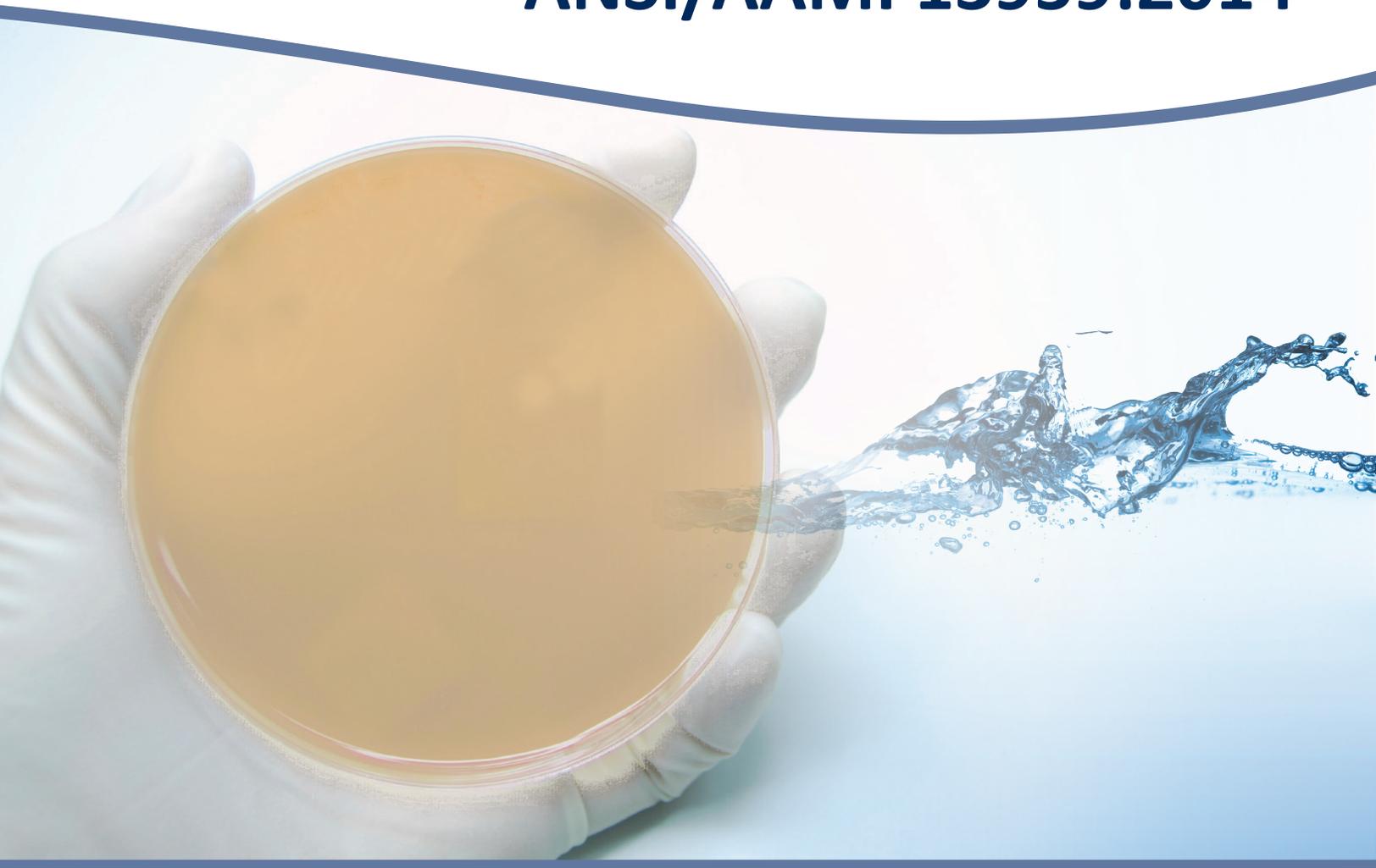


New **AAMI** Water Quality Standard for Hemodialysis

ANSI/AAMI 13959:2014



We See the Future Of Dialysis Water... **Today**

ANSI/AAMI 13959:2014

A New Water Quality Standard for Better Patient Outcomes

The recent adoption of higher standards by AAMI means the quality of water used in dialysis treatment will increase. The new standard has 2 important aspects to it. First, acceptable microbiological levels have been reduced by more than 50%, as noted in the chart below. Second, the testing protocol used to determine bacteria levels is a much more sensitive cultivation technique yet includes a deviation to allow for other test methods. The net result is that existing water system designs may or may not consistently produce water that meets the new standards.

