



Technical Home Evaluation

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Objectives



Understand the Home Technical Regulations



Learn what is required when evaluating an environment for HHD Equipment



Understand potential mitigation options



Explore common Questions and Issues

What Standards are we dealing with?



CMS Regulations



AAMI Standards

RD52 Annex C
AAMI ISO 23500



Manufacturer Instructions for Use



Other New Requirements (NDAC)

V597

- (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

V581

- A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

V589

- To assess a patient's home dialysis environment, a home visit should be conducted at the initiation of home therapy and whenever a problem is identified with either patient health or equipment that could be related to treatment at home. Periodic routine replacement of equipment would not necessarily require a home visit be scheduled. The interdisciplinary team may designate the most appropriate staff member(s) to make the home visit(s).

V593

- The facility home training staff must conduct on-site evaluations of the home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. There should be evidence the source water to be used meets the minimum requirements specified by the manufacturer of the water treatment components or of the integrated system, if such is in use. If the source water requirements are not met, there must be adequate pre-treatment of the source water to meet those requirements. Each home water treatment system must include either an RO or a DI treatment component or alternate technology that achieves AAMI standards, and a method to remove chlorine/chloramines.

V593

- The home patient's record must include review and acknowledgement of any problems with the source water, and a monitoring schedule for the source water. The patient's physician should demonstrate awareness of any issues with the source water, and the plan of care should address any issues with source water for the home HD patient

V593

- The home evaluation should address the storage of supplies, including dialysate concentrate(s). The storage area should provide a year-round environment that meets the manufacturer's recommendations for the storage of supplies.

V594

- testing of the water and dialysate system in accordance with—
- (A) The recommendations specified in the manufacturers' instructions; and
- (B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.

V594

- A chemical analysis of the product water must be done at the start of home treatment and at least once a year near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other than the replacement of disposable components), to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded

V595

- C.3.2 Drain If the home has a septic tank, the septic tank should be able to process the volume of water from a drain [that is one inch or larger in diameter]. It may not be possible to perform nocturnal hemodialysis in a home with a septic tank since this tank may not be able to support the volume of water delivered to it over an extended period (8 hours). Another possible limitation is that the septic system will be exposed to disinfectant chemicals (bleach, peracetic acid, hydrogen peroxide, etc.) which may kill the bacteria needed for the septic tank to function.

V595

- The facility home hemodialysis staff should be familiar with the recommendations in ANSI/AAMI RD52 Annex C, and the facility policies, procedures and practice must reflect those applicable to the home hemodialysis systems in use.

V595

- Records of results of chemical and microbial testing of home hemodialysis water and dialysate should be available in the home setting and at the dialysis facility providing support; the log of these results may be included the patient's medical record or in a separate record.

Evaluating the Home



Key Components of a Technical Home Assessment

- Utilities
 - Water Supply
 - Drain
 - Power
- Environment
- Equipment Selection

ANSI/AAMI RD52:2004, Dialysate for hemodialyzers ; Amendment 1—Annex C: Special considerations for home hemodialysis



