







# Sterilization Process Monitoring: Are Your Practices Current?

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#### LEARNING OBJECTIVES

1. Describe the tools used to monitor sterilization processes
2. Discuss the recommended steam sterilization quality assurance practices provided in ANSI/AAMI ST79 and the Association of periOperative Registered Nurses' *Guideline for Sterilization*
3. Discuss the recommended low-temperature sterilization quality assurance practices provided in Association for the Advancement of Medical Instrumentation and Association of periOperative Registered Nurses standards
4. Review sterilization documentation best practices
5. Review accreditation considerations related to sterilization process monitoring

Accreditation bodies continue to pay close attention to the processing of medical devices. More importantly, the goal of a Central Service/Sterile Processing (CS/SP) professional is to contribute to the best possible patient outcomes by performing meticulous cleaning and effective sterilization of reusable instruments. One important element in achieving this goal is to routinely monitor the performance of the sterilizers in the department. Fortunately, CS/SP professionals don't need to "reinvent the wheel" when it comes to developing monitoring practices. Published evidence-based guidelines are regularly updated and should inform one's practices. This lesson will review current standards and recommended practices for monitoring the sterilization processes commonly used in healthcare facilities. Upon reviewing this lesson, readers are encouraged to compare the recommendations to their facility's practices to determine whether any

policy and procedure revisions are needed in order to align with current guidelines.

#### Objective 1: Describe the tools used to monitor sterilization processes

Regardless of the sterilization modality, a common set of monitoring tools are used as part of an effective quality assurance (QA) program. These tools include physical monitors and chemical and biological indicators (CIs and BIs). CIs and BIs are regulated by the US Food and Drug Administration (FDA) as Class 2 medical devices, meaning the products must be FDA-cleared before they can be offered for sale in the US. The FDA reviews new product submissions from manufacturers to assure the products sold are safe and effective when the product's instructions are followed.

According to the Association of periOperative Registered Nurses' (AORN's) *Guideline for Sterilization* (RP X.d), "Physical monitors (e.g., time, temperature, pressure, humidity, sterilant



concentration) should be reviewed at the end of each cycle. The sterilizer operator should verify that all sterilization parameters were met for every cycle and every sterilization method.” As explained in a rationale statement in ANSI/AAMI ST79, *Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities*, Section 13.5.1, “Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record by means of charts, printouts or digital data. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken.”

CIIs are defined in ANSI/AAMI ST79, Section 2.10, as “Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.” Six types of CIIs are described in ISO 11140-1:2014, the document that sets out performance and labeling requirements for CI manufacturers. The type of CI simply indicates the characteristics and intended use of each indicator. The ISO standard emphasizes that the categorization has no hierarchical significance; in other words, a higher number does not signify a better indicator. An external CI (Type 1 process indicator) is placed on each load item to differentiate between unprocessed and processed items. An internal CI (Types 3, 4, 5 or 6) is placed inside each package. Not all types of indicators are available for all sterilization modalities. For example, Type 2 CIIs are indicators for use in specific tests, such as the Bowie-Dick test used for dynamic air removal steam sterilizers. An important note in ANSI/AAMI ST58, under Section 2.14, reads: “NOTE 1—Chemical indicators Class 2–6 are not applicable to monitoring

the liquid chemical sterilization (LCS)/high-level disinfection (HLD)/gaseous chemical sterilization processes described in this document.”

As staff members using the processed instruments are typically responsible for assessing the result of internal CIIs, it is important to provide Operating Room (OR) colleagues with interpretation guides for the various CIIs used to monitor all the sterilization modalities used at one’s facility.

