



Surfaces in  
**Biomaterials**  
Foundation

**Martell Winters, BS, RM/SM (NRCM), AAMI CISS-RAD – Director of Scientific Competency**

Mr. Winters serves on many AAMI Sterilization Standards Working Groups and represents the U.S.A. at ISO meetings for microbiological methods, aseptic processing and vaporized hydrogen peroxide sterilization. He is also on the AAMI Sterilization Standards Committee and is the AAMI liaison to the AATB Standards Committee. In 1995 he received his Registered Microbiologist (RM) certification, and in 2001 his Specialist Microbiologist (SM) certification in consumer products and quality assurance microbiology from the U.S. National Registry of Microbiologists. In 2018 he helped develop the program, and then certified as an AAMI Certified Industrial Sterilization Specialist in radiation (CISS-RAD).

**Alpa N. Patel, B.S., RM(NRCM) – Principal Scientist**

Alpa Patel is a certified microbiologist and has been part of the medical device industry for 17 years specializing in cleaning/disinfection and sterilization of reusable medical devices, endoscopes and validation of tissue disinfection or sterilization processes. Her current role as a principal scientist at Nelson, involves overseeing test method validations for reprocessing, writing standard test protocols (STP) and standard operating procedures (SOP) for reprocessing and other internal and globally related documents, providing technical consulting for the Reprocessing sections at Nelson Laboratories in Salt Lake City and globally. Alpa presents at Nelson Laboratories' seminars, tradeshow, FDA, AAMI, and client facilities across the U.S and International sites.

**Abstract**

Throughout the COVID-19 crisis there has been a huge emphasis on bringing critical products to the healthcare market in a timely fashion. This has required novel approaches to sterile processing of items such as PPE. Manufacturers, regulators and end users have been pressed to develop new processing methods in a very accelerated fashion. It is important to understand when developing new methods that while accelerated or abbreviated test methods may be required, that does not obviate the need for holistic view ensuring all critical parameters are tested.

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