

Today's Sterilizer Is Not Your Father's Water Heater

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Health care facilities around the world use sterilizers to produce sterile items for patient use. Steam sterilization is a condensing process; the steam vapor gives up its energy to heat the load to the selected temperature. The steps are simple: place packaged or unwrapped items in the chamber, select the correct cycle, and push the start button. In minutes, the sterilization process is complete. Over and over again, sterilizers execute programmed jobs, creating uniform conditions inside pressure vessels to achieve sterilization. An educated and competent operator is needed, however, to select the right cycle.

Although some parallels exist between sterilizers and the average household water heater, today's sterilizer is not your father's water heater. Both pieces of equipment maintain a steady temperature but the similarities end there; today's sterilizers are sophisticated, automatic, and computerized devices. Sterilizers are regulated by the US Food and Drug Administration (FDA) as class II medical devices,¹ requiring that the design and manufacture of the sterilizer be safe and effective.² Sterilizers also have control systems that function via validated software. Periopera-

tive nurses need to understand what regulatory requirements for sterilizers exist, how sterilizer design and performance are validated, how sterilizer cycles function for everyday use, and how sterilization procedures can improve patient outcomes.

EARLY STERILIZERS

Until the 1940s, sterilizers were basic in design and function. Pressure vessels were mounted on open stands. To expose loads to steam, operators simply turned manual valves to let steam in or out of the vessel. Mechanical pressure regulators maintained temperatures at either 250° F (121.1° C) or 270° F (132.2° C). Watches or wall clocks provided a reference for proper exposure time. All sterilizers operated by gravity displacement, meaning that within the vessel, steam displaced the air, which moved out and down through the trap assembly and drain (Figure 1).³

During the late 1950s and 1960s, controls were electromechanical, and jacketed pressure vessels were constructed

ABSTRACT

Today's sterilizers are sophisticated, automatic, and computerized devices that accurately execute programmed jobs, creating uniform conditions inside pressure vessels to achieve sterilization. Specialized knowledge is necessary to ensure that the right cycle is selected; this requires an educated and competent operator.

Perioperative nurses need to understand regulatory requirements for sterilizers, sterilizer design and performance validation, sterilizer cycle functions for everyday use, and everyday sterilization procedures.

Key words: *sterilizer, sterilizer safety, sterilizer device clearance, sterilization, steam sterilization.* AORN J 90 (July 2009) 81-88. © AORN, Inc, 2009.

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of carbon steel with a thin coating of nickel inside the chamber for corrosion protection. Three-horsepower or larger vacuum pumps were introduced during this time period for the preconditioning phase, which enhanced cycle performance. Steam was serially injected during the preconditioning phase while the pressure vessel maintained a vacuum. This addition of steam, while in a vacuum (ie, pressurized) condition, helped remove air.³ Other advances that occurred during this time period included the development of Bowie-Dick test packs. These test packs enabled routine verification of air removal and steam penetration.⁴

All door closure systems were of the compression type, either using radial arm locking devices or electromechanical concentric gears, which clamped around the door. A major problem with these doors was that any door seal failure during a cycle had the potential to

cause serious damage to the sterilizer and injury to the operator.³

Several technological innovations occurred during the late 1970s and early 1980s. The first vertical sliding doors, inherently safer by design, with active gasket seals were introduced. Sterilizer manufacturers used available state-of-the-art technology to develop microcomputer controls, which provided more precise measurements of temperature and pressure. They then created a system for operator feedback on cycle performance with diagnostic codes.

Finally, vacuum pumps were replaced by water ejectors. This obviated the need for the sterilizer to be connected to house water that was no warmer than 60° F (15.6° C) because water ejectors are not as sensitive to water temperatures. Compared to vacuum pumps, water ejectors are less noisy, cost less to maintain, and do not require a three-phase electrical connection. One downside of sterilizers with water ejectors is that they consume large amounts of water compared to sterilizers equipped with vacuum pumps.

PRESSURE VESSELS AND SAFETY CODES

During the last 60 years, pressure vessels have evolved and in some ways have come full circle. For example, vessel shape changed from cylindrical to rectangular to cylindrical again for some manufacturers. Vessel materials, initially stainless steel, moved to nickel-clad carbon steel and then back to stainless steel again. Of the various qualities of stainless steel, the most commonly used today is 316L, which has corrosion-resistant properties.

