



Center for Clinical Standards and Quality /Survey & Certification Group

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TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Change in Terminology and Update of Survey and Certification (S&C)
Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in
Surgical Settings

Memorandum Summary

- ***Change in Terminology: “Flash” Sterilization vs. IUSS:*** Nationally recognized organizations with expertise in infection prevention and control and instrument sterilization processes, and other professional organizations recommend abandoning the use of the term “flash” sterilization, which is now considered outmoded, and replacing it with the term “IUSS.”
- ***Update of S&C Memorandum 09-55 Regarding Standards for Immediate Use Sterilization in Surgical Settings:*** This memo reiterates and updates information regarding nationally recognized infection prevention and control guidelines and professionally acceptable standards of practice with respect to immediate use sterilization and supersedes S&C Memorandum 09-55.

Introduction

To assist surveyors in assessing compliance of sterilization practices in surgical settings with Medicare health and safety standards for hospitals, Critical Access Hospitals (CAHs) and Ambulatory Surgical Centers (ASCs), we are providing an update to S&C Memorandum 09-55 regarding the use of “flash” sterilization. In this memo we:

- Discuss current recommendations from nationally recognized organizations with expertise in infection prevention and control and other professional organizations to abandon the use of the term “flash” sterilization, which is now considered outmoded, and replace it with the term “Immediate Use Steam Sterilization” (IUSS), and clarify the differences between the two; and
- Reiterate and update information regarding nationally recognized infection control guidelines and professionally acceptable standards of practice with respect to IUSS.

Regulatory Requirements

Medicare-participating hospitals, CAHs, and ASCs are subject to Conditions of Participation (CoP) or Conditions for Coverage (CfC) regarding infection prevention and control practices in surgical settings, including but not limited to:

Hospitals:

42 CFR 482.42(a): “The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.”

CAHs:

42 CFR 485.635(a)(3)(vi): CAH policies must include: “A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.”

ASCs:

42 CFR 416.51(a): “The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.... (b)...The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines....”

Change in Terminology: “Flash” Sterilization vs. “IUSS”

Surgical disinfection and sterilization procedures are expected to be consistent with accepted standards of practice to prevent the transmission of infectious disease and protect the health and safety of patients. The technology and terminology in this area can be a source of confusion when assessing sterilization procedures during surveys. IUSS was formerly known as “flash sterilization.” The term “flash sterilization” is now considered by multiple organizations nationally recognized for their expertise in infection prevention and control and sterilization practices and other professional organizations to be an outmoded term that should be replaced with the term “Immediate Use Steam Sterilization” (IUSS). These organizations have also recently described professionally acceptable standards of practice with respect to the use of IUSS.

Background Information: “Flash” Sterilization vs. “IUSS”

Surgical instruments must ordinarily be sterilized using terminal sterilization cycles within rigid sterilization containers, wrappers, or primary packaging designed to maintain the instruments’ sterility and which allow the devices to be stored for later use (“terminal sterilization”).

“Flash sterilization” is a term that was traditionally used to describe steam sterilization cycles where medical instruments and devices:

- are generally not packaged in preparation for sterilization;
- are subjected to an abbreviated steam exposure time and no or minimal drying time; and
- are used promptly (i.e., without being stored).

A 2011 position paper¹ adopted by the Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSCMM) (“Position Paper”) recommended that the term “flash sterilization” be abandoned and replaced by the term IUSS.

The new term, IUSS, is still used to describe the process for steam sterilizing an instrument that is needed immediately, not intended to be stored for later use, and which allows for minimal or no drying after the sterilization cycle.² IUSS is now the preferred term, because “flash” does not adequately convey the fact that sufficient time and a number of steps and safeguards are required to accomplish pre-cleaning procedures that are necessary to ensure sterilization. The old terminology is also not necessarily consistent with current recommendations for the length of cycles needed for IUSS and/or the need to use rigid sterilization containers designed specifically for IUSS.^{3,4}

It should be noted that IUSS is *not* equivalent to “short cycle” sterilization. Regardless of the cycle duration, correct use of a sterilization cycle for a wrapped/contained load that meets the device manufacturer’s instructions for use (IFU) is the equivalent of terminal sterilization and is *not* IUSS if it includes use of a dry time and is packaged in a wrap or rigid sterilization container intended to be stored for later use.

Professionally Accepted IUSS Standards of Practice

Consistent with standards of practice previously articulated by national associations with expertise in infection prevention, the availability of IUSS is not considered an appropriate substitute for maintaining a sufficient inventory of instruments.^{5,6,7,8} While IUSS will accomplish sterilization *if all of the steps before, during, and after the process are performed correctly*, and used in compliance with specific device manufacturer’s; sterilization manufacturer’s; and, if applicable, container manufacturer’s validated written instructions for use (IFU). Practices associated with the outmoded term “flash” sterilization have been implicated in surgical site infections and are considered to pose an increased risk of complications because of potential barriers to thorough completion of all necessary reprocessing steps.^{9,10,11,12,13} IUSS also entails an increased risk of inadvertent contamination during transfer to the sterile field and damage to the instruments,¹⁴ as well as risks related to wet instruments and the potential for burns.¹⁵ Therefore use of IUSS, even when all steps are performed properly, should be limited to situations in which there is an urgent need and insufficient time to process an instrument by using terminal sterilization.^{16,17}

