Disclaimer

Healthcare facilities are required to have written policies approved by their governing body concerning the services that they provide.

NxStage Medical, Inc. has prepared this document to assist you in your preparation of policies and procedures for use with the NxStage System One. The information presented herein is intended as a guide for reference purposes only, and all providers are encouraged to modify these draft policies and procedures based on their own unique needs.

Warnings and precautions, as documented in the NxStage System One™ and/or PureFlow™ User Guides, have not been included in the attached Policies and Procedures. Operators of the equipment should refer to both Policies and Procedures and the User Guides. We encourage providers to include warnings and precautions into their approved Policies and Procedures in a manner consistent with facility protocol.

Efforts have been made to ensure that these policies are based on current information. However, policies and procedures are the responsibility of the healthcare facility and therefore must be reviewed and edited carefully before incorporating into an individual facility's program.

Policy Number: 4
Effective Date:
Reviewed/Revised Date

Water and Dialysate Evaluation and Testing

Guidelines for PureFlow SL in Transitional Care

Purpose:
To provide guidelines for testing, evaluating, and monitoring the quality of water and dialysate used by the hemodialysis patient using PureFlow SL with the NxStage System One (known to CMS as preconfigured system) for compliance with the CMS Conditions for Coverage.
Policy:
Water and dialysate testing and documentation will meet NxStage, CMS, and AAMI standards and guidelines. Documentation of testing, results, and interventions will be maintained at the dialysis center.

TAG#	Sample	Frequency	Test Performed
V593/ V594	Source water: Municipal	Initially to verify source water is within range for the use of PureFlow SL.	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 4), Section 10: Specifications for Source Water Purity Limits.
V594/ V276	Product water	Initially: Test first PAK used near the estimated end of PAK life. Annually: Test near the estimated end of PAK life. No other testing is required, such as at a PAK change or with a Control Unit service swap.	Chemical analysis of the standard AAMI test panel contaminates to ensure AAMI specifications are met.
V595	Product water	Each batch, prior to use of the batch.	Analysis of chlorine/chloramines levels to ensure the AAMI and manufacturer's specifications are met.
V595	Dialysate	Quarterly: Test within the first month of use, near the estimated end of a batch.	Bacteriological and endotoxin analysis to ensure AAMI specifications are met.

Testing Overview

***NxStage technical clarification**:*

- Water quality can be confirmed for all new PureFlow SL patients by performing a standard AAMI test panel then comparing each contaminate level to the corresponding PureFlow SL User Guide Section 10: Specifications for Source Water Purity Limits.
- Source water pressure must be between 20 - 80 psi or 20 to 120 psi with a Pressure Regulator.
- Source water flow must be at least 150ml/min or greater.
- Results of source water may be recorded on Water and Dialysate Testing Log (TM0427) available from NxStage Home Hemodialysis NxDocuments/Forms.

TAG#	Regulation	Interpretive Guidance
V593/ V594 / V276 Product water	Monitoring of the quality of water and dialysate used by hemodialysis patients and testing of the water and dialysate system in accordance with: (A) The recommendations specified in the manufacturer's 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/chloramines testing) water and dialysate.	A chemical analysis of the product water must be done at the start of PureFlow SL 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. When any repairs are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if indicated. Chlorine/chloramine levels must be tested prior to the start of each treatment (or before use of each new batch of dialysate) in accordance with AAMI guidance and manufacturer's recommendations. For batch systems (integrated systems which prepare enough dialysate for multiple treatment), the chlorine/chloramines testing shall be performed at the worst case scenario, i.e. after the preparation of each batch of dialysate, but before use of that batch, from a testing port that meets manufacturer's specifications to be in compliance with the requirements of AAMI.

***NxStage technical clarification**:*

- Draw initial product water near the estimated end of the first PAK life.
- Draw annual product water near the estimated end of PAK life.
- Modifications: NxStage will notify user when modifications are made to the system if additional testing of product water for chemical analysis should be performed.
- Repairs: No non-NxStage "field repairs" are supported by NxStage. Routine service swap of Control Unit provides new or remanufactured equipment following FDA approved Good Manufacturing Practices. Complete self-tests on every PAK and batch ensures proper function of PFSL or the equipment will stop in fail safe condition. Any individual variations in control pressures or flow rate have no impact on water purity.
- New PAK: Testing is NOT required after installing and priming a new PAK.
- Control Unit Swap: Testing is NOT required after changing the PFSL Control Unit hardware.
- Sufficient volume of product water: PFSL dispenses product water from the Conductivity Line of the SAK for initial and repeat chlorine/chloramines testing. The system will automatically go to drain when the operator indicates that the chlorine/chloramines testing has failed. The product water used for testing chlorine/chloramines represents the "worst case scenario" as the samples are representative of the last product water entering the batch.

Documentation:

- Documentation of product water testing and dialysate sampling may be recorded on the NxStage System One Hemodialysis Flowsheet (TM0196).
- Results of product water and dialysate testing may be recorded on Water and Dialysate Testing Log (TM0427).

TAG#	Regulation	Interpretive Guidance
V595 Dialysate	The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.	The result of water and dialysate testing for hemodialysis patients may be included in the patients' medical records or in separate logs. According to AAMI, a log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility

NxStage technical clarification:

- Follow appropriate retesting and retraining procedures in response to any positive test results.
- Dialysate culture should be drawn near the estimated end of SAK life from a sterile connector.
- Dialysate bacteriology testing does NOT need to be tested before starting treatment.
- Testing may begin near the end of SAK life.

Documentation:

- Clinicians may record chlorine/chloramines testing results on the (Sample) NxStage System One Hemodialysis Flowsheet (TM196).
- Clinicians may record water and dialysate sampling on the (Sample) NxStage System One Hemodialysis Flowsheet (TM0196).
- Results of water and dialysate testing may be recorded on the Water and Dialysate Testing Log (TM0427).

References:

CMS 42 CFR Parts 494 Conditions for Coverage for End-Stage Renal Disease Facilities and related CMS ESRD Program Interpretive Guidance (October 3, 2008)
Dialysate Preparation Primer Chronic Hemodialysis with the NxStage PureFlow SL
PureFlow SL User's Guide
AAMI/FDS-RD52:2004/A1 Dialysate for Hemodialysis, Amendment 1- Annex C; Special Considerations for Home Hemodialysis