



Guideline on water treatment facilities, dialysis water and dialysis fluid quality for haemodialysis and related therapies

Clinical Practice Guideline by the UK Renal Association and Association of Renal Technologists

Nic Hoenich^{1,2}, Clinical Scientist, Newcastle University

Robert Mactier¹, Consultant Nephrologist/Lead Clinician, NHS Greater Glasgow & Clyde

Gerard Boyle², Senior Renal Technologist, St George's Healthcare NHS Trust, London

Maurice Harrington², Senior Renal Technologist, Salford Royal NHS Foundation Trust

Elizabeth Lindley^{1,2}, Clinical Scientist, Leeds Teaching Hospitals NHS Trust

Ian Morgan², Senior Renal Technologist, King's College Hospital NHS Foundation Trust

Paul Rylance¹, Consultant Nephrologist, Royal Wolverhampton Hospitals NHS Trust and Patient Safety Lead for the Renal Association

Donal O'Donoghue^{1,3}, Consultant Nephrologist, Salford Royal NHS Foundation Trust and National Clinical Director

¹ Renal Association (RA)

² Association of Renal Technologists (ART)

³ Department of Health

Contents

Introduction

Summary of clinical practice guideline on water treatment facilities, dialysis water and dialysis fluid quality for haemodialysis and related therapies

- 1. Clinical governance of water treatment facilities for haemodialysis**
(Guidelines 1.1-1.3)
- 2. Planning and commissioning of water treatment facilities for haemodialysis** (Guidelines 2.1-2.3)
- 3. Installation and validation of water treatment facilities for haemodialysis**
(Guideline 3.1)
- 4. Operation and maintenance of water treatment facilities for haemodialysis** (Guidelines 4.1 – 4.4)
- 5. Monitoring the quality of product water for haemodialysis and dialysis fluids** (Guidelines 5.1 – 5.5)
- 6. Water treatment facilities for home haemodialysis** (Guidelines 6.1 – 6.4)

Rationale of clinical practice guideline on water treatment facilities, dialysis water and dialysis fluid quality for haemodialysis and related therapies

- 1. Clinical governance of water treatment facilities for haemodialysis**
(Guidelines 1.1-1.3)
- 2. Planning and commissioning of water treatment facilities for haemodialysis** (Guidelines 2.1-2.3)
- 3. Installation and validation of water treatment facilities for haemodialysis**
(Guideline 3.1)
- 4. Operation and maintenance of water treatment facilities for haemodialysis** (Guidelines 4.1 – 4.4)
- 5. Monitoring the quality of product water for haemodialysis and dialysis fluids** (Guidelines 5.1 – 5.5)
- 6. Water treatment facilities for home haemodialysis** (Guidelines 6.1 – 6.4)

Introduction

Water of the appropriate quality used in the preparation of dialysis fluid is an essential requirement of haemodialysis and related therapies. International standards have been developed to promote the installation of fit for purpose water treatment facilities for haemodialysis and to safeguard the routine production of dialysis water suitable for use for haemodialysis and haemodiafiltration.

Quality requirements for the water and concentrates used to prepare dialysis fluid, and for dialysis fluid, are provided in BS ISO 13959; 2009: *Water for haemodialysis and related therapies*, BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies*, and BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* ⁽¹⁻³⁾. In addition the requirements for water treatment equipment are provided in BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies* ⁽⁴⁾. BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis* addresses the quality management of the water treatment system and distribution loop within the renal unit ⁽⁵⁾. Copies of these International Standards may either be purchased at the BSI Online Shop at <http://shop.bsigroup.com/> or can be accessed via subscription to British Standards Online (BSOL) at <http://shop.bsigroup.com/en/Navigate-by/BSOL/>

The rationale for the development of these standards is to protect haemodialysis patients from adverse effects arising from known chemical and microbiological contaminants found in water and improperly prepared dialysis fluid. However, in spite of the availability of standards, there have been instances of failure to achieve the requirements of the standards, particularly in new build renal units where the responsibility for the water treatment plant operation and monitoring lies outside NHS remit and is provided either by external contractors under a private finance initiative (PFI) or by an equivalent scheme. Under these schemes, responsibility for the delivery of infrastructure and services (such as maintenance) required to provide a public service is transferred to a third party in the private sector.

The recommendations in this guideline have been graded using the modified GRADE system whenever appropriate ^(6,7). In addition for clarity and consistency the terminology used in this guideline has been standardised with the BS ISO standards as follows:

“shall” means that compliance with a requirement or a test is mandatory for compliance with the International Standards;

“should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with the International Standards; and

“may” is used to describe a permissible way to achieve compliance with a requirement or test.

“feed water” is used throughout this guideline to mean water supplied to a water treatment system or an individual component of a water treatment system. Synonyms such as raw water, supply water or potable water may be used instead of feed water.

“product water” is used throughout this guideline to mean water produced by a water treatment system or an individual component of a water treatment system. Synonyms such as permeate, treated water, purified water or reverse osmosis water may be used instead of product water. However the use of this terminology does not specify any limits, and consequently the International Standards introduced the term dialysis water.

“dialysis water” is used throughout this guideline to mean water that has been treated to meet the specified limits for chemical and microbial contaminants in BS ISO 13959;2009 and is suitable for use in haemodialysis applications, which include the preparation of dialysis fluid, reprocessing of dialysers, preparation of concentrates and preparation of substitution fluid for online convective therapies

“dialysis fluid” is used throughout this guideline to mean the fluid made from dialysis water and concentrates that is delivered to the dialyser by the dialysis fluid delivery system. Synonyms such as dialysate or dialysis solution may be used in place of dialysis fluid.

This guideline incorporates and updates the section on water quality and water treatment for haemodialysis in the haemodialysis module of the 5th edition of the Renal Association Clinical Practice Guidelines⁽⁸⁾. The guidance has been harmonised with the previous guideline on this topic from the European Renal Association whenever possible⁽⁹⁾ and also links with guidance from the Department of Health on the requirements for water supplies to healthcare facilities⁽¹⁰⁾.

The main aim of this guideline is to assist the entire multidisciplinary team involved in the provision of safe water treatment for haemodialysis by providing a single, user friendly document for the routine delivery of fit for purpose dialysis water and dialysis fluid, which has been peer reviewed and approved by the membership of the Association of Renal Technologists and Renal Association and other stakeholders. This guideline takes account of feedback from two cycles of peer review arising from publication of the first and final drafts on the future guidelines page of the Renal Association website at <http://www.renal.org>

The final version was discussed during an e-Web Seminar on 6th October 2011, which was organised by NHS Kidney Care and was linked to a session of the 2011 annual meeting of the Association of Renal Technologists.

The second aim of this guideline is to reduce adverse events in the planning, installation, operation and maintenance of water treatment facilities in the UK, which have been reported in recent years (Appendix 1) and may cause risks to patients. This is highly relevant at present as approximately 50% of the water treatment facilities for haemodialysis in the UK are at least 10 years old and so are due for refurbishment or replacement. It is NOT intended to replace the national standards and the interpretive guidance MUST be read in conjunction with the appropriate International Standards⁽¹⁻⁵⁾.

The layout of this guideline follows the chronological order on how a water treatment facility for haemodialysis should be planned, designed, installed and validated, operated and maintained, and routinely monitored (Sections 1-5). The final section deals with the special circumstances of providing water treatment for home haemodialysis (Section 6).

References

1. BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,
2. BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*
3. BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies*,
4. BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*
5. BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*
6. Uhlig K, MacLeod A, Craig J et al. Grading evidence and recommendations for clinical practice guidelines in nephrology. A position statement from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int* 2006; 70:2058-2065
7. Atkins D, Best D, Briss PA et al; GRADE Working Group. Grading quality of evidence and strength of recommendations. *BMJ* 2004; 328:1490.
8. *Nephron Clin Pract* 2011;118 (Suppl.1):c1-c390
<http://content.karger.com/ProdukteDB/produkte.asp?Aktion=Ausgabe&Ausgabe=255298&ProduktNr=228539>
9. European Best Practice Guidelines for haemodialysis Part 1. Section IV. Dialysis fluid purity. *Nephrol Dial Transplant* 2002; 17: Supplement 7 S45-S46
http://ndt.oupjournals.org/content/vol17/suppl_7/index.shtml
10. Department of Health guidance on water for healthcare facilities (in press)

Summary of clinical practice guideline on water treatment facilities, dialysis water and dialysis fluid quality for haemodialysis and related therapies

1. Clinical governance of water treatment facilities for haemodialysis

Guideline 1.1 – Designation of water treatment facilities as patient equipment

We recommend that water treatment facilities for haemodialysis are designated as patient-connected equipment. (not graded)

Guideline 1.2 – Responsibility for clinical governance

We recommend that the senior clinician in charge of the renal unit (or designated deputy) has responsibility for the overall clinical governance of the water treatment facility. (1C)

Guideline 1.3 – Responsibility for planning of new or replacement water treatment facilities

We recommend that the clinician (or designated deputy) with responsibility for clinical governance is involved throughout the planning, designation and installation of a new or replacement water treatment facility for haemodialysis. (1C)

2. Planning and commissioning of water treatment facilities for haemodialysis

Guideline 2.1 - Specification of the feed water supply for haemodialysis

We recommend that new build renal units should have a direct feed (drinking or potable) water supply separate from that of the hospital water supply. If existing water treatment systems use a hospital water supply there should be awareness of the potential risks that may arise from the introduction of chemicals into the hospital water supply by hospital engineering staff. To prevent the occurrence of adverse effects arising from such actions the introduction or addition of chemicals into the hospital water supply should not be undertaken without prior consultation with renal services. (1C)

Guideline 2.2 - Setting the design specification for the water treatment infrastructure

Guideline 2.2.1 – Specification of the maximum allowable limits for microbiological contaminants in water produced in new water treatment facilities

We recommend that all new water treatment infrastructures when used with a rigorous proactive sanitisation strategy shall be capable of producing water with concentrations of microbial contaminants and endotoxin < 0.1 CFU/mL and < 0.03EU/mL, respectively. (1D)

Guideline 2.2.2 - Design specification of the water treatment system for haemodialysis

We recommend that the complete water treatment, storage and distribution system shall meet the requirements of all of the following standards: (1B)

BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,

BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*,

BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*.

BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*

Guideline 2.3 – Haemodialysis facilities

Guideline 2.3.1 – Satellite haemodialysis facility

We recommend that the specification for a new or refurbished satellite haemodialysis facility should adhere to the guidelines that are described in Health Building Note 07-01 Satellite Dialysis Unit (2008). (not graded)

Guideline 2.3.2 – Main renal unit haemodialysis facility

We recommend that the specification for a new or refurbished main renal unit haemodialysis facility should adhere to the guidelines that are described in Health Building Note 07-02 Main Renal Unit (2008). (not graded)

3. Installation and validation of water treatment facilities for haemodialysis

Guideline 3.1 – Installation and validation of a water treatment facility for haemodialysis

We recommend that each stage of the installation, performance validation and initial, performance and operational qualification should be agreed and documented in advance and signed off by the manufacturer and the clinician responsible for water quality (or designated deputy). (1C)

4. Operation and maintenance of water treatment facilities for haemodialysis

Guideline 4.1 – Routine maintenance and monitoring of water treatment facilities

We recommend that the maintenance and monitoring plans for the water treatment plant be established using the knowledge acquired during the complete validation process for the water treatment system in accordance with BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis*. Policies and procedures should be set up to ensure that routine maintenance and monitoring are mandatory and are implemented at the earliest opportunity. (1B)

Guideline 4.2 – Operators of water treatment facilities for haemodialysis

Guideline 4.2.1 – Training of operators of the water treatment facility

We recommend that operators should be trained in the use of the water treatment facility by the manufacturer or their UK distributor. The training should be specific to the functions performed. Competence with procedures should be assessed and documented. Periodic audits of the operators' compliance with procedures should be undertaken and documented and there should be an ongoing training programme to maintain the operator's knowledge and skills. (1C)

Guideline 4.2.2 – Continuing education and development of operators of water treatment facilities

We suggest that national organisations, such as the Association of Renal Technologists, should participate in the continuing education and development of operators of water treatment facilities by arranging training sessions at annual meetings and/or co-ordinating regular training days. (2D)

Guideline 4.3 - Monitoring of feed, product and dialysis water for haemodialysis

Guideline 4.3.1 – Routine testing of feed, product and dialysis water for haemodialysis

We recommend that routine testing procedures for water for dialysis should form part of the renal unit policy. Each water treatment facility should have standard operating procedures in place for sampling, monitoring and recording of feed and product water quality. (1C)

Guideline 4.3.2 – Frequency of monitoring of product and dialysis water for haemodialysis

We recommend that the minimum frequency of monitoring of water for dialysis should be as follows (1D):

Contaminant	Frequency of testing
Total chlorine	At least weekly
Total viable counts	At least monthly
Endotoxin	At least monthly
Chemical contaminants other than chlorine	At least every 3 months

Considerable daily as well as seasonal variations in the chlorine and chloramine levels of the water entering the water treatment plant (feed water) are known to exist and therefore the guidance to test weekly for chlorine/chloramine at least weekly should be regarded as an absolute minimum. If practical and feasible, testing for chlorine or chloramine on a daily or shift basis is recommended. It is however recognised that such an approach may place an undue burden on staff and, if it can be demonstrated that the chlorine levels in the feed water are consistently low (<0.5 mg/L) and chloramines are not used, then weekly monitoring of the dialysis water is sufficient. However, if chloramines are used and the level of chlorine in the feed water exceeds 1.0 mg/L, daily or shift based monitoring should be adopted.

Guideline 4.3.3 – Records of monitoring of product and dialysis water for haemodialysis

We recommend that records should be kept of all chemical and microbiological test results and remedial actions. If the interval between sample testing exceeds those indicated in the Table in 4.3.2, documentation should be in place to demonstrate that the sampling schedule used has been based on trend analysis. The operating procedures should include details of the procedures to be followed if the prescribed limits are exceeded. (1C)

Guideline 4.4 – Mutual responsibilities of water supply companies and renal units

We recommend that renal units shall inform the water supply companies of the location of all home haemodialysis patients as well as haemodialysis units so that the water companies are empowered to inform the renal unit of changes in feed water delivery to the patient’s home in terms of supply and composition. The water companies should also advise the renal unit if there are plans to alter the range of chemicals added to the water supply to ensure compliance with the drinking water directive. (not graded)

5. Monitoring the quality of product water for haemodialysis and dialysis fluids

Guideline 5.1: Chemical contaminants in product water used for the preparation of dialysis fluid

We recommend that the concentrations of chemical contaminants in product water used to prepare dialysis fluid shall not exceed the limits stated in BS ISO 13959; 2009: *Water for haemodialysis and related therapies*. A programme of improvement should begin immediately if routine monitoring demonstrates that concentrations of chemical contaminants exceed the maximum allowable limits. (1B)

Guideline 5.2: Microbiological contaminants in product water used for the preparation of dialysis fluid

Guideline 5.2.1 – Maximum allowable concentrations of microbiological contaminants in product water used for the preparation of dialysis fluid

We recommend that the quality of water produced by the water treatment facility shall meet the concentration limits for microbiological contaminants detailed in BS ISO 13959:2009. This states that dialysis water shall contain a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml. If routine monitoring demonstrates microbiological contaminant levels in excess of 50% of the maximum permitted levels a programme of corrective measures should be commenced immediately. (1B)

Dialysis water containing a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml is also the starting point in the production of ultrapure dialysis fluid or for on-line infusion fluid used in haemodiafiltration. To meet the appropriate requirements, the dialysis fluid will require further filtration by ultrafilters incorporated in the dialysis machine. Testing of replacement fluid for on-line haemodiafiltration is difficult and it is more important to check that quality assurance procedures are in place for monitoring filter integrity.

Guideline 5.2.2 – Methods of measuring microbiological contaminants in product water used for the preparation of dialysis fluid

We recommend that the test procedures used for monitoring microbial contamination of water for dialysis be standardised and appropriate to the type of organisms found in water. The test procedures should be adhered to stringently. (1C)

Guideline 5.3 - Preparation and composition of dialysis fluid

Dialysis fluid is produced by the mixing of dialysis water with acid and bicarbonate concentrates and the microbiological contaminant levels for acid and bicarbonate concentrates are defined in BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies*. For dialysis fluid thus produced, or if non bicarbonate buffered or modified bicarbonate buffered dialysis fluid is used, we recommend that the microbiological contaminant levels of the dialysis fluid should not exceed those cited in BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*. (1B)

Guideline 5.4 - Quality of dialysis fluid

We recommend that dialysis fluid production uses dialysis water produced by compliance with the requirements of BS ISO 13959; 2009: *Water for haemodialysis and related therapies*. The dialysis fluid thus produced should additionally comply with the requirements of BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*.