All pressure vessels (ie, sterilizers, boilers) sold in the United States are designed to meet construction standards established by the American Society of Mechanical Engineers.⁵ Electrical safety design requirements for medical devices started in the United States with Underwriters Laboratory standards⁶ and today are coordinated with the International Standards Organization.⁷ In Canada, pressure vessel and electrical safety codes are coordinated by Health Canada, the department of the Canadian federal government responsible for helping Canadians maintain and improve their health.⁸

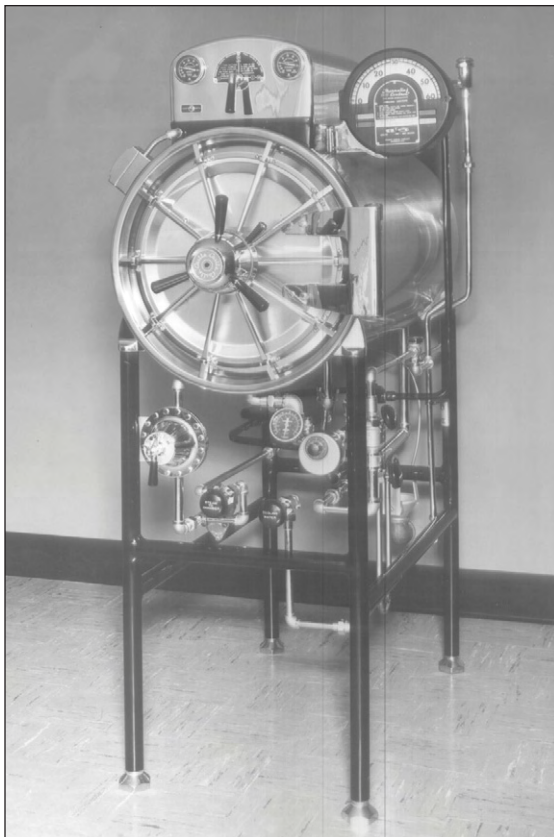


Figure 1 • A manual Wilmont Castle sterilizer, circa 1940.

STERILIZER DESIGN AND STANDARDIZED STERILIZATION CYCLES

Most perioperative nurses have seen a sterilizer in the sterile core area, in a substerile room, or in a central supply department. Many nurses, however, may not be familiar with the various components that make up the sterilizer. A sterilizer manufactured for health care facilities consists of the following major components:

- a pressure vessel mounted on a frame or stand;
- interior chamber-loading accessories for shelves or mobile load cars;
- an upper and lower piping package;
- a paneling package for the front (ie, the operator interface) and, if necessary, the side panels;
- an electronic control package;
- shipping materials; and
- a manufacturer's instruction manual.

DEVICE CLEARANCE. As class II devices, all sterilizers require a 510(k) predicate device clearance by the FDA before commercial distribution.⁹ The most important elements of the clearance process are cycle performance and related labeling claims for intended use instructions, such as flash cycles for nonporous items or vacuum cycles for either unwrapped or wrapped items.

DESIGN, CONSTRUCTION, AND CYCLE DEVELOPMENT. The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) have produced a steam sterilizer manufacturer's guidance document for design, construction, and cycle development.¹⁰ The *ANSI/AAMI ST8* outlines sterilization challenges for gravity displacement and dynamic air removal (ie, vacuum) sterilizers, including flash cycles for both. As mentioned earlier, gravity cycles displace the air inside the sterilizer as the steam pressure increases. A dynamic air removal cycle mechanically removes the air from the sterilizer and the load using both positive and negative pressure pulses during the preconditioning phase.

The *ANSI/AAMI ST8* defines several cycles typically used in health care facilities. These cycle types are described in user guidance documents such as AORN's recommended practices and the *ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility*

Gravity cycles displace the air inside the sterilizer as the steam pressure increases. Dynamic air removal cycles mechanically remove the air from the sterilizer and the load using both positive and negative pressure pulses during the preconditioning phase.

*Assurance in Healthcare Facilities.*¹¹ Gravity cycles can be used for wrapped and unwrapped items. There are two types of cycles for unwrapped items: the three-minute flash cycle for nonporous items (eg, solid metal) and the 10-minute flash cycle for porous items (eg, rubber, instruments with lumens); both cycles expose the items to temperatures between 270° F and 275° F (132.2° C and 135° C).