AAMI Microbiological Standards for Dialysis Water

Microbiological Level	Previous Standards	New Standards	Previous Action Level	New Action Level
Colony Forming Units	< 200 CFU/mL	< 100 CFU/mL	≥ 50 CFU/mL	≥ 50 CFU/mL
Endotoxin Units	< 2 EU/mL	< 0.25 EU/mL	≥ 1 EU/mL	≥ 0.125 EU/mL





Microbiological Testing Procedure

In an effort to harmonize procedures for measuring microbiological levels in dialysis water, AAMI adopted the ISO standards back in 2009, but has since incorporated a deviation to those standards that ISO was unwilling to agree upon. As a result, AAMI issued their own 2014 Standards with alternative methods for microbiological testing, causing it to be the only deviation from the ISO Hemodialysis Standards. The specific ISO culture methods are still part of the AAMI Standard thereby allowing for a more precise cultivation technique that procedural provides growth conditions which favor microorganisms that thrive in water.

There are 3 main elements of these procedures: Agar Medium, Incubation Temperatures and Incubation Time. In many cases, the clinic does not perform the procedure but sends the samples to a certified laboratory for processing. Laboratories will need to be instructed as to the clinics stated method of testing.

The first culture method incorporates the ISO Standard. Here the two acceptable **Agar Mediums** are Tryptone Glucose Extract Agar (TGEA) or Reasoner's 2A supplemented with 4% sodium bicarbonate, or equivalent. Blood or chocolate agar are listed as unacceptable and are not be used. **Incubation Temperatures** that mirror actual water environment are normally between 15-25°C, not at the current 35°C. Therefore this standard requires the temperature to be maintained between 17°C to 23°C. In order to give the microorganisms time to develop, it has been determined that a longer **Incubation Time** of 168 hours (7 days) provides an accurate indication of viable bacteria, which is a change from the 48 hours at 35°C.

The second culture method that AAMI specifically adds into the 2014 Standard calls for **Agar Mediums** Trypticase Soy Agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE). These are to be stored at **Incubation Temperatures** of 35°C for 48 hours of **Incubation Time** prior to assaying.

Both ISO and AAMI still include wording that indicates other comparative and validated test methods may also be used.

Results: The more strict cultivation conditions simulate dialysis water environment and have been demonstrated to produce higher levels of bacteria as compared to previous conditions. Although higher levels of bacteria are expected, some testing has shown little difference between the old and new conditions. However, the deviation within AAMI allows for a quicker response time should results be outside acceptable parameters.

ANSI/AAMI 13959:2014 Water Quality Standard

What Can You Do?

For existing water systems, you should perform testing using the latest standard to ensure that your water system is producing water that meets the new requirements. As a result, you may need to increase the disinfection frequency, or add additional filtration or a combination of both in order to meet the new standard. Mar Cor Purification can help you evaluate the options.

For those considering new water systems, the use of heat for daily disinfection of the water distribution loop has been proven to be a state of the art design to minimize bacteria growth. The CWP central and WRO 300 H portable Reverse Osmosis Systems are designed for daily heat disinfection. The use of endotoxin retentive filters can also provide a level of safety for the water system.

If you have any questions about the latest AAMI Standards or what can be done to improve your water system's compliance to the standard, a Mar Cor Purification representative is available to help. Mar Cor Purification will be happy to meet with you to review your existing water system and to discuss options for any future water system design. Call us at 1-800-633-3080 or visit us on the web at www.mcpur.com.

Mar Cor Purification Medical Products & Services



Medical Water Systems

Mar Cor Purification is one of the largest and most experienced water purification suppliers to the Medical/Hemodialysis market. Mar Cor Purification has the largest equipment and service offerings and provides complete, installed, medical device registered water systems throughout North America. Each system is serviced from one of our nationwide service offices, which are stocked with critical medical device spare parts.



Medical Water Products

Mar Cor Purification offers a wide variety of medical water products and services, in addition to water systems, to ensure that hemodialysis clinics and their employees have the equipment, products, information, and service to effectively provide their patients with the highest quality water available. From product support, to essential parts, to ongoing education, We have the resources to keep your water treatment system and clinic running smoothly.



Medical Water Services

Mar Cor Purification is one of the largest and most experienced water purification companies in North America. We have been servicing medical water treatment equipment for over 40 years and have an experienced nationwide team of technicians qualified to work on your medical water systems. We have a service office within 100 miles of over 70% of the U.S. Medical customers.



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