Standard dialysis fluid is considered as the minimum quality, ultrapure dialysis fluid is recommended for routine haemodialysis and ultrapure dialysis fluid is mandatory for creating on-line prepared substitution fluid used in convective therapies such as on-line haemodiafiltration. The process used for the production of on-line prepared substitution fluid shall be validated to produce fluid that is sterile and non-pyrogenic. (1B)

Guideline 5.5 - Responsibility for policies for monitoring and recording of quality of dialysis water and dialysis fluid

We recommend that the senior renal technologist shall be the person responsible for ensuring concordance with policies for monitoring and recording of the quality of dialysis water and dialysis fluid. If this person is absent from work, procedures shall be in place to ensure continuance of policies. (not graded)

6. Water treatment facilities for home haemodialysis

Guideline 6.1 – Maintenance of the water and power supply

We recommend that the utility companies providing water and power to the patient's home be notified that home dialysis is being performed, and that they have details of patients' addresses on their risk

register to ensure that patients are notified of any proposed interruption of supply and that restoration of supply is a priority. (not graded)

Guideline 6.2 – Training of the patient and/or helper

We recommend that the patient and/or helper in the home should be formally trained in the correct operation and maintenance of the water treatment equipment by an appropriately trained technologist. There should be a record of the training, and the patient and /or helper should keep a log of the maintenance and monitoring procedures. (not graded)

Guideline 6.3 – Home haemodialysis installations

We recommend that all installations for home haemodialysis should include carbon filters/beds with built in redundancy, heat disinfection, portable reverse osmosis and point of use ultrafiltration. (1C)

Guideline 6.4 – Frequency of monitoring of feed and product water used for home haemodialysis

Guideline 6.4.1 – Frequency of monitoring of feed water used for home haemodialysis

We recommend that feed water from a private well should be tested for chemical and microbial quality at least every six months whereas the chemical and microbial quality of feed water from municipal suppliers should be assessed annually using data obtained from the supplier. (1C)

Guideline 6.4.2 – Frequency of monitoring of product water used for the preparation of dialysis fluid for home haemodialysis

We recommend that the chemical and microbial quality of the water used for the preparation of dialysis fluid for home haemodialysis should be monitored at least every six months. (1C)

Rationale of clinical practice guideline on water treatment facilities, dialysis water and dialysis fluid quality for haemodialysis and related therapies

1. Clinical governance of water treatment facilities for haemodialysis

Guideline 1.1 – Designation of water treatment facilities as patient equipment

We recommend that water treatment facilities for haemodialysis are designated as patient-connected equipment (not graded)

Guideline 1.2 – Responsibility for clinical governance

We recommend that the senior clinician in charge of the renal unit (or designated deputy) has responsibility for the overall clinical governance of the water treatment facility. (1C)

Guideline 1.3 – Responsibility for planning of new or replacement water treatment facilities

We recommend that the clinician (or designated deputy) with responsibility for clinical governance is involved throughout the planning, designation and installation of a new or replacement water treatment facility for haemodialysis. (1C)

Rationale for 1.1-1.3

The water treatment facilities for haemodialysis and related therapies should be designated as patient-connected equipment to ensure compliance with the regulations and standards which have been established for such equipment. This safeguard also highlights that the ultimate responsibility for clinical governance for the water treatment facility should rest with the clinical director of the renal unit or a designated deputy, since they are responsible for the clinical care of the patient ⁽¹⁾. The clinician in charge of the renal unit may appoint a deputy, who may be a senior renal technology specialist or a consultant renal specialist, to take responsibility for the water treatment facility and act as line manager for clinical governance.

In the current NHS infrastructure the users and operators of water treatment facilities for haemodialysis may not be the same, for example in a renal unit funded through PFI or an equivalent scheme the operator of the water treatment plant may be an external contractor whilst the user is the renal service. In other instances, the operation of the water plant may be by members of the renal services technical staff or NHS estates staff. Irrespective of the structure, there should be clear lines of communication established between the nephrologist, who is ultimately responsible for the clinical care of the patient, and internal or external staff responsible for the operation and maintenance of the equipment. Good record keeping in association with robust lines of communication should also exist between senior renal unit personnel and those who undertake the monitoring and maintenance of the water equipment plant to ensure that there is a timely transfer of information. The MHRA has produced guidance on managing medical devices to outline a systematic approach to the purchasing, deployment, maintenance, repair and disposal of medical devices ⁽²⁾ and concordance with this guideline should ensure that the maintenance and monitoring of water treatment facilities for haemodialysis are performed by the equivalent of NHS renal technologists who have a full understanding of theory/maintenance of water treatment for haemodialysis.

Given that the senior clinician and/or technologist will have responsibility for clinical governance of the water treatment facility it is essential that they are closely involved at each stage of the planning, designation, installation and validation of new or replacement water treatment facilities for haemodialysis ⁽¹⁾. Commissioners and contractors of new build or refurbished water treatment facilities should liaise with an ART approved, NHS employed, renal technologist who has the scope of practice to give advice on the specification, selection process and installation of the new water treatment facility.

References

1. ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*
2. Managing Medical Devices. Guidance for healthcare and social services organisations, MHRA DB2006(05), November 2006

2. Planning and commissioning of water treatment facilities for haemodialysis

Guideline 2.1 - Specification of the feed water supply for haemodialysis

We recommend that new build renal units should have a direct feed (drinking or potable) water supply separate from that of the hospital water supply. If existing water treatment systems use a hospital water supply there should be awareness of the potential risks that may arise from the introduction of chemicals into the hospital water supply by hospital engineering staff. To prevent the occurrence of adverse effects arising from such actions the introduction or addition of chemicals into the hospital water supply should not be undertaken without prior consultation with renal services. (1C)

Rationale

Individual components used in the water treatment infrastructure can vary due to feed water quality and product water requirements. The technical features of the water treatment component of that system should be based on the criteria detailed in ISO 26722. In addition to the general specifications outlined the system design should also comply with local building and water regulations. If the feed water is from a private well, an annual analysis of the quality of the product water may not be sufficient to ensure that the treatment system will remove all of the contaminants present and a more frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks or agricultural waste and chemicals. Such monitoring may not need to be the full chemical analysis if only certain contaminants are known to be of concern.

Recently there have been episodes of contamination of water used for haemodialysis arising from the chemical disinfection of hospital water supplies to minimize the presence of Legionella as the chemicals used are not effectively removed by the water treatment plants in renal units. A separate water supply to the renal unit is preferred as this will minimize the risk of adverse events from inadvertent contamination of the hospital water supply by such chemicals.

Guideline 2.2 - Setting the design specification for the water treatment infrastructure

Guideline 2.2.1 – Specification of the maximum allowable limits for microbiological contaminants in water produced in new water treatment facilities

We recommend that all new water treatment infrastructures when used with a rigorous proactive sanitisation strategy shall be capable of producing water with concentrations of microbial contaminants and endotoxin < 0.1 CFU/mL and < 0.03EU/mL, respectively. (1D)

Guideline 2.2.2 - Design specification of the water treatment system for haemodialysis

We recommend that the complete water treatment, storage and distribution system shall meet the requirements of all of the following standards: (1B)

BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,

BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*,

BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*.

BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*

Rationale

In drawing up the initial design specification providers and users are encouraged to obtain detailed descriptions of all treatment processes used by the water utility, together with the operating manuals and maintenance procedures from the manufacturer or the vendor providing the water purification and distribution system to permit informed decisions to be made.

The design specification of new water treatment facilities for haemodialysis should refer to and meet all of the BS ISO standards ⁽¹⁻⁴⁾.

Commissioners should state clearly in the contract specification for tenderers, suppliers and manufacturers of a new or refurbished water treatment facility that the water treatment facility shall comply with the requirements of BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*, which when combined with a rigorous and proactive sanitisation strategy shall be capable of producing water with concentrations of microbial contaminants and endotoxin of < 0.1 CFU/mL and < 0.03EU/mL respectively. The chain of logic for recommending a higher pre-specification than needs to be delivered routinely is:

- a) The above specifications for high quality product water are readily achievable by modern water treatment facilities (personal communication with units in the UK). Penne EL et al reported that monthly microbiological monitoring of a range of water treatment facility infrastructures in Holland using a proactive sanitisation program revealed that the product water had <0.1 CFU/ml in 567 of 685 (82.8%) samples and < 0.03 EU/mL in 653 of 663 (98.5%) samples ⁽⁵⁾
- b) The product water from high specification water treatment facilities should only infrequently exceed the maximum allowable concentration limits for microbiological contaminants of < 100 CFU/ml and endotoxin concentration < 0.25 EU/ml required in BS ISO 13959:2009. In such facilities Penne EL reported that only 6 of 685 (0.9%) samples breached 100 CFU/ml and 2 of 663 (0.03%) samples exceeded 0.03 EU/mL.
- c) The routine delivery of high quality product water into the water distribution system should reduce the risk of the growth of biofilm. Prevention of the development of biofilm facilitates the operation and maintenance of the water distribution system and should extend the time before replacement is required.
- d) This approach highlights the need for a rigorous proactive sanitisation strategy as well as appropriately configured water treatment facilities.
- e) Routine production of high quality product water should be an additional safeguard to the use of point of use filtration in the preparation of ultrapure dialysis fluid from product water and concentrates. Manufacturers of point of use filtration guarantee the production of ultrapure dialysis fluid as long as the product has less than the maximum allowable levels of microbiological contaminants listed in ISO 13959 and the ultrafilters are used according to the manufacturers' instructions.
- f) The use of ultrapure dialysis fluid is associated with a range of clinical benefits ⁽⁶⁻⁹⁾. Its use for haemodialysis has been associated in the short term with lower indices of inflammatory response (serum CRP and IL-6), in the medium term with better preservation of residual renal function, nutritional status and correction of anaemia and in the longer term may reduce the risk of complications due to dialysis-related amyloidosis. Although the clinical benefits of ultrapure dialysis fluid have not been established in a large scale randomized trial it would seem prudent to ensure that water is as pure as reasonably possible.
- g) The European Best Practice Guideline recommends the use of ultrapure dialysis fluid for all haemodialysis treatments ⁽¹⁰⁾.