Wrapped items may be sterilized in a dynamic air removal cycle or a gravity cycle. Temperature in a dynamic air removal exposure cycle for wrapped items is 270° F (132.2° C) for an exposure time of four minutes or 275° F (135° C) for three minutes. The temperature for wrapped items in a gravity-displacement cycle may be 250° F (121.1° C) for an exposure time of 30 minutes, 270° F (132.2° C) for 15 minutes, or 275° F (135° C) for 10 minutes. All wrapped-goods cycles require a drying phase. Unwrapped items undergoing a flash cycle, on the other hand, are expected to be wet at the end of the cycle.

To achieve a sterility assurance level (SAL) of 10⁻⁶, each cycle is "challenged" with biological indicators at 50% of the user-recommended exposure time.¹⁰ Thus, the user recommended exposure time has a 100% safety factor built in (ie, the overkill method). All cycle development work measures the temperature at the drain (ie, the coldest point) for control with an additional temperature measurement capability

in the jacket. Temperatures measured at the drain during the exposure phase can be within 0.9° F (0.5° C) above the selected temperature.¹⁰ This control is maintained throughout the exposure phase when a series of steam solenoid valves to the jacket and to the chamber are opened and closed in the water supply and the drain valve at specific points during the cycle in an alternating fashion by a program in the software. Pressure measurements also are made but are primarily used for cycle transition points.

Monitoring the process includes using resistive temperature devices for chamber and jacket temperatures and a chamber pressure transducer. These devices require routine, design-specific calibration. Sterilizer manufacturers are required to validate the sterilizer's performance; therefore, replacement components should be the manufacturer's authorized parts. Not all solenoids are created equal, so adhering to this protocol maintains the approved labeling claims and prevents having an adulterated, unvalidated product.

Cycle development is accomplished in a laboratory environment, using multiple temperature-sensing wires (ie, thermocouples) inside the chamber and challenge loads to create a thermal mapping of the complete cycle (Figure 2). Typically, up to 24 thermocouple wires are fed into the chamber through a gland (ie, an opening in a gasket seal) or through the piping. When the data are acquired, a computer program turns the data into a cycle graph, illustrating temperature and pressures in color codes for easy viewing, evaluation, and comparison to previous graphs.

CHALLENGE LOADS. There are five basic challenge loads defined in the *ANSI/AAMI ST8*. These are the

- 16-towel fabric pack referred to as "the gold standard" for an air removal challenge;
- minimum 16-lb metal-mass load, although 25 lbs will be the future challenge;
- Bowie-Dick test;
- air-leak test for dynamic air removal cycles; and
- liquid load, which has been tested but is not recommended for health care facility practice.¹⁰

Each test is performed with biological indicators as well as chemical indicators. The 16-towel

fabric pack, when constructed as recommended, has a density of 11.3 lbs/cu ft. The towels must be freshly laundered, a certain size, and made of 100% cotton material. For dynamic air removal cycles, only one pack is included. It is placed over the chamber drain, either on chamber shelving or load equipment; using only one 16-towel fabric pack in a dynamic air removal cycle is the greater challenge because of the "small-load effect." For wrapped gravity cycles, a full load of test packs is tested.

For the instrument challenge, at least 16 lbs of metal instruments are placed in a wire-mesh instrument tray and wrapped with muslin, then placed in a fully loaded chamber with similarly wrapped instrument trays. The acceptance criteria include 100% biological indicator kill results at half the recommended exposure time.

At the completion of a wrapped cycle, there must be no visible signs of moisture. For the 16-towel fabric pack, the acceptance criterion for dryness is less than 3% weight gain of the pack. The acceptance criterion for the instrument challenge is a 20% weight gain of the cotton wicking towel placed under the metal load.

The purpose of the Bowie-Dick test is to measure air removal and steam penetration.



Figure 2 • Temperature-sensing wire is fed inside the chamber through a gasket gland.

