Competency Record for Sonic Cleaning

Name: ________________________________________________________

Competency Achieved: ________________________________ (Date)

Evaluator: ______________________________________________________

Learner: _________________________________________________________

Comments:______________________________________________________
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________________________________________________________________

Background information on sonic testing

ST 79; 2009A section 7.5.3.3 states this on weekly testing “…Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software…” Sonic cleaners are considered mechanical cleaning equipment by AAMI.

"Cleaning, not sterilization (or disinfection) is the first and most important step in any instrument processing protocol. Without first subjecting the instrument to a thorough, validated and standardized (and ideally automated) cleaning process, the likelihood that any disinfection or sterilization process will be effective is significantly reduced”.

The ultrasonic cleaning process cleans dirty surgical instruments so they can be handled safely, repackaged, and sterilized for a future surgery. The danger of handling instruments contaminated with blood is obvious in this age of hepatitis, CJD and HIV. The procedures for sterilizing instruments are based on years of scientific testing of cleaning instruments. If surgical instruments are not clean, the procedures are ineffective. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used.
An ultrasonic cleaner enables thorough cleaning of equipment by ultrasonic agitation that dislodges soil from instruments.

Ultrasonic cleaners do not disinfect instruments. They are used to assist with the cleaning of instruments that cannot be adequately cleaned manually such as spiral wound instruments like biopsy forceps.

Ultrasonic vibration at the frequency used for cleaning does not kill microorganisms and infective aerosols may be produced. It is for this reason that the lid of the tank must be tightly closed during operation.

Ultrasonic cleaners work by subjecting instruments to high frequency, high-energy sound waves. This causes the soil to be dislodged from instruments and drop to the bottom of the tank, or be sufficiently loosened that it will be removed during the rinsing process.

The detergent used in the ultrasonic tank must be carefully selected in accordance with advice from the tank's manufacturer. Optimally it will be a neutral, low-foaming product and enzymatic cleaners will have enhanced benefits in this process.

**Degassing of cleaning solutions is extremely important in achieving satisfactory cleaning results. Fresh solutions or solutions which have cooled must be degassed before proceeding with cleaning. Degassing is done after the chemical is added and is accomplished by operating the ultrasonic energy and raising the solution temperature. The time required for degassing varies considerably, based on tank capacity and solution temperature, and may range from several minutes for a small tank to an hour or more for a large tank. An unheated tank may require several hours to degas. Degassing is complete when small bubbles of gas cannot be seen rising to the surface of the liquid and a pattern of ripples can be seen.**

**Routine cleaning**
Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least daily or more frequently if solution soiled.

**Performance testing**
The efficacy of the ultrasonic cleaner should be tested at a minimum weekly and daily if possible. The results of the testing shall be documented as part of the proof of process.

Sonic cleaners fail for many reasons. Tests should provide a means of monitoring the variables that influence the effectiveness of the ultrasonic cleaning process. Some of these variables are water, time, detergent, enzyme,
temperature, high pH, agitation, speed, initial heat, drying, obstructions, and insufficient amount of chemicals and equipment failure.

Proper cleaning is critical. The SonoCheck™ test kit provides an independent objective test of clean and allows the Sterile Processing professional to monitor and ensure proper cleaning in the sonic process.

AAMI does list a sonic cleaner as a piece of medical equipment in section 7.5.3.3; there are other references that support the minimum of weekly testing of all type of sonic equipment with or without “retro flow pulse adapter”.

Section 10.2 and ANNEX D states “...Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices…”

Section 7.5.3.3 states “…Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software…”

The 2011 AORN RP for Cleaning and Care of Surgical Instruments and Powered Equipment Recommendation XXII –Quality section is now supporting the testing of mechanical instrument washers before initial use, weekly during service, and after major maintenance.

JCAHO in standard E.C.6.20 it states that medical equipment is maintained, tested and inspected

So in accordance with ANSI/AAMI ST79-2009; ANSI/AAMI TIR12-2005; JCAHO EC6.20-2005, and AORN, Healthmark recommends at least weekly monitoring of the cleaning efficacy of any sonic cleaning unit with the following verification tests:

- **Verification** of sufficient cavitation energy with the Sonocheck™ monitoring vials*. Designed to change color (blue to yellow) when the ultrasonic cleaner is supplying sufficient energy and conditions are correct (degassed water, temperature, etc.) the Sonocheck™ is an easy to use and interpret method for monitoring cavitation energy. Failure to change color indicates that either the sonic bath conditions were not correct, or a failure of one or more of the ultrasonic transducers.
JCAHO and AAMI both recommend that Sterile Processing department have process performance in place. Using the sonic check according to the manufacture’s guidelines helps ensure adherence to both JCAHO and AAMI standards and having a properly functioning cleaning process.
Competency Statement: Complies with policy and procedure for testing the

Key
1 = Performs independently and consistently. Ask for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

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<thead>
<tr>
<th>Critical Behaviors</th>
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<tr>
<td>Read manufactures manual for your specific sonic cleaner</td>
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<td>Completed / Attended the Self Study program supplied by the Vendor</td>
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<td>Describes the purpose of sonic cleaning at your facility</td>
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<td>Selects and wears the appropriate personal protective equipment</td>
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<td>Gather appropriate supplies to perform test on sonic cleaner</td>
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<td>Inspect sonic cleaner according to manufacture recommendations &amp; hospital policy (document results)</td>
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<tr>
<td>1. Prepare a bath of cleaning solution (water and detergent) in compliance with instructions for use by the sonic manufacturer and the detergent manufacturer.</td>
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<td>2. De-gas the bath in accordance with ultrasonic manufacturer's instructions.</td>
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<td>Insure that the bath is within the proper temperature range as provided by the detergent manufacturer</td>
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<td><strong>Make sure that the ultrasonic cleaner has been degassed prior to running the test.</strong></td>
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<tr>
<td>1. Select the appropriate number of SonoCheck™ vials and as shown below based on tank volume and choose the layout that matches the size of the equipment to be tested.</td>
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<td>2. Place the SonoCheck™ (s) as indicated below in an empty ultrasonic basket and place the basket in the ultrasonic cleaner that has been de-gassed.</td>
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<td>3. Run the equipment as directed by the ultrasonic manufacturer and record the test results on the “Log Sheet” located on hmark.com.</td>
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4. All SonoChecks™ should change from blue/green to yellow within specified time. The time needed for the color change will indicate the level of energy and degree of cavitation provided by the ultrasonic cleaner.
   - A negative result will indicate a blind spot of ultrasonic energy.

In case of an unsatisfactory result, refer to the SonoCheck™ troubleshooting guide.

Small tank = Up to 5 ltrs
Medium tank = 5 to 20 ltrs
Large = Above 20 ltrs

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<tr>
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- Understand that a color change from blue/green to yellow indicates presence of cavitation energy.
- Failure for color change to yellow indicates a failure to achieve sufficient cavitation energy to clean. Ultrasonic energy is localized and failure to achieve color change may indicate one or more sonic transducers are failing.

Record all results in a log

Report any unsatisfactory results to the proper management for corrective action according to the policy of your facility.