At the planning stage, the following should also be considered:

- ***Product water capacity during sanitization***
If heat sanitization is planned for the system, the distribution loop is sanitized along with the links from the distribution loop to the dialysis machines. The demand for water during such sanitization is higher than required by the dialysis machines during operation.
- ***Product water capacity during the winter months.***
Commonly, reverse osmosis systems capacity is rated at a specified incoming water temperature. There should be awareness that such temperatures may not be achieved during the winter months, and the efficiency of the system will fall. To meet the required water demand there may be a need to pre heat the feed water or to install a plant with increased capacity to compensate for the fall in reverse osmosis efficiency during the winter months.
- ***Sanitization of the system***
Integrated heat sanitization of the distribution system and the haemodialysis machines is recommended as this method can be performed regularly with less disruption to dialysis schedules than chemical sanitization. If chemical sanitization is to be used, the period of down time should be sufficient to enable the chemicals to be rinsed completely from the system prior to the commencement of the next dialysis shift.

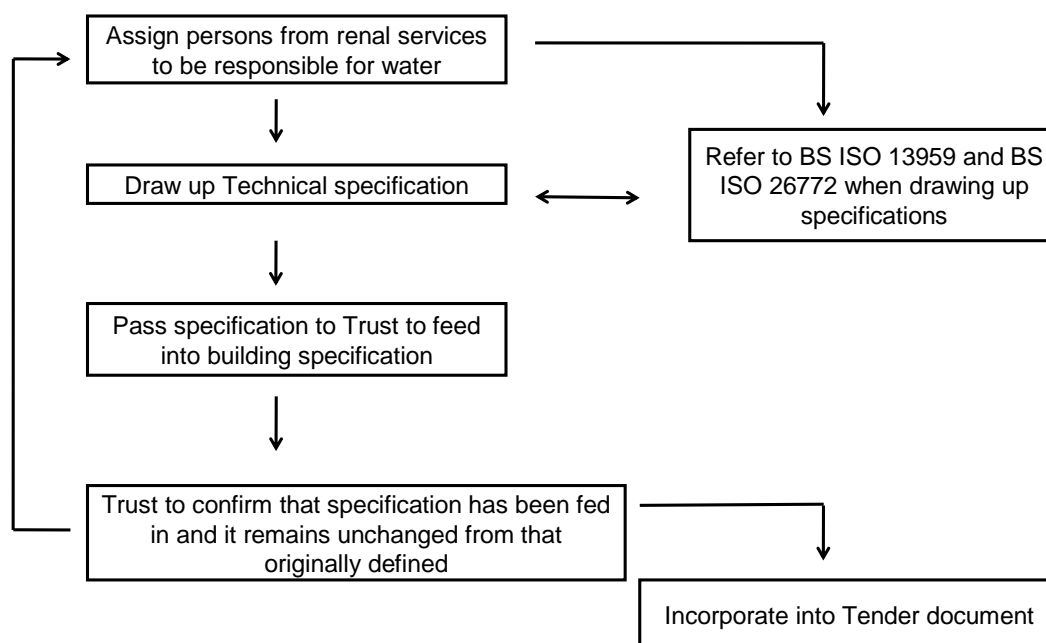
If it is possible to sanitize the haemodialysis machines at the same time as the distribution ring, then this should be done as this is the easiest and simplest. It may be that the system size will not permit all of the machines to be sanitized at the same time or the dialysis schedules will not allow all to be done at the same time. If this is the case then the renal service should endeavour to arrange the fitting of a dead space loop, which can be fitted to any machine but may require adaptation of the distribution point at the wall.

- ***Compliance with BS ISO 13958; 2009: Concentrates for haemodialysis and related therapies*** Compliance is only necessary if the hospital/renal unit is producing its own concentrates. If the concentrate is purchased from a commercial supplier they will have already complied with this requirement.
- ***Central concentrate delivery system***
The installation of a central concentrate delivery system should be considered in new water treatment facilities to reduce waste associated with the use of point of use concentrate containers.
- ***Connectors for untreated water outlets within the dialysis area***
Whenever possible untreated water outlets in dialysis areas should be disabled. If the presence of untreated water outlets in the dialysis area cannot be avoided, steps should be taken to ensure that it is not possible to connect the water inlet of a dialysis machine to an untreated water outlet. The provision of potable water outlets for supplying single patient water treatment systems may occasionally be necessary due to capacity issues or the requirement for emergency dialysis during routine maintenance of the water treatment plant or distribution system. In such circumstances the connectors should permit a water treatment system but not the haemodialysis machine to be connected to the potable water outlet.
- ***Contingency plans in the event of system failure or malfunction.***
Contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply or electrical service following a natural disaster or water main break. Planning should also address how to deal with sudden changes in municipal water quality.

The layout of the water treatment system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance. Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, when used should be configured to sound in the patient treatment area as well as in the water treatment room.

Figure 1 summarises the planning of the design specification of a new water treatment facility for haemodialysis.

Planning



References

1. BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,
2. BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*
3. BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*
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10. European Best Practice Guidelines for haemodialysis Part 1. Section IV. Dialysis fluid purity. *Nephrol Dial Transplant* 2002; 17: Supplement 7 S45-S46
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Guideline 2.3 – Haemodialysis facilities

Guideline 2.3.1

We recommend that the specification for a new or refurbished satellite haemodialysis facility should adhere to the guidelines that are described in the NHS Estates Health Building Note 07-01 Satellite Dialysis Unit (2004). (not graded)

Guideline 2.3.2

We recommend that the specification of a new or refurbished main renal unit HD facility should adhere to the guidelines that are described in the NHS Estates Health Building Note 07-02 Main Renal Unit. (not graded)

Rationale

The need for high quality water treatment facilities for haemodialysis is highlighted in the recent WHO guidance on water safety in buildings. ⁽¹⁾ Water treatment facilities installed in all new and refurbished satellite and main renal unit HD facilities should be integrated within the specification that is required for a modern haemodialysis unit which has been outlined in the National Service Framework for Renal Services ⁽²⁾ and documented in detail in Health Building Notes 07-01 and 07-02 for satellite and main renal units respectively, published by the Department of Health ^(3,4).

There has been need for guidance on the detailed specification of water treatment facilities as well as the building of haemodialysis units ^(3,4) so that the dialysis water is fit for purpose for modern haemodialysis therapies (haemodiafiltration and high flux haemodialysis). There have been a number of instances of water treatment facilities failing to meet the users' specifications after installation leading to delayed use of the facility, clinical risk and financial penalties (Appendix 1). Concordance with all three sections of guidelines 1 and 2 in this document will improve corporate governance and should reduce the risk of installing below standard water treatment facilities in future.

References

1. Water safety in buildings. WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland, March 2011. http://whqlibdoc.who.int/publications/2011/9789241548106_eng.pdf
2. The National Service Framework for Renal Services Part 1: Dialysis and Transplantation, Department of Health, London, UK, January 2004. (www.doh.gov.uk/nsf/renal/index.htm)
3. Renal Care. Health Building Note 07-01: Satellite Dialysis Unit. ISBN 9780113228140, Department of Health, 2008
4. Renal Care. Health Building Note 07-02: Main Renal Unit. ISBN 9780113228119, Department of Health, 2008

3. Installation and validation of water treatment facilities for haemodialysis

Guideline 3.1 – Installation and validation of a water treatment facility for haemodialysis

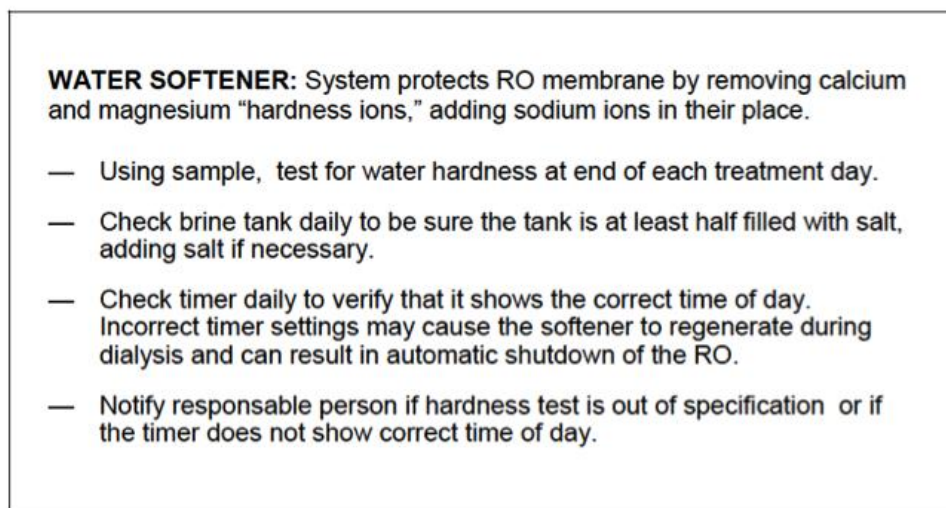
We recommend that each stage of the installation, performance validation and initial, performance and operational qualification should be agreed and documented in advance and signed off by the manufacturer and the clinician responsible for water quality (or designated deputy). (1C)

Rationale for the 6 sequential stages of guideline 3.1

3.1.1 Installation

The installation of the water treatment infrastructure should be by qualified personnel in line with the manufacturer's recommendations. On completion schematic diagrams that identify components, valves, sample ports, and flow direction should be available and the system appropriately marked. Major water system components should be marked in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

Figure 2 shows an example of the type of labelling which is required for each component of the water treatment system to describe how each component is tested and its action limits.