ISO 11140-1:2014 provides manufacturers with symbols to be used as abbreviated descriptions of the various sterilization processes. These symbols help CS/SP technicians know at a glance which process a particular CI is designed to monitor. Symbols for the methods of sterilization commonly used in US healthcare facilities, and that one may see on individual CIIs and/or their packaging, include:

Symbol	Process
STEAM	Steam sterilization
EO	Ethylene oxide sterilization
VH2O2	Vaporized hydrogen peroxide sterilization

BIIs contain live bacterial spores and are used to assess the lethality of the sterilization process. *Geobacillus stearothermophilus* is used to monitor both steam and hydrogen peroxide sterilizers while *Bacillus atrophaeus* is used to monitor ethylene oxide (EtO) sterilizers. Performance requirements for BIIs are provided in the ISO 11138 series of standards. CS/SP technicians should select BI(s) that are FDA-cleared, ISO 11138 compliant, and intended to monitor the sterilization cycle(s) they use. For all sterilization modalities, it is recommended that a control BI (with the same lot code as the test BI), be

incubated each day a test BI is incubated.

As terminally sterilized instruments are packaged for sterilization, ANSI/AAMI ST41 and ANSI/AAMI ST79 provide end-user guidance for the assembly of BI process challenge devices (BI PCDs). These PCDs are intended to simulate the products being sterilized and provide a defined challenge to the sterilization process that is equal to or greater than the most difficult item routinely processed. Commercially-available, pre-assembled BI PCDs provide a consistent challenge. The FDA requires commercially-available BI PCDs to be equivalent in performance to the reference AAMI PCD.

## Objective 2: Discuss the recommended steam sterilization quality assurance practices provided in ANSI/AAMI ST79 and the Association of periOperative Registered Nurses’ Guideline for Sterilization

ANSI/AAMI ST79 is the go-to document for steam sterilization, and was revised in 2017. AORN’s *Guideline for Sterilization* was updated in 2018 and is part of the 2019 edition of AORN’s *Guidelines for Perioperative Practices*. The recommendations in these two resources are generally consistent.

### Routine Load Release

When removing a processed load from a steam sterilizer, CS/SP technicians decide whether to release the load after careful evaluation of the available data. This data includes: the physical monitor (e.g., the printout), which is checked to verify the cycle parameters were met; and the inspection of the external CIIs. All packages should have a Type 1 external CI, unless the internal CI is visible for inspection. Internal CIIs are inspected by the person opening the set. ANSI/AAMI ST79, Section 13.5.2.2.2, recommends that “one or more internal chemical



In addition to requiring a release decision about each load, a robust quality assurance (QA) program includes routine efficacy testing using BI PCDs. If a sterilizer is designed to be used for multiple types of cycles, ANSI/AAMI ST79 recommends testing each cycle type used (per Section 13.7.1).

indicators should be placed within each package, tray or rigid container. These indicators can be any type (Type 3, 4, 5 or 6) but, preferably, a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters.” Guidance on routine load release is split into two subcategories: non-implant loads and implant loads.

**Non-implant loads:** Loads that do not contain an implant should be monitored using physical monitors and CIs, and may be monitored with a PCD containing a BI; a BI and a Type 5 CI; a Type 5 CI; or a Type 6 CI. The use of a PCD is optional.

**Implant loads:** As BIs are the only monitoring tool that demonstrate the lethality of the sterilization process, ANSI/AAMI ST79:2017, Sections 13.5.3.2 and 13.6.3, recommend that implant loads be monitored with a PCD containing a BI and a Type 5 integrating indicator. The implant should be quarantined until the BI result is available. In defined emergency situations, the implant can be released on the basis of the Type 5 integrator contained within the PCD, but the BI should still be incubated and the result documented (per Section

13.6.3). ST79:2017 provides an example Exception Form for emergency load release documentation in Annex K. Periodically reviewing the stated “reason for immediate use steam sterilization (IUSS)” on these exception forms can be a source of process improvement ideas. AORN’s revised *Guideline for Sterilization* continues to state that IUSS should not be used for implantable devices. If it must be done in an emergency, the IUSS cycle should be monitored with a PCD containing a BI and Type 5 CI (per RP V.d.4 and V.d.5).