The Position Paper and/or the other nationally recognized sources referenced below describe the following professionally accepted standards for the use of IUSS:

- The Position Paper emphasizes that “[c]leaning, decontamination, and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilization exposure parameters being used.”^{18,19,20}

- The same multistep process used to prepare the instrument for terminal sterilization must be completed for IUSS.²¹ Cleaning must be performed in an area that has all of the equipment (e.g. sinks and mechanical and/or ultrasonic washers), cleaning agents, tools (e.g. brushes), water quality and availability of information needed to follow the medical device manufacturer's IFU regarding both cleaning and IUSS.²²
- The parameters (exposure time, temperature, and drying times [if any drying is recommended]) of an IUSS cycle must be determined after reviewing the IFUs for each of the following: the instrument/device to be sterilized, the sterilizer, and the containment device.^{23,24}
- According to the Position Paper,²⁵ the device manufacturer's written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities and the packaging. The Position Paper includes the following: "NOTE: 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."
- Each IUSS cycle must use physical monitors (time, temperature, pressure) (which were previously called "mechanical" monitors). Each IUSS cycle must also use a Class 1 chemical indicator(s) (CI) outside each sterilization container/package unless the internal Class 4, 5 or 6 CI which must be used inside each package is visible. The Class 6 CI must be used in the cycle for which it is labeled. A biological indicator (BI) must be used at least weekly for the cycle used for IUSS. If more than one exposure time is used at a single temperature, then only the shortest exposure needs to be tested. The results for all of these indicators must be documented.^{26,27,28}
- If IUSS must be used for an implantable device, the name of the patient/patient's unique identifier and any other information needed to accurately link the instrument processed using IUSS back to the patient must be recorded.^{29,30,31}
- Medical instruments and devices that are processed by IUSS must be contained in a rigid sterilization container or packaging labelled for the IUSS cycles used, or in a tray. Containment devices must be validated by the manufacturer and cleared by the U.S. Food and Drug Administration (FDA) for use in IUSS.^{32,33}
- At the conclusion of the sterilization process, exogenous contamination must be prevented during transport.^{34,35} Trained personnel knowledgeable in aseptic transfer technique must open the container, read the CI, and remove the contents if the CI(s) indicate a pass result, to prevent the containment device being stored for later use or held from one procedure to another.^{36,37}

- For aseptic transfer, the IUSS containment device must be immediately transferred from the sterilizer to the point of use, opened, and the contents delivered to the sterile field.³⁸
- The items are assumed to be wet and hot and need to be transported in a manner to minimize both exogenous contamination and injury to personnel. Sterile heat protective gloves (e.g. potholders or towels) may be used to carry the containment device directly to the point of use.^{39,40,41}

According to the Position Paper,⁴² IUSS is not acceptable in the following situations:

- For implant devices, except in a documented emergency situation when no other option is available.

Note: IUSS might be used during emergencies when no option is available, for example⁴³, when an implant device has been contaminated and there is no sterile replacement available, or cannot be packaged and terminally sterilized.⁴⁴ If this situation is unavoidable, the facility must ensure that any implant subjected to IUSS is accurately traceable to the recipient patient.^{45,46,47} Facilities must be able to document that the sterilization process was effective and that the implant was safe to use in the patient. This includes documentation of load identification, patient's name/patient's unique identifier, and results of the BI and a Class 5 CI.^{48,49,50}

- For post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or other prion-associated diseases;
- On devices or loads that have not been validated with the specific cycle used; or
- On devices that are sold by the manufacturer already processed and packaged as sterile and intended for single-use only.

Survey Procedures

An infection prevention and control program to prevent the transmission of infectious disease and protect the health and safety of patients as required under the CoPs/CfCs will be consistent with the national standards of practice. If there is evidence to establish that the answer to any of the following questions is “no” or the provider or supplier is using IUSS in a manner that places its patients at risk for infection, a citation under the appropriate infection control CoP/CfC is warranted.

- Is IUSS reserved for immediate use needs (e.g., used only emergently), when a needed instrument has been contaminated and there is no sterile replacement available, or for a patient care item that cannot be packaged, sterilized and stored before use)?
- Is there a process in place to ensure IUSS is not used for implants (in most circumstances, as described above); instruments used on patients with known or suspected CJD or similar disorders; devices or loads not validated with the specific cycle; and single-use devices?