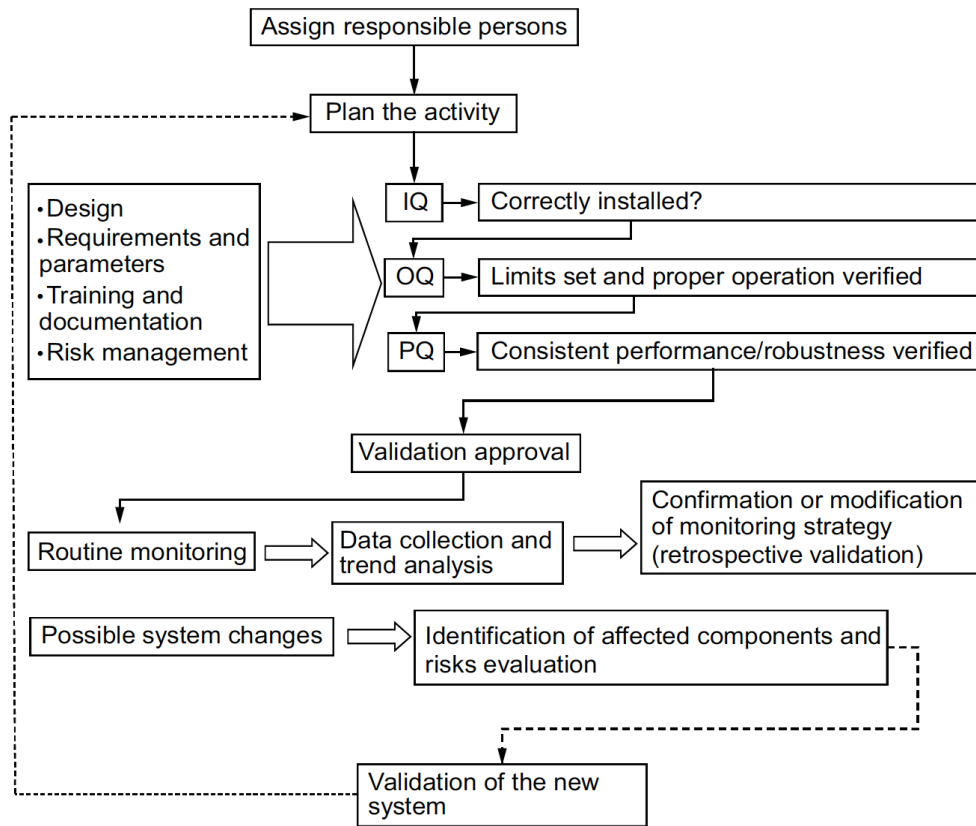


3.1.2 Performance validation

The validation process should provide documentary evidence that the system will consistently produce water, dialysis fluid, or substitution fluid meeting the quality requirements of ISO 13959 or ISO 11663. The contractor or supplier of the water treatment system should draw up the validation plan, which must be submitted to and approved by a member of the renal services with responsibility for clinical care of the patient.

It is recognised that not all nephrologists will have sufficient background knowledge for such approval and a designated technical expert may deputise on their behalf. If such a designated person is not part of the renal team, this should be clearly indicated on the documentation together with signed approval from a member of the renal team.

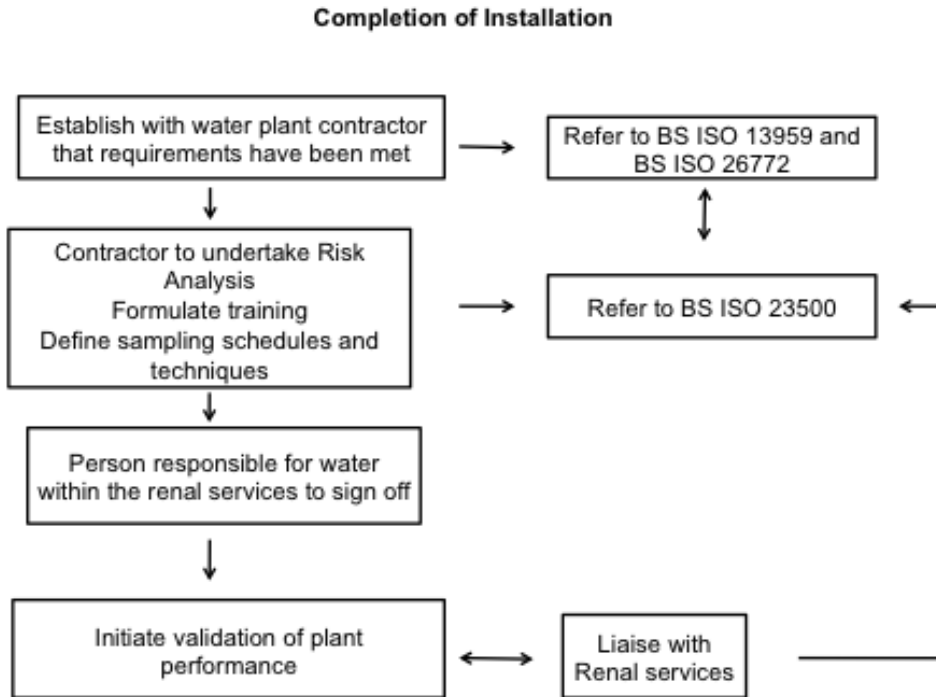
Figure 3 shows an example of a validation process (IQ = Initial or Installation Qualification, OQ = Operational Qualification, PQ = Performance Qualification).



3.1.3 Completion of installation of water treatment facility

The water treatment facility when completed should be confirmed to have met all aspects of the design specification. This needs to be agreed and signed off by the manufacturer/installer, commissioning team and by the person within the renal service with responsibility for clinical governance of the water treatment facility (Guidelines 1.2 and 1.3).

Figure 4 shows the essential action required on completion of building of the water treatment facility.



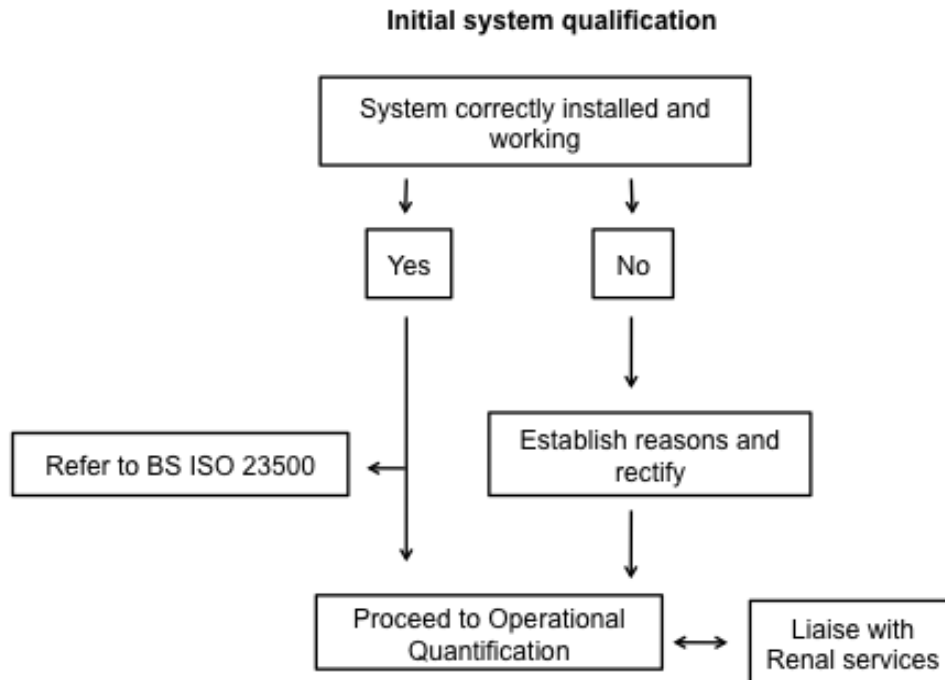
3.1.4 Initial qualification

On completion of installation, full system documentation should be available including system flow diagrams, layout, log books and operator’s manuals. Following completion of the installation, an installation qualification is performed. The purpose of this is to define and provide documented proof that the system has been installed in accordance with the approved plans and the manufacturer’s technical requirements and specifications.

Problems have arisen from a lag between completion of the installation process and the commencement of the validation process. To avoid such problems, it is imperative that the water treatment plant and distribution system are not left for any period during which there is fluid present in the system but there is no flow through the system and that the system is run in accordance with manufacturers instructions regarding disinfection procedures and frequencies following the completion of the installation process.