### Routine Efficacy Testing

In addition to requiring a release decision about each load, a robust QA program includes routine efficacy testing using BI PCDs. If a sterilizer is designed to be used for multiple types of cycles, ANSI/AAMI ST79 recommends testing each cycle type used (per Section 13.7.1). The recommended frequency for routine sterilizer efficacy monitoring with a BI PCD is at least weekly, but preferably every day that the sterilizer is used (per Section 13.5.3.2). Guidance on the specific BI PCD to be used is provided in the following three sections:

#### Sterilizers larger than 2 cubic feet

**(Section 13.7.2):** The use of a pre-assembled, disposable BI PCD, equivalent

in challenge to the AAMI 16-towel PCD, is recommended. ANSI/AAMI ST79 states that disposable PCDs “provide standardization and reduce variability and potential for error.” The PCD is placed in a loaded chamber in the area most challenging to sterilant penetration. ANSI/AAMI ST79:2017 does not have a separate section on routine monitoring of IUSS cycles. As sterilizers used for IUSS have a chamber size larger than 2 cubic feet, routine testing of dynamic-air-removal IUSS cycles falls under this section (e.g., they should be monitored with a pre-assembled, commercially-available BI PCD. In IUSS cycles, routine testing may be done in an empty chamber).

**Table-top sterilizers (less than or equal to 2 cubic feet, Section 13.7.3):** To monitor table-top sterilizers, the user assembles a representative BI PCD. For example, if items are pouched for sterilization, the BI PCD is created by placing a BI, CI and an instrument in a pouch. Routine testing is done in a fully-loaded chamber.

**Gravity-displacement cycles (Section 13.7.4):** “For routine monitoring of gravity-displacement cycles, a representative of the same type of tray to be routinely processed by gravity-displacement cycles should be selected to serve as the PCD. Each type of tray configuration routinely used for gravity-displacement cycles should be tested separately.” The PCD should be placed on the bottom shelf of an otherwise empty chamber. Routine testing of gravity displacement IUSS sterilizers falls into this section.

In each case, it is recommended that a control BI, having the same lot code as the test BI, be incubated each day a test BI is incubated. Acceptance criteria includes a negative result for the test BI and a positive result for the control BI.



With the availability of rapid readout BIs, many healthcare facilities have adopted a policy of monitoring every steam sterilization load to simplify staff training, ensure uniform patient care, and avoid costly recalls that can include surgeon and patient notifications.

### Bowie-Dick Testing

For dynamic air removal sterilizers, routine Bowie-Dick testing is a key element of the QA program. “A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load. A Bowie-Dick test pack is used in conducting this test (see ANSI/AAMI/ISO 11140-5). A shortened cycle (e.g., a cycle omitting the drying phase) should be run first to heat the sterilizer. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day” (per Section 13.7.6). While facilities may assemble their own towel test packs, ANSI/AAMI ST79 recommends the use of commercially-available, pre-assembled Bowie-Dick test packs. The test pack is placed in an otherwise empty, pre-heated chamber over the drain.

### Objective 3: Discuss recommended low-temperature sterilization quality assurance practices provided in Association for the Advancement of Medical Instrumentation and Association of periOperative Registered Nurses Standards

EtO and vaporized hydrogen peroxide (VH2O2) sterilizers are used to sterilize items that cannot tolerate the high temperature and/or moisture in steam sterilization cycles. The relevant evidence-based guidelines for these sterilization modalities are:

- ANSI/AAMI ST41:2008(R) 2018, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*
- ANSI/AAMI ST58:2013, *Chemical*

*sterilization and high-level disinfection in health care facilities*

- *Guideline for Sterilization* in the 2019 edition of AORN’s *Guidelines for Perioperative Practice*.

In large facilities, VH2O2 sterilizers are used many times each day and instruments are quickly returned to patient use. A robust QA program, which includes routine sterilizer efficacy testing using the suite of monitoring tools described above, is therefore essential. The use of physical monitors is discussed in Section 9.5.1 of ANSI/AAMI ST58. Three key quotes from this section are: “At the end of the cycle and before items are removed from sterilizer, the operator should examine and interpret the chart or printout to verify that cycle parameters were met and initial it to allow later identification of the operator”; “If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used”; and “...physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.”

