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ANSI/AAMI ST24 Updated to Reflect Technological Changes

AAMI logo

As leaders in the medical device industry seek ways to optimize the application of ethylene oxide (EO) sterilization, it is more important than ever to ensure that medical device manufacturers and healthcare facilities are following up to date practices and have state of the art technology.

The Association for the Advancement of Medical Instrumentation (AAMI) today announces that it has updated its standard on EO sterilizers for use in health care facilities to incorporate new technologies and address challenges faced by the industry. ANSI/AAMI ST24:2024 *General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities* is the fourth edition of an AAMI standard that was last updated two decades ago.

This updated standard addresses the labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. ANSI/AAMI ST24 is immediately relevant to medical device manufacturers and sterile processing departments in hospitals, clinics and labs, as the medical device industry faces supply concerns and a regulatory landscape transformed by the Environmental Protection Agency's new Final Rule concerning EO.

As such, the updated standard addresses:

- Labeling, performance, safety, and installation requirements for EO emission control systems.
- Sterilizer construction, components, and accessories.
- Sterilizer safety, including worker safety, thermal hazards, air filtration, and exposure monitoring.
- Requirements for registration, labeling, container safety, shipping, and emissions related to sources of EO.

- Test methods and procedures that can be used to demonstrate conformance with the standard.

This edition of ANSI/AAMI ST24 was updated and produced by AAMI's Hospital EO Sterilizers Working Group, comprised of experts from hospitals, medical device manufacturers, and regulators. Working group co-chair Ted May, CEO at Anderson Sterilizers, sees the updated ANSI/AAMI ST24 as a vital resource.

According to May, "It has been over twenty years since the third edition of ANSI/AAMI ST24 was published. During this period, the use of ethylene oxide in health care facilities has changed significantly. The fourth edition of ANSI/AAMI ST24 has been revised to include EO sterilization systems that have been cleared by the FDA since the last edition was published and were not adequately described in the previous edition. This edition also de-emphasizes the large EO tank and mixture-based systems, which were the standard for healthcare EO sterilization in 1999 but are no longer in use. This fourth edition of ANSI/AAMI ST24 better reflects current practice of EO healthcare sterilization."

The updated standard will serve as a critical resource for manufacturers and healthcare delivery organizations that use ethylene oxide sterilization in-house, May concluded.

ANSI/AAMI ST24:2024 can be accessed or purchased via AAMI ARRAY. Journalists and writers interested in a sample copy of the standard are encouraged to reach out to the AAMI Media Team via dvisnovsky@aami.org.

Topics: **AAMI Standards** • **AAMI Sterilization**

About AAMI

AAMI (www.aami.org) is a nonprofit organization founded in 1967. It is a diverse community of more than 10,000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective health technology. AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for health technology and sterilization professionals.

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