Furthermore, it is highly desirable that the entire system is run for short periods on a daily basis. If this is not possible then suitable alternate approaches will need to be established and discussed with a designated technical expert. If the designated technical expert is not part of the renal team, this should be clearly indicated on the documentation together with signed approval from a member of the renal team.

Figure 5 summarises the initial system qualification process.

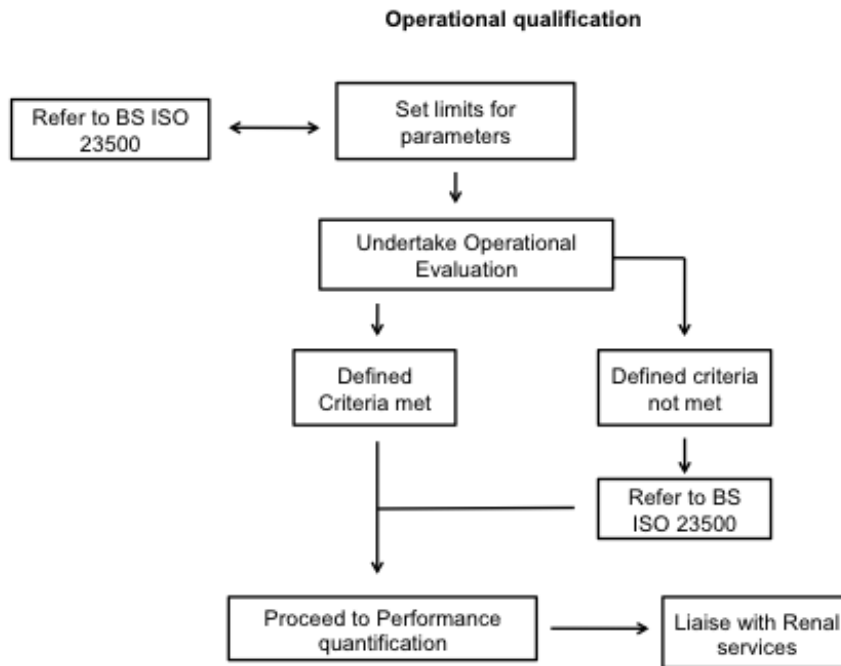


3.1.5 Operational qualification

The initial qualification of the water treatment system is followed by an operational qualification, the purpose of which is to verify the proper operation of the system, including operating range, set point, interlock and functional testing. On completion the following information should be available:

- test records;
- set up record;
- calibration schedule;
- sampling procedures;
- maintenance plans (e.g. disinfection, filter changes, etc.) and monitoring plans (e.g. conductivity, microbiological analysis);
- records of operator(s) training.

Figure 6 summarises the operational qualification process.



3.1.6 Performance qualification

Performance qualification generally follows a successful completion of the validation plan. The purpose of the performance qualification is:

- demonstration that the plant has been installed in accordance with the design plans and follows the manufacturer's procedures for installation (i.e. Installation Qualification);
- demonstration of the consistency and robustness of the system under local operational conditions.
- demonstration that the system performs all the required actions and can be operated in accordance to relevant technical manuals (i.e. Operational Qualification).

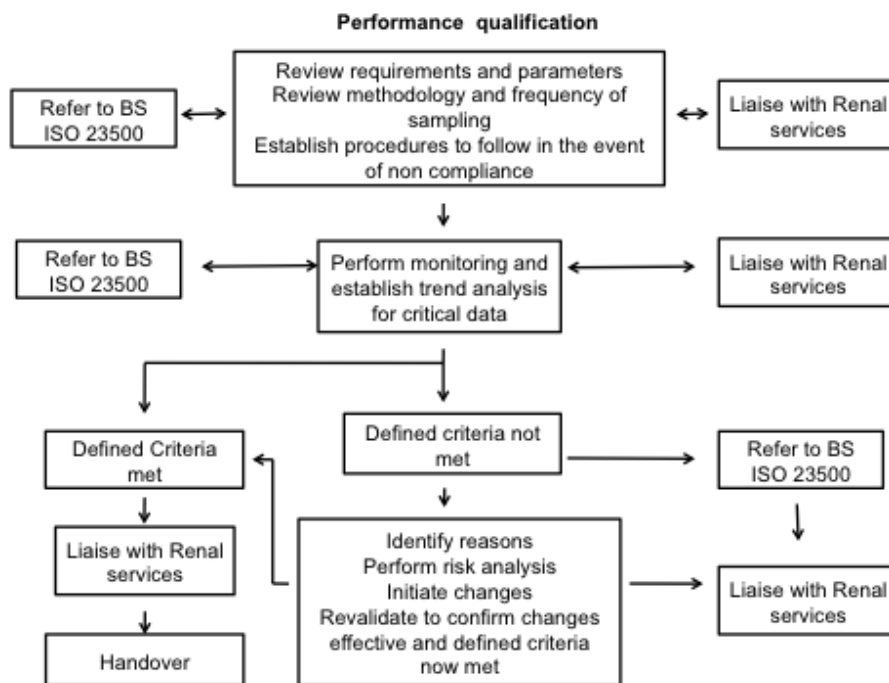
During this period all the information about the system behaviour is collected and fine-tuning of the action levels performed. During the performance quantification phase of the system, the testing frequency of the microbiological parameters is kept at a higher level to create a 'trend analysis' to identify any deviations from the requirements outlined in BS ISO 13959; 2009: Water for haemodialysis and related therapies and to ensure that the dialysis fluid produced with the treated water meets the requirements of BS ISO 11663; 2009: Quality of dialysis fluid for haemodialysis and related therapies^{1,2}.

On completion of the Performance Qualification, the following information should be available:

- test records;
- chemical and microbial analyses;
- key performance indicators [for example, pre treatment efficiency, reverse osmosis (RO) recovery/rejection rate, etc];
- (initial) trend analysis.

For newly installed systems, the person with overall clinical responsibility for dialysis (possibly supported by technical experts) may authorize use of dialysis fluid for patient treatments once chemical and microbiological analyses show full compliance with the quality requirements in the manufacturer's specifications, and any applicable regulatory requirements.

Figure 7 summarises the performance qualification process.



References

1. BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,
2. BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*

4. Operation and maintenance of water treatment facilities for haemodialysis

Guideline 4.1 – Routine maintenance and monitoring

We recommend that the maintenance and monitoring plans for the water treatment plant are established using the knowledge acquired during the complete validation process for the water treatment system which are in accordance with BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis*. Policies and procedures should be set up to ensure that maintenance and monitoring are mandatory and are implemented at the earliest opportunity. (1B)

Guideline 4.2 – Operators of water treatment facilities for haemodialysis

Guideline 4.2.1 – Training of operators of the water treatment facility

We recommend that operators should be trained in the use of the water treatment facility by the manufacturer or their UK distributor. The training should be specific to the functions performed. Competence with procedures should be assessed and documented. Periodic audits of the operators' compliance with procedures should be undertaken and documented and there should be an ongoing training programme to maintain the operator's knowledge and skills. (1C)

Guideline 4.2.2 – Continuing education and development of operators of water treatment facilities

We suggest that national organisations, such as the Association of Renal Technologists, should participate in the continuing education and development of operators of water treatment facilities by arranging training sessions at annual meetings and/or co-ordinating regular training days. (2D)

Guideline 4.3 - Monitoring of feed, product and dialysis water for haemodialysis

Guideline 4.3.1 - Routine testing of feed, product and dialysis water for haemodialysis

We recommend that routine testing procedures for water for dialysis should form part of the renal unit policy. Each water treatment facility should have standard operating procedures in place for sampling, monitoring and recording of feed and product water quality. (1C)

Guideline 4.3.2 – Frequency of monitoring of product and dialysis water for haemodialysis

We recommend that the minimum frequency of monitoring of water for dialysis should be as follows (1D):

Contaminant	Frequency of testing
Total chlorine	At least weekly
Total viable counts	At least monthly
Endotoxin	At least monthly
Chemical contaminants other than chlorine	At least every 3 months

Considerable daily as well as seasonal variations in the chlorine and chloramine levels of the feed water are known to exist and therefore the guidance to test weekly for chlorine/chloramine at least weekly should be regarded as an absolute minimum. If practical and feasible, testing for chlorine or chloramine on a daily or shift basis is recommended. It is however recognised that such an approach may place an undue burden on staff and, if it can be demonstrated that the chlorine levels in the feed water are consistently low (<0.5 mg/L) and chloramines are not used, then weekly monitoring of the dialysis water would be sufficient. However, if chloramines are used and the level of chlorine in the feed water exceeds 1.0 mg/L, the daily or shift based monitoring should be adopted.