Commercially available process challenge devices or freshly laundered cotton towels, folded and stacked as defined, are used for the Bowie-Dick test. "An indicator sheet is placed at the geometric center of the folded towels. When the towels are folded correctly for length, width, and height, the pack should weigh 8.8 lbs (4 kg) (+/- 5%)." ^{10(p19)} A standard Bowie-Dick challenge test cycle is run at 273° F (133.9° C) for 3.5 to four minutes of exposure time, with little or no dry time programmed. ¹¹

After the cycle, the test is evaluated for pass/fail results. Not all commercially available Bowie-Dick tests are created equally for pass/fail results. Some commercially available Bowie-Dick test packs meet the *ANSI/AAMI ST8* requirement of 1 mm Hg per minute (0.13 kilopascal [kPa]/0.019 pounds per square inch absolute [PSIA]) leak rate over a measured time period. Other Bowie-Dick test may not be designed to meet this requirement. ^{10(p23)}

The purpose of the air-leak test is to document how tight the pressure vessel is. Leaks into the chamber can be either air or steam. The air-leak test is performed during the drying phase under vacuum. After a defined vacuum depth (ie, pressure level) is achieved, all controls are turned off. The vacuum depth is measured at the beginning and at the end of the defined time period. The pressure level acceptance criterion as defined in the *ANSI/AAMI ST8* is a rate equal to or less than 1 mm Hg per minute (0.13 kPa/0.019 PSIA) over the defined time period, typically 15 minutes.

The design development and engineering phases are complete when the product design (ie, hardware) is documented and the software to operate the cycle has been validated. The next phase is the transfer to production. When the FDA clearance is granted, the new sterilizer may be introduced for marketing, sales, and commercial distribution. Each sterilizer produced must exactly match the released product design when it is shipped.

STERILIZATION CYCLES

The *ANSI/AAMI ST8* outlines the design criteria for safety, temperature tolerances, measurements, and cycle types but does not define the specific method for air removal. Individual ster-

ilizer manufacturers validate their own cycles through performance testing. Moist heat sterilization of heat stable items is more efficacious than low-temperature, heat-sensitive processes because saturated steam under pressure penetrates so well and is highly lethal to microorganisms. The key for steam sterilization is access to all surfaces and that the steam must be at least 97% dry steam with the remaining portion consisting of the moisture content. The presence of a little moisture is essential for process lethality. Too much moisture causes wet loads, but too little causes dry steam (ie, superheat) similar to the inside of a household oven. Dry-heat sterilization takes considerably longer to achieve conditions for sterilization than does saturated steam.

Sterilization cycles designed and validated by the sterilizer manufacturer follow the cycles defined in the *ANSI/AAMI ST8*. Pressure gauges and temperature displays are mounted on the front of the sterilizer. These gauges move up and down as the cycle progresses. After the cycle is complete, the individual removing the items from the sterilizer should review the printed cycle documentation for accuracy and appropriateness on the sterilizer printout by performing a visual check of the cycle selected (eg, Was the appropriate cycle selected? Did the cycle have successful time at the selected temperature?). Cycle graphs are an easy way to understand the various phases of both gravity and dynamic air removal cycles. Figures 3, 4, and 5 show a few typical generic graphs used daily in today's health care facilities.

FRACTIONATED CYCLES. During the last several years, use of the term fractionated cycles has appeared in medical device user instructions, especially from European companies that validate sterilization instructions using European-style health care steam sterilization cycles. ^{12,13} The theory behind the fractionated cycle is that air is removed while avoiding moisture creation inside lumens that could block steam penetration and surface contact. Current US steam sterilizers do not have vacuum cycles that perform a fractionated cycle. The major difference between European steam sterilization cycles and those currently cleared for the US market is the initial preconditioning phase

number of excellent resources, including ANSI/AAMI ST79¹¹ and AORN's "Recommended practices for sterilization in the perioperative practice setting"¹⁴ that should be the primary source documents for cleaning and sterilization policies and procedures. Cleaning and sterilization instructions from the medical device and sterilizer manufacturers also should be followed, especially for complex devices and those with instructions for extended exposure times. Perioperative personnel require education and ongoing training to maintain competency (eg, critical thinking skills on determining appropriate sterilization cycles depending on load content), which helps ensure positive patient outcomes.