Water Supply/Quality



Water Pressure

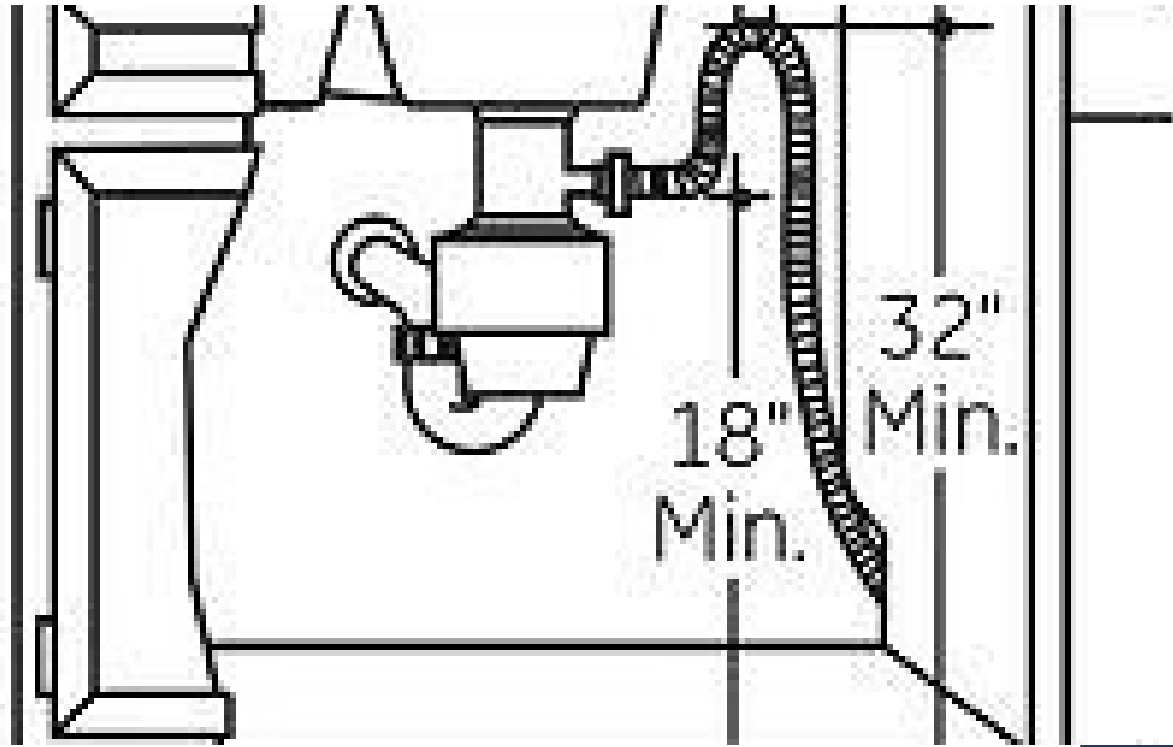


Instructions for Use

	2018 AAMI Standard Limits	Units	11/7/2018	
			Results	Diff.
Aluminum	0 - 0.01	mg/L	0.338	NA
Antimony	0 - 0.006	mg/L	<0.005	NA
Arsenic	0 - 0.005	mg/L	<0.002	NA
Barium	0 - 0.1	mg/L	0.031	NA
Beryllium	0 - 0.0004	mg/L	<0.0004	NA
Cadmium	0 - 0.001	mg/L	<0.0010	NA
Calcium	0 - 2	mg/L	19.01	NA
Chromium	0 - 0.014	mg/L	<0.005	NA
Copper	0 - 0.1	mg/L	<0.005	NA
Fluoride	0 - 0.2	mg/L	0.8	NA
Lead	0 - 0.005	mg/L	<0.002	NA
Magnesium	0 - 4	mg/L	1.624	NA
Mercury	0 - 0.0002	mg/L	<0.0002	NA
Nitrate	0 - 2	mg/L	<0.20	NA
Potassium	0 - 8	mg/L	3.847	NA
Selenium	0 - 0.09	mg/L	<0.005	NA
Silver	0 - 0.005	mg/L	<0.003	NA
Sodium	0 - 70	mg/L	25.999	NA
Sulfate	0 - 100	mg/L	14.3	NA
Thallium	0 - 0.002	mg/L	<0.002	NA
Zinc	0 - 0.1	mg/L	<0.005	NA