Guideline 4.3.3 – Records of monitoring of product and dialysis water for haemodialysis

We recommend that records should be kept of all chemical and microbiological test results and remedial actions. If the interval between sample testing exceeds those indicated in the Table in 4.3.2, documentation should be in place to demonstrate that the sampling schedule used has been based on trend analysis. The operating procedures should include details of the procedures to be followed if the prescribed limits are exceeded. (1C)

Guideline 4.4 – Mutual responsibilities of water supply companies and renal units

We recommend that renal units shall inform the water supply companies of the location of all home haemodialysis patients as well as haemodialysis units so that the water companies are empowered to inform the renal unit of changes in feed water delivery to the patient's home in terms of supply and composition. The water companies should also advise the renal unit if there are plans to alter the range of chemicals added to the water supply to ensure compliance with the drinking water directive. (not graded)

Rationale for 4.1-4.4

The manufacturer of the water treatment plant and distribution system should demonstrate that the requirements for microbial contamination are met throughout the complete system at the time of installation⁽¹⁾. No specific recommendations regarding the frequency of monitoring are made but it should be performed at least monthly in respect of the product water and after any maintenance work on the water treatment system. The frequency of monitoring of the feed (or raw water) quality may be performed less frequently. For home installations it may be impractical to maintain a monthly testing programme and to ensure adequate patient safety the dialysis machine should be fitted with point of use filtration.

The laboratory tests required to demonstrate compliance with the recommendations for monitoring of chemical contamination of dialysis water should be carried out during commissioning and thereafter three monthly or following alterations to the water treatment plant. The frequency of testing may be modified once local trends have been established, but should not fall below annually. An initial full test on the supply water is advisable and regular monitoring of water quality data from the supplier is essential when tests are omitted based on low levels of contamination in the water supply.

The absence of any type of bacteriostat in the water following treatment makes it susceptible to bacterial contamination downstream of the water treatment plant. Microbial contamination may be enhanced by stagnant areas within the distribution network or irregular cleaning. The presence of microbial contamination contributes to the development of biofilm which may also be found in the dialysis fluid pathway of the proportionating system, particularly when non-sterile liquid bicarbonate concentrate is used. Such biofilm is difficult to remove and results in the release of bacteria and bacterial fragments (endotoxins, muramylpeptides, and polysaccharides). The dialysis membrane prevents transmembrane passage of intact bacteria but bacterial fragments have molecular weights that allow them to pass across the membrane into the bloodstream. Considerable differences exist in the adsorption capacity of such membranes, which may permit the passage of short bacterial DNA fragments⁽²⁻⁴⁾. Current proportionating systems incorporate filters for the removal of such fragments on the basis of size exclusion and hydrophobic interaction. The aim of implementing a disinfection programme is to prevent formation rather than elimination of biofilm and a routine testing procedure for microbiological contaminants in dialysis fluid, dialysis water and feed water should form part of the renal unit policy. It is not necessary to perform microbiological monitoring of dialysis fluid or substitution fluid if production paths are fitted with validated microbiological filters operated and monitored within the manufacturer's instructions.

Testing for chemical contaminants will normally include continuous conductivity monitoring of the water leaving the reverse osmosis system, and regular in-house checks of hardness and total chlorine (5).

a) Frequency of monitoring of total chlorine

There is increasing use of chlorine dioxide or other chemicals to prevent growth of Legionella bacteria in hospital water systems and if the dialysis unit draws water from such a system rather than a direct “rising main” supply to the renal unit, then residual chlorine dioxide and a range of by products such as chlorite, chlorate and organic disinfection by products (DBP) may be present in the feed water. It should be recognised that such chemicals are not effectively removed by the water treatment plants in renal units and their use should be undertaken only after consultation with the renal services. Furthermore, current guidance on the control and monitoring of chlorine dioxide in water for dialysis varies⁽⁵⁻⁷⁾. Water providers may without prior warning to consumers change from using chlorine to using the more stable chloramine. Thus it is recommended that testing for "total chlorine" is performed. It is also recommended that dual carbon beds be used in series with daily “chlorine” testing to ensure that the patients are not exposed to chlorine /chloramine. As the removal of these compounds is critically dependent upon carbon filtration, technical staff performing the testing should ensure data on the carbon filter empty bed contact time required for the effective removal of these compounds are available.

b) Methods of measurement and removal of “chlorine”

Monitoring of chlorine and chloramine in water is commonly performed by the use of the diethyl-p-phenylene diamine (DPD) test. Users of this test should be aware that when chlorine dioxide is used residual chlorine dioxide and a range of by-products such as chlorite, chlorate and organic disinfection by-products (DBP) may be present. The accuracy of the DPD test for the measurement for such residuals has not been quantified, and for accurate methods of quantification the reader is asked to refer to:http://www.epa.gov/ogwdw/mdbp/alternative_disinfectants_guidance.pdf

When chlorine dioxide is used chlorite and chlorate are produced in varying amounts but can be removed by the use of either granular activated carbon (GAC) or powdered activated carbon (PAC). Currently there are no specific recommendations for their levels in water used for dialysis purposes. However the US Environmental Protection Agency (EPA) recommends that in drinking water the total concentration of chlorine dioxide, chlorite, and chlorate should be less than 1.0 mg/L as Cl₂. Consequently, it is prudent to ensure that levels if present are substantially below those recommended for potable water to minimize patient risk. If chlorine dioxide is used, then renal service technical staff are advised to contact the supplier of their carbon material to ensure that the removal characteristics for chlorine and chlorate are known and sufficient to ensure that the patient is not placed at risk.

c) Frequency of monitoring of chemical contaminants other than chlorine

The concentrations of chemical contaminants other than “chlorine” should be performed at least three monthly. Depending upon trend analysis, the frequency of monitoring may be increased to six months. The frequency of monitoring will also be dependent on whether the feed water is via a direct or indirect tanked supply. If the feed water is via a tanked supply, more frequent checks may be necessary, especially if chemicals are introduced into the tank locally to control bacterial proliferation. No chemicals should be introduced into the tank without prior consultation of the renal services, and renal unit technical staff should ensure that this is incorporated into the hospital’s operating procedures and that the tank area supplying the renal unit is appropriately marked.

d) Frequency of monitoring of microbial contaminants and endotoxin

Total viable counts and endotoxin levels should be monitored at least monthly. A scheme should be drawn up which defines the points at which the sampling is performed. The sampling points should include the RO outlet, and the furthest point in the distribution loop. In addition the return point as well as a randomly selected feed point to a proportionating system should be included.

e) National standards and testing of feed (drinking) water

National standards and testing of feed (drinking) water, The European Union Drinking Water Directive, sets quality standards for drinking water quality at the tap (microbiological, chemical and organoleptic parameters) and the general obligation, that drinking water must be wholesome and clean. It also obliges Member States to regularly monitor drinking water quality and to provide to consumers adequate and up-to-date information on their drinking water quality.

Within the United Kingdom, these requirements are incorporated in the Water Supply (Quality Regulations) 2000 for England and Wales, the Water Supply (Water Quality) (Scotland) Regulations 2001, and the Water Supply (Water Quality) Regulations (Northern Ireland) 2009. The responsibility for monitoring lies with the water utilities who routinely monitor water at their treatment works and in samples drawn from the supply network. The water company results are independently monitored by the Drinking Water Inspectorate (DWI). Compounds monitored routinely, include calcium, sulphate, magnesium, sodium and potassium as well as manganese, iron, aluminium, nitrates and phosphorus. Additionally copper, zinc, lead, pesticides, PAH (polynuclear aromatic hydrocarbons) and bacteria are also monitored. To ensure compliance in respect of bacteria chlorine or chloramine is added to the water. Typically water companies keep the level of residual disinfectant in the form of free or combined chlorine to 0.5 mg/l or less, however during maintenance of the pipe network higher levels may be present. The water company will provide a water quality report showing the maximum and minimum level of residual chlorine in the local water supply on request and detailed information for all contaminant levels routinely monitored under the Water Supply Regulations can be found at: <http://dwi.defra.gov.uk/about/annual-report/2010/index.htm>

Water to hospitals as well as to individual homes may be derived from private sources such as wells or boreholes. Such supplies are subject to the Private Water Supplies Regulations (2009) and subject to Local Authority monitoring. Contaminant levels are monitored in a comparable manner to the water supplied by water utilities and the above web site provides detailed information.

It is important that renal units are aware of their water supplier, and develop a working relationship with their supplier's technical department to ensure that they are informed in a timely manner of any proposed changes to the water treatment or whenever feed water chemical contaminants significantly exceed routine values. This applies to home as well as hospital water treatment facilities and is especially important for chemicals documented to be toxic to haemodialysis patients e.g. aluminium, chloramine, copper, fluoride and lead⁽⁸⁾. Such a relationship does not negate the responsibility for routine feed water monitoring. If renal technologists are not responsible for the routine monitoring of the water quality, procedures should be in place to ensure that the persons performing the testing are made aware of changes in a timely manner.

