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Sterile Processing Week: AAMI's 'Need to Know' List for SPDs

Topics: Sterilization



Every year, on the second week of October, the communities of AAMI, HSPA, and the greater healthcare community celebrate Sterile Processing Week. This week recognizes the committed specialists who work in sterile processing departments and/or perform sterile processing functions in healthcare delivery organizations, making a powerful and positive difference in patient care every day.

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sterile processing community. Your dedication to ensuring the safety and well-being of patients does not go unnoticed," said Amanda Benedict, vice president of Sterilization, AAMI. "Your hard work and expertise are invaluable to the healthcare industry and to patient safety, and we appreciate you more than words can express. From all of us at AAMI, thank you for your unwavering dedication and professionalism."

Sterilization professionals and technicians are crucial to AAMI's broad healthcare technology community as well as the safety of hospitals, medical equipment, devices, and instrumentation. Their efforts are invaluable to AAMI's mission to elevate the development, management, and use of safe and effective health technology. As such, AAMI regularly publishes resources and standards to aid the sterile processing community.

What follows is a list of this year's most popular AAMI resources, news stories, and guest columns, showcasing healthcare sterile processing's most "need to know" insights from 2024.

New Guidance on Dilator and Ultrasound Processing for Healthcare Facilities of Any Size

The newly published document, AAMI TIR99:2024, *Processing Of Dilators, Transesophageal And Ultrasound Probes In Health Care Facilities*, provides comprehensive information for healthcare providers and sterile processing professionals

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best practices "regardless of the setting where ultrasound probes are used or processed."

Perspective: AAMI TIR99, Handy Reprocessing Insights for Ultrasound Probes & Dilators

The proper processing and disinfection of medical equipment is of utmost importance to ensuring that patients are receiving the best possible care, while also preventing healthcare-acquired infections. In this Sterilization Central guest column, expert Garland-Rhea Grisby shares how the new Technical Information Report fills knowledge gaps you may have not considered.

Researchers Find Worrying Trend in Sterile Processing Departments

Nearly one-third of surveyed sterile processing departments reported having no tracking system in place to manage their sterilization process, according to preliminary results of an investigative research project supported by the AAMI Foundation. Insufficient resources and high workload may be to blame.

From the Studio: New Guidance Incoming!

On Guidance for Chemical Sterilization - a MAJOR Overhaul

After ten years of evolving technologies and scientific understanding, the gold standard for guidance for chemical sterilization, AAMI/ANSI ST58, has undergone

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discuss what is found in the updated document and what comes next for end users and standards developers alike.

How to Process Devices Outside the SPD

With more and more medical devices processed outside of the sterile processing department, new AAMI guidance is needed to ensure these devices are correctly disinfected and rendered safe for handling and next patient use. Horlando Cintron of Memorial Sloan Kettering Cancer Center joined us in the AAMI Studio to discuss a new AAMI Technical Information Report (TIR) that will fill this knowledge gap.

UV Disinfection - Guidance for Manufacturers and Users

During the COVID-19 pandemic, ultraviolet (UV) light became commonly used as a disinfectant, but not always the right way. If used incorrectly, it can damage medical devices. Alpa Patel of Nelson Labs discusses forthcoming AAMI guidance on UV disinfection of medical devices that will provide useful guidelines for medical device manufacturers and sterile processing professionals alike.

Forthcoming Revisions to AAMI's IFU Guidance from SPD Insight

What should medical device manufacturers include in their instructions for use (IFUs)? Amanda Benedict, AAMI Vice President of Sterilization, spoke with Dr. Atila Nozari of Solventum and Damien Berg of HSPA about the upcoming revision of

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Learn more about what the future holds for this revision!

FDA Officially Recognizes AAMI Sterilization Standards

Two AAMI/ANSI/ISO standards related to the sterilization of medical devices have been added to FDA's database of recognized consensus standards. ANSI/AAMI/ISO 11140-1:2014; *Sterilization of health care products—Chemical indicators -Part 1: General requirements* addresses chemical indicators used in sterilization process monitoring, while ANSI/AAMI/ISO 13004:2022; *Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method VDmaxSD* is industry-facing and relates to healthcare products supplied to healthcare delivery organizations.

EtO in the News

Ethylene oxide usage has been a hot topic throughout 2024, with the medical device industry facing cost concerns and a regulatory landscape transformed by the recent Environmental Protection Agency rule that imposed new emissions requirements. What does this have to do with your sterile processing department? AAMI experts describe how changes in how devices are sterilized before they reach health systems can also impact how sterile processing and infection prevention professionals approach new devices and IFUs.

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Since the mid-19th century, ethylene oxide (also known as EO or EtO) has been a sterilization workhorse, However, questions regarding its safe use have led some medical device sterilization facilities to seek alternatives. Industrial sterilization experts Odell and Hodge showcase a few of those alternative modalities and discuss key considerations when assessing a product's readiness for an alternate form of sterilization.

Updated Guidance on EO Sterilization

The revamped AAMI technical information report (TIR) 16 provides a badly needed update to existing guidance on the microbiological aspects of ethylene oxide sterilization and includes information on the design and qualification for biological indicator or parametric release processes. AAMI TIR16:2023; *Microbiological aspects of ethylene oxide sterilization* was produced by AAMI's Industrial Ethylene Oxide Sterilization Working Group.

EO Sterilization: FDA and Industry Weigh the Future

At the 2024 AAMI/FDA neXus, experts from FDA and industry discussed the future of EO sterilization. New technologies, collaboration, and even a paradigm shift may concern device manufacturers and reprocessing professionals alike.

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