The most important step in the sterilization process is cleaning—if the item is not clean, the sterilization phase may not be effective. The cleaning methodology practiced in the central supply department is the standard of care for the entire health care facility. Cleaning shortcuts used to meet quick turnaround requirements should be prevented and eliminated. Cleaning is defined in ANSI/AAMI ST79 as removing all visible soil and reducing particulate matter and the number of microorganisms and potential pyrogens.¹¹ When the item or items are clean, the next step is to prepare the items for packaging in a tray or container. The maximum weight limit recommended for instrument sets should not exceed 25 lbs, including the tray or container.¹¹

Selecting the right steam sterilization cycle involves making several choices within a decision tree (ie, algorithm) after the item or items are clean and packaged. Most wrapped or contained sets use vacuum cycles. Gravity displacement cycles for wrapped items or items in a container, though rare, may be used if specified by the device manufacturer. The ANSI/AAMI ST79 provides two minimal cycle time and temperature tables for gravity and for dynamic air removal cycles.^{11(p68,69)} Temperature ranges vary by the particular sterilizer manufacture, so perioperative nurses must follow the written manufacturer instructions. Typical exposure time for wrapped or contained vacuum cycles are four minutes at 270° F (132.2° C) or three minutes at 275° F (135° C).

When flash sterilization is required, it should not be used as a substitute for adequate instrumentation inventory. Furthermore, flash sterilization of implants is not recommended. Flash cycles are divided into two types: cycles for nonporous items (eg, solid metal) and cycles for porous items (eg, lumen items or rubber). Per ANSI/AAMI ST79, flash sterilization is defined as "a process designed for the steam sterilization of patient care items for immediate use"^{14(p668)} and can be either gravity displacement or dynamic air removal cycles. Gravity displacement exposure time for metal or nonporous items is three minutes at 270° F (132.2° C) to 275° F (135° C). For loads of metal items with lumens or porous items, the gravity displacement cycle exposure time is 10 minutes at 270° F (132.2° C) to 275° F (135° C). When the dynamic air removal cycle is used for flash sterilizing either porous or nonporous items, the exposure time is three minutes at 275° F (135° C) or four minutes at 270° F (132.2° C). Personnel should follow the sterilizer manufacturer's instructions for flash tray weight limitations.

At the end of the flash cycle, items are assumed to be wet, so a method to deliver the items aseptically to the sterile field for use is required. An operator's checklist to document each flash cycle should include at least the

- reason for the flash cycle,
- description of the item or items,
- patient's name for whom the item or items will be used,
- cycle type and selected parameters,
- verified printed cycle values,
- date and time, and
- operator's name.¹⁴

Monitoring sterilization processes should include the use of biological and chemical indicators and should be performed daily in accordance with recommended practices.

CONCLUSION

Today's steam sterilizer certainly is not your father's water heater. Sterilizers are sophisticated medical devices designed to generate precise conditions to achieve sterilization. The exposure time has a built-in safety factor to ensure an efficacious and lethal process. One of

the most critical factors in the sterilization process is the competency of the user. Following recommended practices for cleaning, wrapping or packaging items, and loading sterilizers increases the probability of successful outcomes. Delivery of a sterile item for use requires a well-designed sterilizer used by a knowledgeable operator who is educated in proper sterilization techniques. — **AORN** —

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Today's Sterilizer Is Not Your Father's Water Heater

PURPOSE/GOAL

To educate perioperative nurses about validated sterilizer design, performance, and cycle functions and how sterilization procedures improve patient outcomes.

BEHAVIORAL OBJECTIVES

After reading and studying the article on modern sterilizers, nurses will be able to

1. explain the steam sterilization process,
2. describe modern steam sterilizers, and
3. discuss challenge loads.

