Developing a QC/QA Program for

Water Purification and Distribution

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The goal and focus of any health care provider is to do no harm. Delivering the highest quality of care possible is a key element in achieving this goal. But what is quality? In the hemodialysis treatment environment, where standardization has yet to be achieved in procedures, practices, equipment, staff qualifications, and job descriptions, the definition of quality may not be universal, but delivering the best care possible often depends on the level to which we are able to "quantify quality."

In the context of water purification and distribution systems for hemodialysis, what is universally accepted is this: developing and adopting activities that regularly assess compliance, collect and document data, and establish goals and parameters that sustain positive outcomes will provide a high level of assurance and confidence that systems are in place to produce safe and high quality water for dialysis use.

Quality assurance and quality control measures for dialysis water treatment refer to the activities directed toward ensuring that the water to be used during the course of treatment and in related applications can consistently meet the parameters, standards, and recommended practices established by authorities, manufacturers, and industry.

Quality control (QC) can be defined as the mechanisms established to measure non-conforming method performance. Actual performance is measured, it is compared to predefined goals, and the difference is acted upon. Essentially, QC refers to the routine technical activities the purpose of which is error control. Quality assurance (QA) refers to the overall management system that includes the organization, planning, data collection, quality control, documentation, evaluation, and reporting activities of the program. Quality assurance can be viewed as the system used to verify that the entire analytical process is operating within acceptable limits. It is intended to guarantee or ensure quality.

Individuals responsible for the maintenance, repair, and continual monitoring of dialysis water treatment systems are varied in skill, knowledge, accountability, and responsibilities. A technician performing the daily water checks one day may be performing a different task, such as reprocessing or clinical care, the next day. Also, the subject of water treatment in dialysis is an area that is sometimes neglected or inadequately presented in the training curriculum of dialysis technicians. Therefore, it is imperative that the quality control structure for a dialysis facility is designed to be a comprehensive, simple template that accommodates the skill, competency, and knowledge level of the varied individuals assigned the responsibility of water systems surveillance.

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Risk-Based Approach to QA/QC

Hazard identification and risk assessment are essential for understanding the vulnerability of the water treatment system and in planning effective risk management strategies to ensure water quality and safety. Hazard refers to a source of (potential) harm to the functioning of the water system. Risk refers to the chance or possibility of a hazard causing this harm to the functioning of any aspect of the water system (1).

All potential hazards and hazardous events should be included and documented regardless of whether they are under direct control of the facility. Once the potential hazards and their causes have been identified, the level or risk associated with each hazard must be estimated so that priorities for action can be established and documented. Also, identifying the priority hazards and risks will aid in the development of policy and procedures, which form the necessary tools for surveillance and training for staff. Some examples of typical hazardous events and causes are:

- Variations in potable water quality
- Seasonal variations
- Improper water treatment design
- Inadequate backwash or regeneration cycles
- Inadequate disinfection
- Failure of alarms and monitoring equipment
- Inadequate operational monitoring
- Biofilm
- Improper loop and holding tank design
- Chlorine/chloramine breakthrough
- Equipment malfunction
- Natural disaster

Standards

Quality must demonstrate and reflect the operational integrity of critical components and critical functions. The quality expected is achievable by applying standards that direct and determine explicit methods, parameters, and outcomes. Standards, therefore, can define quality (2). Ideally, a standard is a formal, written policy and set of procedures, performed by qualified individuals using proper equipment, that adheres to current, acceptable levels of practice. It should be presented in a form that is easily understood by those who are expected to conform to it, and it should also conform to appropriate and authoritative references (i.e., AAMI).

In the development of policy and procedure, the practical approach is to organize the document in such a structure with content that it is comprehensive, detailed, and easy to follow.

- Comprehensive: the document should include rationales, background information, and references to specific recommended practices (i.e., AAMI RD52).
- Detailed: the procedures should include all specific items necessary to accomplish the procedure.
- Easily followed: the rule is that the policy and procedure should be written so that an individual not knowledgeable in the subject can understand and follow the written policy and procedure.

Renal Technology Department Quality Management Report
Period Covered: January 2005

Technology Aspect	Item	Expected Outcome	Jan/Feb/Mar Results	Apr/May/June Results	Jul/Aug/Sep Results	Oct/Nov/Dec Results
Medical Device and Equipment Safety (MDE)	1. Bicarb central delivery disinfected weekly.	**100%**	100%			
	2. Acid concentrate/bicarb lot # documented at time of use	**100%**	100%			
	3. Medical device problem or (trend not to exceed 3x in 3 mos.)	**No Trend**	0			
Equipment Maintenance and Electrical Safety (EMS)	1. E.S. performed every 12 mos.	**100%**	100%			
	2. P.M. is current	**100%**	15/16 94%			
Water System (WS)	1. Water cultures within AAMI standard	**100%**	41/41 100%			
	2. Water analysis within AAMI standard	**100%**	100%			
	3. R.O. System disinfect quarterly/PRN	**100%**	1/16			
	4. R.O. check performed daily	**100%**	100%			
Dialyzer	1. Blood leak incidents	**No Trend**	0			

Period covered	Analysis/Evaluation	Action/Improvement Plan/Goal Date/ Individual Responsible:
QTR Summary	(EMS1) Annual Safety inspection performed this month on in-center and home hemo and P.D. equipment. (EMS2) 16 machines due maintenance. Machine #208 due and pulled in January. P.M. performed on 2/03/05; 3 days delinquent, but pulled from service on time. (WS4) Granville City Water engineer M. Walker notified the facility of increasing the feed water chloramine level to 2.5 mg/L at point of use.	(EMS1) Next scheduled safety inspection 1/2006. (EMS2) No action required. Machine was not in use until P.M. completed. (WS4) No action required; continued surveillance.
Miscellaneous:		

Table 1. *Sample QM report.*

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Documentation for Technical Activities

The daily technical activities for water treatment can differ from facility to facility, even within an LDO. The individuals performing the daily technical activities can also differ from day to day. The rotation of staff, the level of experience, and background of the individuals involved can complicate the activity of error control. Quality control documentation should be developed in a manner in which measured actual performance and non-conforming performance can easily be compared with goals and expected values, regardless of the diversity of the individuals performing the technical activity. The documentation should include all the facts necessary to immediately recognize non-conformance at the point of measurement.

"The physician in charge of dialysis has the ultimate responsibility for selecting a water treatment system and maintaining the performance of that system once it has been installed and its performance has been verified" (3). The physician must be included and participate in evaluating and verifying that the technical activity of quality control is maintaining safe and quality outcome. As an anecdotal example, I review the quality control records on a weekly basis. I perform and submit a monthly summary of technical activities to my medical director. We meet and review the summary of the monthly activities for his approval and signature. (See Table 1.)

In summary, the practical guidance for developing a QC/QA program is to identify the hazards and risk, develop a program that accommodates the diversity of staff, and, finally, establish a method that is simple, comprehensive, and immediately identifies non-conformance. ■

References

1. **Environmental Protection Branch, Saskatchewan Environment.** Quality Assurance and Quality Control for Water Treatment, May 2003, EFB 242.
2. **Katz, Jacqueline M.** Managing Quality: A Guide to System-wide Performance, Mosby-Year Book, Inc, 1997.
3. **AAMI.** ANSI/AAMI RD62:2001. Water treatment equipment for hemodialysis applications.