- Are instrument(s) to undergo IUSS first cleaned and disinfected following the manufacturer's IFU?
- Is there evidence that all of the personnel who perform IUSS:
 - Have the necessary time, equipment, supplies and facilities readily available;
 - Have been trained and are able to correctly follow the manufacturer's IFU(s) regarding IUSS with respect to each instrument, sterilizer(s), and container(s) and cleaning supplies they are using for IUSS; and
 - Have had their competency initially verified before they undertake IUSS, and periodically thereafter?
- Can personnel provide evidence that the sterilizer cycle being used for IUSS is indicated in the device manufacturer's IFU?
- Are physical monitors used documented to record that cycle parameters are met for each load?
- Is there evidence that the sterilizer is being maintained as required by the manufacturer's IFU?
- Is the rigid sterilization container/packaging, or tray used in a particular cycle consistent with how it is labeled by the manufacturer?
- Is the rigid sterilization container being used for the load consistent with its manufacturer's recommendations for IUSS (e.g. load weight, configuration of instruments)?
- Are the CIs used labeled for use in this cycle by their manufacturer?
- Is a Class 1 CI placed outside each sterilization container/package unless the internal Class 4, 5 or 6 CI used inside each package is visible?
- Is a Class 4, Class 5, or Class 6 CI placed within each container?
- Is the BI (if used), labeled for use for this cycle by its manufacturer?
- If IUSS must be used on an implantable device, is each such load checked with a BI and a Class 5 CI labelled for use with that cycle?^{51,52}
- Are all monitoring tests (physical, chemical and biological (if used)) results evaluated by trained personnel at the conclusion of the IUSS process before use of the instrument(s) or device(s)?
- Are instruments that are sterilized using IUSS aseptically transported, and cooled prior to use? Note: Instrument or items may be cooled aseptically in cold sterile water.
- Is there evidence that the healthcare provider or supplier is monitoring personnel for adherence to policy and procedures for IUSS reprocessing?

Questions concerning this memorandum should be addressed to: hospitalscg@cms.hhs.gov

Effective date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

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cc: Survey and Certification Regional Office Management

Endnotes

¹ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM).

Immediate-Use Steam Sterilization. Undated. Accessed 4/22/2014 at:

http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf

² Ibid.

³ AORN. Recommended practices for sterilization in the perioperative practice setting. *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, 2014. www.aorn.org

⁴ Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST 79:2010 & A1:2010 & A2:2011 & A3:2012&A4:2013 (consolidated text) www.aami.org

⁵ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM)., Accessed 4/22/2014.

⁶ AORN, 2014.

⁷ Association for the Advancement of Medical Instrumentation. 2013.

⁸Centers for Disease Control (CDC). *Guideline for Disinfection and Sterilization in Healthcare Facilities*. 2008. <http://www.cdc.gov/hicpac/pubs.html>

⁹ Ibid.

¹⁰Seavey R. Immediate use steam sterilization: Moving beyond current policy. *American Journal of Infection Control*. 2013;41:S46-S48.

¹¹ McConkey SJ, L'Ecuyer PB, Murphy DM, et al. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. *Infect Control Hosp Epidemiol*. 1999;20:533-8.

¹² Babcock HM, Carroll C, Matava M, L'ecuyer P and Fraser V. Surgical site infections after arthroscopy: outbreak investigation and case control study. *Arthroscopy*. 2003;19:172-81.

¹³ Lopansri, B. et al. Protracted Outbreak of Postarthroscopy Infections Associated with Flash Sterilization of Instruments, Presented on March 20, 2010 at the Fifth CDC Decennial International Conference on Health-care Associated Infections in Atlanta, GA; Accessed on April 22, 2014.
<https://shea.confex.com/shea/2010/webprogram/Paper2792.html>

¹⁴ CDC, 2008.

¹⁵ Rutala WA, Weber DJ, Chappell KJ. Patient injury from flash-sterilized instruments. *Infect Control Hosp Epidemiol.* 1999;20:458.

¹⁶ AORN, 2014

¹⁷ Association for the Advancement of Medical Instrumentation. 2013

¹⁸ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Accessed 4/22/2014.

¹⁹ AORN, 2014.

²⁰ Association for the Advancement of Medical Instrumentation. 2013

²¹ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Accessed 4/22/2014.

²² Seavey, 2013.

²³ AORN, 2014.

²⁴ Association for the Advancement of Medical Instrumentation. 2013.

²⁵ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Accessed 4/22/2014.

²⁶ AORN, 2014.

²⁷ Association for the Advancement of Medical Instrumentation. 2013.

²⁸ CDC, 2008.

²⁹ AORN, 2014.

³⁰ Association for the Advancement of Medical Instrumentation. 2013.

³¹ CDC, 2008.

³² AORN, 2014.

³³ CDC, 2008.

³⁴ AORN, 2014.

³⁵ CDC, 2008.

³⁶ AORN, 2014.

³⁷ Association for the Advancement of Medical Instrumentation. 2013.

³⁸ Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Accessed 4/22/2014.

³⁹ AORN, 2014.

⁴⁰ Association for the Advancement of Medical Instrumentation. 2013.

⁴¹ CDC, 2008.

⁴² Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Accessed 4/22/2014.

⁴³ Association for the Advancement of Medical Instrumentation. 2013

⁴⁴ CDC, 2008.

⁴⁵ AORN, 2014.

⁴⁶ Association for the Advancement of Medical Instrumentation. 2013.

⁴⁷ CDC, 2008.

⁴⁸ AORN, 2014.

⁴⁹ Association for the Advancement of Medical Instrumentation. 2013.

⁵⁰ CDC, 2008.

⁵¹ AORN, 2014.

⁵² Association for the Advancement of Medical Instrumentation. 2013.