

COVID-19 and Standards

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Objectives

- Review guidance needs indicated by AAMI stakeholders in light of the COVID-19 pandemic
- Highlight existing and new AAMI standards resources relevant to decontamination and disinfection
- Describe emerging areas of need

About AAMI

- The Association for the Advancement of Medical Instrumentation (AAMI) was founded in 1967.
- AAMI brings together a diverse community of more than 9,000 healthcare technology professionals united by one important mission—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.
- AAMI's Standards Program includes ~230 technical committees consisting of thousands of volunteers developing and maintaining medical device standards and technical documents on a wide range of crucial devices and topics including sterilization of health care products.

Critical Needs

- High volume of inquiries
- Primarily pertaining to:
 - Ventilators
 - Personal protective equipment (PPE)
 - Decontamination, disinfection, sterilization
- Primarily originating from:
 - Manufacturers (including new)
 - Health care facilities

AAMI Response

- Pulled together a COVID-19 resource page (<https://www.aami.org/news-resources/covid-19-updates>)
- Developed new consensus reports
- Made several relevant AAMI standards and technical information reports publicly accessible
 - ANSI/AAMI PB70:2012, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*
 - AAMI TIR11:2005/(R)2015, *Selection and use of protective apparel and surgical drapes in health care facilities*
 - AAMI TIR68:2018, *Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces*
- Developed numerous webinars
 - *AAMI and IAHCMM Town Hall: Sterilization and COVID-19* (March 30, 2020)
 - *N95 Mask Decontamination and Reuse Webinar* (April 24, 2020)
 - *Emergency Use Authorizations for the Decontamination of N95 Respirators* (May 4, 2020)

Future direction

- Derived from stakeholders' needs
- Address gaps in existing guidance
- The more we know...



THANK YOU!

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