

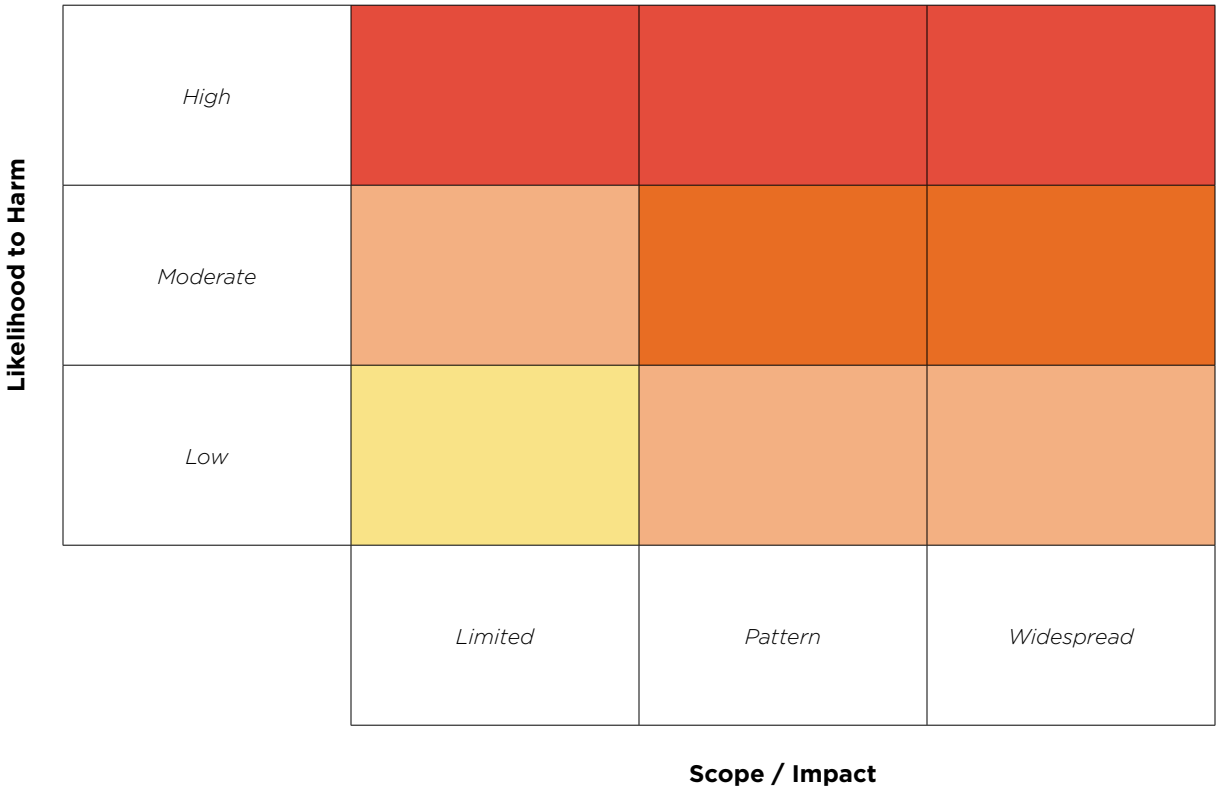
Risk Assessment Template		
Assessment date		
Describe the issue Include likelihood of harm, scope/impact (see Appendix C)		
	Scope/Impact:	
	Likelihood to harm:	
Proposed recommendation		
Key participants List collaborators names and roles		
Definitions		
Evidence	**Arguments FOR the proposed recommendation:** (i.e., follow the MIFU as written)	**Arguments AGAINST the proposed recommendation:** (i.e., follow the MIFU as written)

Risk Assessment Template	
Reports of sentinel events or safety alerts, if applicable	
Risk mitigation strategies Include audit process, frequency and reporting governance	
Final recommendation(s) Include approval process and governing body for the final recommendation/risk assessment	
Communication plan for recommendation	
Cite references and guidance documents used for assessment	
Timeframe for reassessment	Determine a timeframe that is appropriate for the device or equipment
Key participant(s) responsible for follow-up, if applicable	

Appendix C: Risk Benefit Matrix [SAFER™ Matrix]

A risk-benefit matrix[9], such as the sample below or another variation, can be used for a comprehensive analysis of the safety and effectiveness of alternative recommendations. The matrix is a visual tool used to represent the likelihood of harm (see Y axis) and scope/impact (see X axis) of potential risks and benefits. Definitions for the terms used to describe the scope/impact can be found below. For each risk or benefit, the likelihood of harm and the scope/impact are assessed and then plotted on the matrix for visual review. Evaluating the probability and impact of each alternative recommendation allows for informed decisions to be made appropriately.

Probability x Impact = Risk



Scope/impact definitions

Scope/Impact	Definition	Examples
Limited	This category signifies that the issue is a unique occurrence that is not representative of typical or regular practice. It suggests that the event is isolated and not indicative of a broader systemic problem.	**Physical therapy/rehab gym equipment:** Equipment used only in a rehab gym or unit with dedicated rehab space, which is not transported to other units or facilities. An example of infection prevention concern is the MIFU may specify cleaning agents that are not registered as EPA-registered disinfectants.
Pattern	A "pattern" suggests that the issue has occurred multiple times and has the potential to impact more than a limited number of people. It indicates that the issue is not a random event but a recurring problem that could impact a significant portion of the patient population or staff.	**Incubators and warmers:** These devices may be moved between units in pediatric settings and have complicated cleaning and disinfection steps in the MIFU as well as references to practices reserved for devices requiring high-level disinfection or sterilization. An example of an infection prevention concern is that the MIFU outlines a multi-step cleaning and disinfection process that is difficult to integrate into workflows (i.e., cleaning and disinfection may need to occur in two locations due to hospital workflows). An unclear MIFU can lead to inadequate cleaning and disinfection between patients.
Widespread	This category indicates that the issue is not just a few isolated incidents but rather a systemic problem that affects a large number of individuals. It suggests a failure within a process or system that impacts a majority of patients, staff, or visitors.	**Glucose meter:** A device widely used across the healthcare facility, often requiring use of test strips, which can be brought in and out of patient rooms, increasing the risk of cross-contamination. The manufacturer of a device requires the use of a disinfectant that is effective against bloodborne pathogens. An example of an infection prevention concern is MIFU limits disinfectant choices and provides complicated directions for use that are not easily translated into the daily workflow of a healthcare setting.

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