While CIs and BIs for steam sterilizers are typically indicated to monitor certain cycle parameters, the indications for use for VH2O2 monitoring products are generally more specific. It is important to select CIs and BIs that are FDA cleared for the particular VH2O2 sterilizer(s) and cycle(s) used at one’s own facility. Let’s review the recommend use of these tools.

**External CIs:** “A CI should be used on the outside of each package, unless the internal indicator is visible. The CI is examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process.” (ANSI/AAMI ST58:2013, Section 9.5.3.2)

**Internal CIs:** An internal CI should be used inside each package, tray and containment device to be sterilized. (ANSI/AAMI ST58:2013, Section 9.5.3.2) As explained in AORN’s *Guideline for Sterilization*, before placing a tray or item on the sterile field, the internal CI should be examined for a pass result. (RP X.c.4)

**BIs:** AORN recommends that “*Geobacillus stearothermophilus* spore BIs should be used for routine load release, routine sterilizer efficacy monitoring, and sterilizer qualification testing. (RP X.i.1) CS/SP staff typically place a BI and an internal CI in a peel pouch indicated for use in VH2O2 sterilizers, orient the pouched BI per the BIs instructions for use (IFU), and then locate the pouched BI in the sterilizer chamber as recommended by the sterilizer manufacturer.

The frequency of routine BI monitoring is worded slightly differently by AAMI and AORN. ANSI/AAMI ST58 states that “a PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle.” (Section 9.5.4.3). AORN is more specific and states that “routine sterilizer efficacy monitoring should be performed every day the sterilizer is used for each cycle type (e.g., standard, advanced, lumen, non-lumen), preferably with each load.” (RP X.i.2) As the sterilization parameters can differ significantly for each VH2O2 cycle type programmed on a sterilizer, this recommendation to test each cycle type is prudent. Indeed, with the availability of BIs that provide a result in 30 minutes or less, and the understanding that this sterilization modality is technique-sensitive, many facilities have implemented the best practice of monitoring every load.

The physical monitor and CI recommendations for monitoring EtO sterilizers are analogous to those





for VH2O2 sterilizers. In addition to verifying the sterilization parameters, the CS/SP technician should verify that the desired aeration time has elapsed before opening the chamber door. As mentioned previously, a different organism, *Bacillus atrophaeus*, is used to monitor EtO sterilizers. Both ANSI/AAMI ST41 and AORN's *Guideline for Sterilization* recommend that every EtO load be monitored with a BI PCD. Instructions for user-assembly of a routine BI PCD are provided in ANSI/AAMI ST41, but most facilities opt for the consistency of a commercially-available, pre-assembled BI PCD that is equivalent in challenge to the ANSI/AAMI PCD.

#### Objective 4: Review sterilization documentation best practices

It is important to accurately and promptly document both the cycle information and the associated monitoring results for each sterilization process. Every processed item (peel pouch, wrapped pack, rigid container, etc.) should be traceable to the load in which it was sterilized. This is usually accomplished by labeling each package with a lot control number including the sterilization date, the sterilizer number and the load number.

Both paper record-keeping and electronic systems are acceptable methods of documentation. AORN's *Guideline for Sterilization* states that "an electronic instrument tracking system may be used." (RP X.e.2) The use of an electronic system can facilitate the location and retrieval of load items both on a day-to-day basis and in the event of a recall. Instrument tracking software can also help ensure that compliant records are kept for each sterilization cycle.

The following information should be recorded and maintained for each sterilization cycle:

1. Lot number (processing date, sterilizer number and cycle number);
2. Specific contents of the lot or load;
3. Critical parameters for the specific sterilization method;
4. Name or initials of the operator;
5. Applicable sterilization process monitoring results; and
6. Patient name/identifier (for IUSS cycles).

In addition to sterilization cycle records, a maintenance record should be kept for each sterilizer. The sterilizer instruction manual should provide guidance on routine care, preventive maintenance and calibration of the sterilizer. The maintenance record should provide a continuous history of all scheduled and unscheduled service.