QUESTIONS

1. Steam sterilization is a _____ process; the steam vapor gives up its energy to heat the load to the selected temperature.
 - a. vaporizing
 - b. distilling
 - c. displacing
 - d. condensing
2. Sterilizers are regulated by the US Food and Drug Administration (FDA) as a class _____ medical device
 - a. I
 - b. II
 - c. III
 - d. IV
3. Compared to vacuum pumps used in early sterilizers, water ejectors
 1. are less noisy.
 2. are not as sensitive to water temperatures.
 3. consume smaller amounts of water.
 4. do not require a three-phase electrical connection.
 5. cost less to maintain.
 - a. 1 and 3
 - b. 2 and 4
 - c. 1, 2, 4, and 5
 - d. 1, 2, 3, 4, and 5
4. The most common type of stainless steel used to construct sterilizers today is 316L because it is easiest to mold into cylindrical and rectangular shapes.
 - a. true
 - b. false
5. Temperatures measured at the drain during the exposure phase can be within _____ above the selected temperature.
 - a. 0.9° F (0.5° C)
 - b. 1.8° F (1° C)
 - c. 2.7° F (1.5° C)
 - d. 3.6° F (2° C)
6. For the 16-towel pack challenge, the acceptance criteria for dryness is less than _____ weight gain of the pack.
 - a. 3%
 - b. 6%
 - c. 10%
 - d. 16%
7. The Bowie-Dick test
 1. is a commercially available process challenge device that consists of freshly laundered, folded, and stacked cotton towels.
 2. has an indicator sheet placed at the geometric center of the pack.
 3. is evaluated for pass/fail results.

4. is run at 273° F (133.9° C) for 3.5 to four minutes of exposure time.
5. measures air removal and steam penetration.
6. requires little or no dry time.
- a. 1, 3, and 5**
b. 2, 4, and 6
c. 1, 3, 4, 5, and 6
d. 1, 2, 3, 4, 5, and 6
8. The key for steam sterilization is that the steam must be at least _____ dry steam with the remaining portion consisting of the moisture content.
- a. 91%**
b. 93%
c. 95%
d. 97%
9. Dry-heat sterilization takes considerably longer to achieve conditions for sterilization than does saturated steam.
- a. true**
b. false
10. The most important step in the sterilization process is
- a. air removal.**
b. cleaning.
c. moisture content.
d. decontamination.
e. steam penetration.

The behavioral objectives and examination for this program were prepared by Rebecca Holm, RN, MSN, CNOR, with consultation from Susan Bakewell, RN, MS, BC, director, Center for Perioperative Education. Ms Holm and Ms Bakewell have no declared affiliations that could be perceived as potential conflicts of interest in publishing this article.

This program meets criteria for CNOR and CRNFA recertification, as well as other continuing education requirements.

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THIS EVALUATION is used to determine the extent to which this continuing education program met your learning needs. Rate these items on a scale of 1 to 5.

PURPOSE/GOAL

To educate perioperative nurses about validated sterilizer design, performance, and cycle functions and how sterilization procedures improve patient outcomes.

OBJECTIVES

To what extent were the following objectives of this continuing education program achieved?

1. Explain the steam sterilization process.
2. Describe modern steam sterilizers.
3. Discuss challenge loads.

CONTENT

To what extent

4. did this article increase your knowledge of the subject matter?
5. was the content clear and organized?
6. did this article facilitate learning?
7. were your individual objectives met?
8. Did the objectives relate to the overall purpose/goal?

TEST QUESTIONS/ANSWERS

To what extent

9. were they reflective of the content?
10. were they easy to understand?
11. did they address important points?

LEARNER INPUT

12. Will you be able to use the information from this article in your work setting?
 - a. yes
 - b. no
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<input type="checkbox"/>	1	2	3	4	5	6	7	8	9	0
<input type="checkbox"/>	1	2	3	4	5	6	7	8	9	0
<input type="checkbox"/>	1	2	3	4	5	6	7	8	9	0

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1	1	2	3	4	5	11	1	2	3	4	5
2	1	2	3	4	5	12	1	2	3	4	5
3	1	2	3	4	5	13	1	2	3	4	5
4	1	2	3	4	5	14	1	2	3	4	5
5	1	2	3	4	5	15	1	2	3	4	5
6	1	2	3	4	5	16	1	2	3	4	5
7	1	2	3	4	5	17	1	2	3	4	5
8	1	2	3	4	5	18	1	2	3	4	5
9	1	2	3	4	5	19	1	2	3	4	5
10	1	2	3	4	5	20	1	2	3	4	5

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- a. need for continuing education contact hours
- b. price
- c. subject matter relevant to current position
- d. number of continuing education contact hours offered

What other topics would you like to see addressed in a future continuing education article? Would you be interested or do you know someone who would be interested in writing an article on this topic?

Topic(s): _____

Author names and addresses: _____