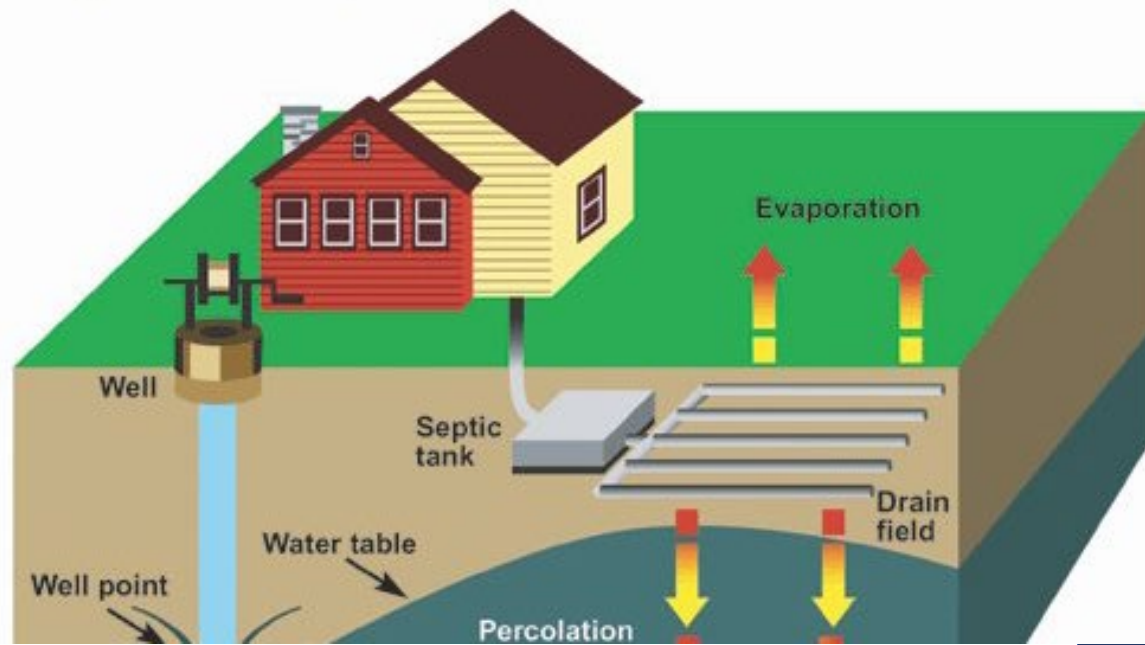
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Thallium	0 - 0.002	mg/L	<0.002	NA
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Contaminant	Source Water (mg/L)
Aluminum	0.2
Chloramines	4.0
Free Chlorine	4.0
Total Chlorine	4.0
Copper	1.3
Fluoride	4.0
Lead	0.015
Nitrates (as N)	10
Sulfate	250
Zinc	5
Calcium	No Limit
Magnesium	No Limit
Potassium	No Limit
Sodium	No Limit
Antimony	0.006
Arsenic	0.01
Barium	2
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Mercury	0.002
Selenium	0.05
Silver	0.1
Thallium	0.002