#### Objective 5: Review accreditation considerations related to sterilization process monitoring

For facilities accredited by The Joint Commission (TJC), the agency's 2019 Hospital Accreditation Standards continue to include standards relevant to sterilization process monitoring. Among these are:

**EC 02.04.03:** "The hospital inspects, tests and maintains medical equipment." And under this standard, Element of Performance 4, "the hospital conducts performance testing of and maintains all sterilizers. These activities are documented."

**IC 02.02.01:** "The hospital reduces the risk of infections associated with medical equipment, devices and supplies."

**LD 04.03.07:** "Patients with comparable needs receive the same standard of care, treatment and services throughout the hospital."

For the past several years, the TJC has shared that too many healthcare facilities are cited for failing to adhere to standard IC 02.02.01. Their latest initiative to help facilities become more compliant with IC.02.02.01 was to issue new scoring revisions for this standard in September 2017.

For the past several years, the TJC has shared that too many healthcare facilities are cited for failing to adhere to standard IC 02.02.01. Their latest initiative to help facilities become more compliant with IC.02.02.01 was to issue new scoring revisions for this standard in September 2017. The scoring revisions, which took effect immediately, included topics from point-of-use cleaning to drying of endoscopes. This lesson focuses only the new scoring related to sterilization process monitoring. According to TJC, surveyors should issue citations when:

- Routine sterilizer monitoring with a BI required by the state or per evidence-based guideline is not followed and recorded.
- Non-implant load is released without physical monitoring of cycle and external and internal CIs.



To ensure the best possible patient outcomes, it is important to have a robust QA program in place for all sterilization modalities. Accreditation bodies expect sterilization process monitoring policies to be based on current, evidence-based guidelines. Two great resources, ANSI/AAMI standards and AORN guidelines, provide comprehensive sterilization monitoring recommendations and are generally concurrent.

- Implant loads are released without routine sterilizer monitoring, a BI and a type 5 integrating indicator (aka, integrator).
- BI is not read before implant release (unless allowed in emergent situations by facility policy and policy was followed).

To avoid being cited for early implant release, many facilities rely on BIs that provide fast results.

To comply with Standard LD 04.03.07, healthcare systems can have standardized

sterilization monitoring policies available throughout the system and audit to verify compliance to these policies wherever sterilization may be done. Alternatively, some systems adopt the approach of centralizing sterilization to guarantee a uniform standard of care. CS/SP professionals should ask whether their facility has standardized sterilization monitoring policies between CS/SP and the OR.

### Conclusion

To ensure the best possible patient outcomes, it is important to have a robust QA program in place for all sterilization modalities. Accreditation bodies expect sterilization process monitoring policies to be based on current, evidence-based guidelines. Two great resources, ANSI/AAMI standards and AORN guidelines, provide comprehensive sterilization monitoring recommendations and are generally concurrent. It is recommended to set aside time to review policies and procedures to ensure they are aligned with these evidence-based guidelines. As a next step, it is prudent to audit the facility's sterilization records for completeness, legibility and compliance with the policy. If there are gaps, it is important to implement training to ensure staff members know how to complete the required documentation, either on paper or through the use of an electronic software program. **C**

### Resources

Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2017.

Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities*. ANSI/AAMI ST58:2013.

Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*. ANSI/AAMI ST41:2008(R)2018.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products - Chemical indicators - Part 1: General requirements*. ANSI/AAMI/ISO 11140-1:2014. 2014.

Association of periOperative Registered Nurses. *Guideline for Sterilization in Guidelines for Perioperative Practice, 2019 Edition*.

The Joint Commission. 2019 Hospital Accreditation Standards.

The Joint Commission. *4-1-1 on Survey Enhancements: New scoring revisions for IC.02.02.01 now in effect*. Accessed 1/11/19 <https://www.jointcommision.org/issues/article.aspx?Article=G%2fxUdh%2fVKujxJ12FY7q2i0ousSBZsyucrGSdk%2bHj108%3d>

US Food and Drug Administration. *Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions*. Issued October 4, 2007.



