DNV·GL

DNV GL Healthcare USA, Inc.	ADVISORY NOTICE	Notice No: 2019-HC10

Advisory Notices are designed to provide official information relative to Hospital Accreditation, Certification, and Compliance activities. Should you have any questions about the content of this notice, please e-mail dnvclientdropbox@dnvgl.com.

DATE:	**June 20, 2019**
SUBJECT:	**Immediate Use Steam Sterilization**
DISTRIBUTION	**All DNV GL Healthcare Accredited or Certified Hospitals, Applicant Hospitals, DNV GL Healthcare Employees, and Interested Parties**
APPROVED BY:	**Troy McCann, Director, DNV GL Healthcare Accreditation Services**

August 29, 2014 S&C: 14-44-Hospital/CAH/ASC
"The device manufacturer's instructions are not always compatible with the sterilizer instructions or the instructions for the container/ wrapper. Device manufacturers' instructions are sometimes unclear, incomplete, or require processes or cycles that are not available in the health care facility. Where instructions conflict or are insufficient, the device manufacturer should be contacted for more information/guidance. If differing instructions cannot be resolved and the instrument is urgently needed, the device manufacturer's instructions must be followed."

DNV GL does not endorse any specific manufacturer or product for corrective action plans for Immediate Use Steam Sterilization (IUSS). This decision should be determined by the organization to best suit the needs of the organization. The requirement is for the organization to ensure that the instruments that are being used are disinfected, sterilized and stored according to manufacturer's instructions for use (IFU) and professionally recognized standards of practice.

The organization should ensure that instruments/devices that are processed utilizing any containment device meet the manufacturer's IFU of the instrument/device being sterilized. The instrument/device manufacturer's instructions are not always compatible with the sterilizer instructions or the instructions for the containment system/wrapper. Where instructions conflict or are insufficient, the instrument/device manufacturer should be contacted for more information/guidance. The organization should retain documented information to verify this has been completed prior to sterilizing the instrument/device in the containment system.

For example, if you are processing an instrument where the manufacturer's IFUs state a 4 minute exposure time and a 30 minute dry time is required in a rigid containment system for terminal sterilization and you are utilizing a rigid containment system whose IFUs state a different dry time can reach terminal sterilization, DNV GL surveyors would expect to see documentation from the instrument manufacturer that this is acceptable for terminal sterilization of their device. It is important that the instrument/device manufacturer states this is acceptable for terminal sterilization for this to not be considered immediate use steam sterilization.

In addition, please note if during survey activity it is identified that the organization is utilizing IUSS in a manner that places its patients at a risk for infection an NC-1 Condition level will be issued. Such reasons could include but not limited to insufficient instruments to complete scheduled cases, or vendor supplied/loaner instruments not arriving far enough in advance of scheduled cases to run a complete cycle as instructed by the manufacture's IFU.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-14-44.html

Any questions/ comments can be forwarded to the DNV GL Client Drop Box:
DNVclientdropbox@dnvgl.com

Regards,
For DNV GL Healthcare USA, Inc.

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