Drains

Septic effluent percolates to the water table



Septic



Electrical



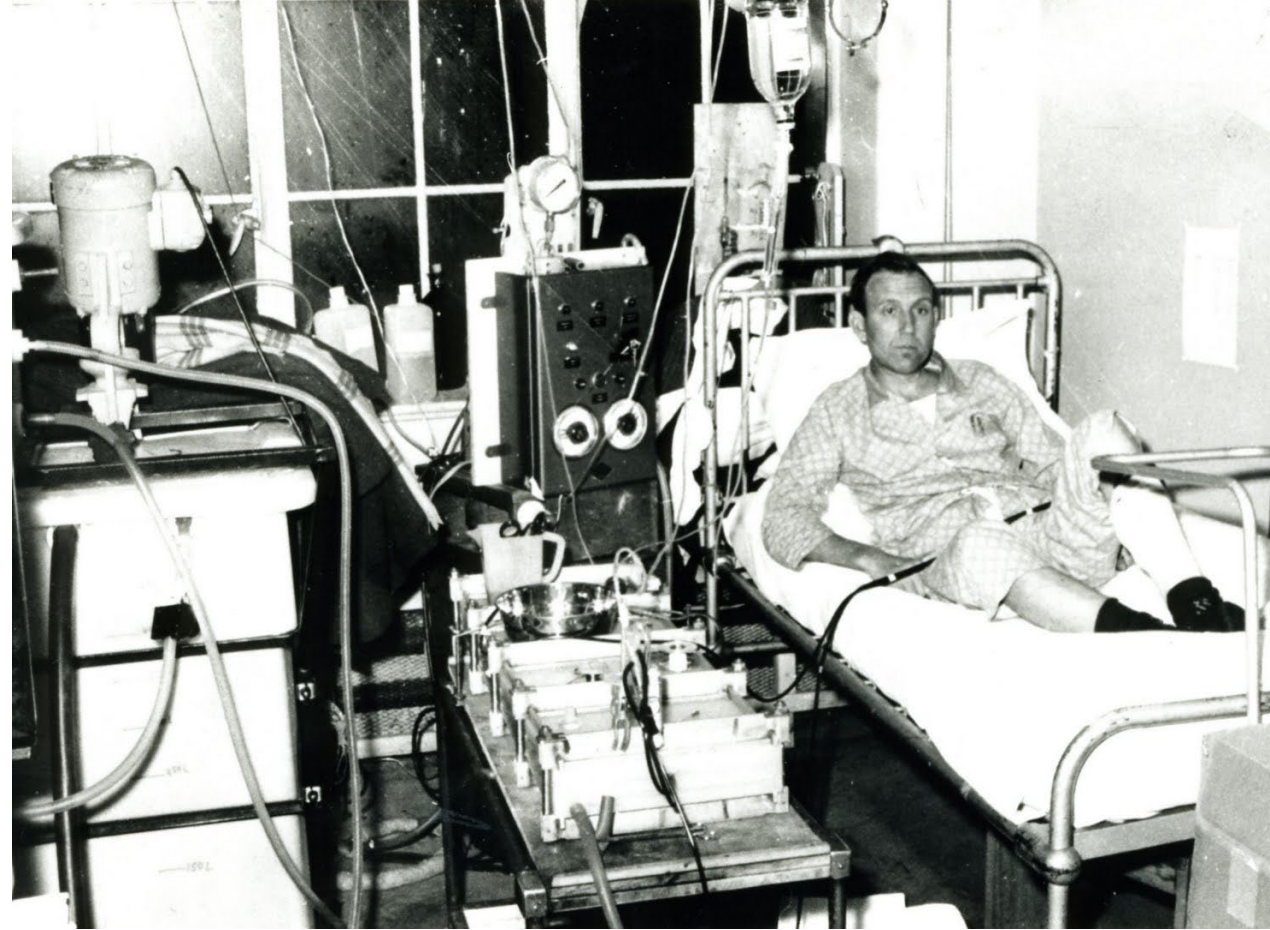








Environment



Treatment Area



Equipment Selection

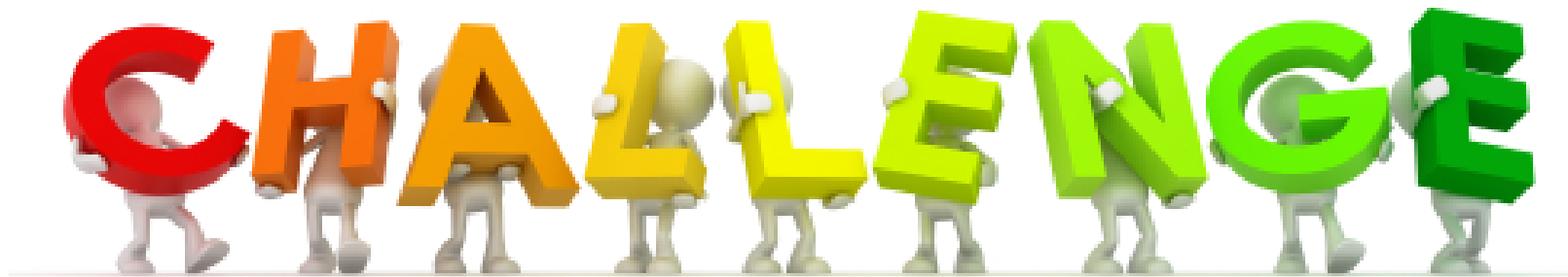


Important to Remember

- Assess the home before you select the equipment
- Report findings to the Team
- Form a plan to execute needed modifications
- Use the expert for the task at hand
- Don't be afraid to STOP if needed



Common



Challenge #1

- A technical home assessment was performed at Mr. Smiths home. During the assessment, you noted the following concerns:
 - The patient has a Well and Septic system
 - The Patient's electrical panel is full and does not have room for more outlets

Challenge #2

- The Home Nurse calls the biomedical Technician and states that Mr. Jones has been training in the center and plans to go home next week. They need the home to be ready for Mr. Jones and his water system and dialysis machine by the end of this week.

Challenge #3

- A water analysis from the source (feed) water for the training facility came back and shows high levels of Nitrates above safe drinking water standards.

Questions?