# CRCST Self-Study Lesson Plan Quiz -

## Sterilization Process Monitoring: Are Your Practices Current?

Lesson No. CRCST 165 (Technical Continuing Education - TCE) • Lesson expires March 2022

1. A daily Bowie-Dick test should be done in which type of sterilizer?
  - a. Ethylene oxide sterilizer
  - b. Gravity-displacement immediate use steam sterilization sterilizer
  - c. VH202 sterilizer
  - d. Dynamic air removal steam sterilizer
2. A positive control biological indicator with the same lot number as the test biological indicator should be incubated at what frequency?
  - a. Each time a test biological indicator is incubated
  - b. Daily
  - c. Weekly
  - d. Monthly
3. ANSI/AAMI ST79:2017 recommends that all loads containing implants be monitored with a process challenge device that contains:
  - a. A biological indicator and a Type 5 chemical indicator
  - b. A biological indicator only
  - c. A Type 5 chemical indicator
  - d. A Type 6 chemical indicator
4. In documented emergency situations only, which monitoring tool within the biological indicator process challenge device may be used for early release of an implant processed in a steam sterilization cycle?
  - a. A Type 5 chemical integrator
  - b. A Type 6 chemical indicator
  - c. A Type 1 process indicator on the biological indicator
  - d. A Type 1 process indicator on the biological indicator process challenge device
5. The recommended monitoring frequency for ethylene oxide sterilizers is:
  - a. Monthly
  - b. Weekly
  - c. Daily
  - d. Every load
6. Per the Association of periOperative Registered Nurses' *Guideline for Sterilization*, the recommended monitoring frequency for vaporized hydrogen peroxide sterilizers is:
  - a. Weekly, preferably daily
  - b. Daily
  - c. Every day the sterilizer is used for each cycle type, preferably with each load
  - d. Every load
7. Per ANSI/AAMI ST79, the recommended routine monitoring frequency for steam sterilizers is:
  - a. Weekly, preferably daily
  - b. Daily
  - c. Every day the sterilizer is used for each cycle type and, preferably, with each load
  - d. Every load
8. The Joint Commission's new scoring revisions for IC 02.02.01 includes citations for:
  - a. Releasing an implant before the biological indicator is read
  - b. Failing to routinely monitor sterilizers with a biological indicator, as recommended by evidence-based guidelines
  - c. Releasing non-implant loads without the use of physical monitors and external and internal chemical indicators
  - d. All the above
9. Central Service/Sterile Processing technicians should select a biological indicator that:
  - a. Contains the appropriate spore for the sterilizer being monitored
  - b. Is cleared by the US Food and Drug Administration
  - c. Is intended to monitor the specific sterilization cycle(s)
  - d. All the above
10. Physical monitors should be reviewed after each cycle to:
  - a. Verify sterilant penetrated the load item
  - b. Verify the lethality of the cycle
  - c. Verify the cycle parameters were met
  - d. Verify the sterilizer is calibrated
11. The individual opening a processed package at the point of use should:
  - a. Verify a lot number is attached to the package
  - b. Verify the external chemical indicator has changed
  - c. Verify the internal chemical indicator has a pass result
  - d. All the above
12. Type 1 "exposure" indicators are intended to:
  - a. Verify sterilant has penetrated into a rigid container
  - b. Allow differentiation between processed and unprocessed items
  - c. Demonstrate the efficacy of a vacuum system on a pre-vacuum steam sterilizer
  - d. Demonstrate the lethality of the cycle
13. To ensure traceability of each load item, the lot control number should include:
  - a. The sterilization date
  - b. The sterilizer number
  - c. The load number
  - d. All the above
14. Accreditation bodies expect healthcare facility sterilization process monitoring policies to be based upon which of the following?
  - a. Community standards
  - b. Current, evidence-based guidelines
  - c. US Food and Drug Administration regulations
  - d. Occupational Safety and Health Administration regulations
15. In addition to a lot number, the information to be recorded for each sterilization cycle should include:
  - a. Specific contents of the lot or load
  - b. Critical parameters for the specific sterilization method
  - c. Applicable sterilization process monitoring results
  - d. All the above

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