References

1. ISO 23500; 2011: Guidance for the preparation and quality management of fluids for haemodialysis and related therapies
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7. Ward RA. Dialysis water as a determinant of the adequacy of dialysis. *Semin Nephrol* 2005; 25:102-111
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5. Monitoring the quality of product water for haemodialysis and dialysis fluids

Guideline 5.1: Chemical contaminants in product water used for the preparation of dialysis fluid

We recommend that the concentrations of chemical contaminants in water used to prepare dialysis fluid shall not exceed the limits stated in BS ISO 13959; 2009: *Water for haemodialysis and related therapies*. A programme of improvement should begin immediately if routine monitoring demonstrates that concentrations of chemical contaminants exceed the maximum allowable limits. (1B)

Rationale

Knowledge of the potentially harmful effects of trace elements and chemicals continues to expand and techniques of water treatment are continuously being modified. Recommendations for the maximum allowable concentrations of chemical contaminants have been prepared by a variety of standard developing organisations, professional societies and pharmacopoeias, such as AAMI ⁽¹⁾, International Standards Organisation ⁽²⁾ and the European Pharmacopoeia ⁽³⁾. While there is general agreement concerning the maximum allowable levels of inorganic chemicals with documented toxicity in haemodialysis patients (aluminium, chloramines, copper, fluoride, lead, nitrate, sulphate, and zinc) there are some exceptions e.g. the current edition of the European Pharmacopoeia does not explicitly specify maximum allowable levels for copper or chloramines. Of note none of the standards and recommendations includes limits for specific organic chemical contaminants. The rationale for this omission is that organic chemicals with specific toxicity in haemodialysis patients have not been identified and that carbon adsorption and reverse osmosis removes most organic compounds. However, there has been a recent report of patient exposure following inadequate removal of organic chemicals in the preparation of dialysis water ⁽⁴⁾.

Tables 1-3 below list all the contaminants for which a maximum allowable limit is defined for water for dialysis in ISO 13959:2009 ⁽²⁾.

Table 1: Maximum allowable concentrations of chemical contaminants in dialysis water for which monitoring is mandatory (reproduced from ISO 13959)

Chemical contaminant	Maximum recommended concentration (mg/l=ppm)
Aluminium	0.01
Calcium	2 (0.05mmol/l)
Total chlorine	0.1
Copper	0.1
Fluoride	0.2
Magnesium	4 (0.15 mmol/l)
Nitrate (as N)	2 (equates to 9 mg/l NO ₃)
Potassium	8 (0.2 mmol/l)
Sodium	70 (3.0 mmol/l)

All of the above chemical contaminants when indicated should be tested initially every 3 months apart from total chlorine concentrations which should be tested at least weekly. As considerable daily as well as seasonal variations in the chlorine and chloramine levels of the water entering the water treatment plant (feed water) are known to exist, the guidance to test weekly for chlorine/chloramine at least weekly should be regarded as an absolute minimum. If practical and feasible, testing for chlorine or chloramine on a daily or shift basis is recommended. It is however recognised that such an approach may place an undue burden on staff and, if it can be demonstrated that the chlorine levels in the feed water are consistently low (<0.5 mg/L) and chloramines are not used, then weekly monitoring of the dialysis water is sufficient. However, if chloramines are used and the level of chlorine in the feed water exceeds 1.0 mg/L, the daily or shift based monitoring should be adopted. The maximum recommended concentration for total chlorine is 0.1mg/l (ppm) in ISO 23500 ⁽⁵⁾.

Table 2 defines a group of contaminants for which the drinking water limit is 2 to 5 times the recommended limit for dialysis ⁽⁶⁾. In water treated by reverse osmosis, these contaminants will only exceed the limits in Table 2 if they occur at relatively high levels in the water supplied to the unit. These contaminants can be omitted from routine tests if data is available to show that the levels in the water supplied to the unit rarely exceed the limit in Table 2. Such data is generally available on request from the municipal water supplier and reviewed on an annual basis. Tests on the drinking water should be undertaken every 6 months if it is obtained from a private source and used for the provision of water for dialysis either in the hospital or home.

Table 2: Maximum allowable concentrations of chemical contaminants in dialysis water which may be omitted from routine monitoring (reproduced from ISO 13959)

Chemical contaminant	Maximum recommended concentration (mg/l=ppm)
Arsenic	0.005
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Sulphate	100

The final group of contaminants (barium, beryllium, silver, thallium, tin and zinc) are those for which a limit has been defined for water for dialysis and there is no limit specified for drinking water in the UK. These trace elements are not considered to occur in levels that give cause for concern and, if low levels are present, they are removed effectively by reverse osmosis. Testing is only required if there is evidence of high levels in the local water supply (zinc, for example, can be introduced in the pipework). Selenium (ISO limit 0.09 mg/l) and Antimony (ISO limit 0.006 mg/l) have been excluded from the requirements for monitoring as the limit for drinking water in the UK is lower than the limit for water for dialysis ⁽⁷⁾.

Table 3: Maximum allowable concentrations of chemical contaminants in dialysis water which only require monitoring when indicated.

Chemical contaminant	Maximum recommended concentration (mg/l = ppm)
Barium	0.1
Beryllium	0.0004
Silver	0.005
Thallium	0.002
Zinc	0.1

Compliance with the requirements listed in Tables 1-3 can be shown by using chemical analysis methods validated by the United Kingdom Accreditation Service, methods referenced in an applicable pharmacopoeia, and/or another equivalent analytical method, provided the accuracy of the method used has been validated to detect the levels shown

The manufacturer or supplier of a complete water treatment system should ensure that the recommended system is capable of meeting the above requirements based on a feed water analysis and allowing for seasonal variation in feed water quality. The complete water treatment, storage and distribution system should meet the requirements of ISO 26722 ⁽⁸⁾ and be shown to be capable of meeting the requirements of ISO 13959 ⁽²⁾ at the time of installation.

References

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5. BS ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*

6. The Water Supply (Water Quality) (England and Wales) Regulations 2000. Statutory Instrument No. 3184. Prescribed concentrations and values. <http://www.dwi.gov.uk/regs/si3184/3184.htm#sch1>
7. <http://dwi.defra.gov.uk/stakeholders/legislation/wqregs2007cons.pdf>.
8. BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*

Guideline 5.2: Microbiological contaminants in product water used for the preparation of dialysis fluid

Guideline 5.2.1 – Maximum allowable concentrations of microbiological contaminants in product water used for the preparation of dialysis fluid

We recommend that the quality of water produced by the water treatment facility shall meet the concentration limits for microbiological contaminants detailed in BS ISO 13959:2009. This states that dialysis water shall contain a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml. If routine monitoring demonstrates microbiological contaminant levels in excess of 50% of the maximum permitted levels a programme of corrective measures should be commenced immediately. (1B)

Dialysis water containing a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml is also the starting point in the production of ultrapure dialysis fluid or for on-line infusion fluid used in haemodiafiltration. To meet the appropriate requirements, the dialysis fluid will require further filtration by ultrafilters incorporated in the dialysis machine. Testing of replacement fluid for on-line haemodiafiltration is difficult and it is more important to check that quality assurance procedures are in place for monitoring filter integrity.

Guideline 5.2.2 – Methods of measuring microbiological contaminants in product water used for the preparation of dialysis fluid

We recommend that the test procedures used for monitoring microbial contamination of water for dialysis be standardised and appropriate to the type of organisms found in water. The test procedures should be adhered to stringently. (1C)

Rationale

The dialysis membrane was regarded as an effective barrier against the passage of bacteria and endotoxin (potent pyrogenic materials arising from the outer layers of bacterial cells) from dialysis fluid to blood. This produced a complacent attitude towards the purity of dialysis fluid until about 20 years ago when several in vitro studies showed that intact membranes used in dialysers are permeable to bacterial contaminants⁽¹⁻²⁾. The pore size of the membrane appears to be less important than the thickness of the membrane or the capacity of the membrane to adsorb bacterial products. Consequently low flux (standard) dialysis does not necessarily translate into higher microbiological safety than high flux dialysis or haemodiafiltration. Patients receiving standard dialysis treatment with low flux cellulose-based membranes (thickness 6–8 microns), may therefore be at greater risk of pyrogenic reactions (see below) than those treated using thicker synthetic membranes which have higher capacity to adsorb bacterial endotoxin.

Water produced for the preparation of dialysis fluid produced by older, existing water treatment plants may not be suitable for use in ultrapure treatments unless it is further treated by point of use ultrafiltration. Nevertheless, the microbiological quality of the water produced should comply with the requirements of BS ISO 13959; 2009: *Water for haemodialysis and related therapies*, namely that total viable microbial counts shall be less than 100 CFU/ml, and the endotoxin content shall be less than 0.25 EU/ml, which is suitable for use for low flux haemodialysis. If routine monitoring demonstrates microbiological contaminant levels in excess of 50 CFU/ml and 0.125 EU/ml for bacteria and endotoxin (i.e. 50% of the maximum permitted levels) a programme of corrective measures should be commenced immediately⁽³⁾. However it is important to recognise that an increase in the concentrations of microbial contaminants and/or endotoxin below 50% of the maximum allowable levels can indicate that microbial growth is present and/or disinfection procedures are inadequate as shown in the Table below (personal communication Rolf Nystrand).

Total viable counts (CFU/ml)	Interpretation	Endotoxin concentrations (EU/ml)	Interpretation
<1	System is in perfect order	-	-
1-5	System is in good order	<0.03	System is in good order
6-10	Surface growth is in “start up”	0.03-0.1	Microbial growth is present and residuals from former growth are present
11-50	Surface growth is established	0.1-0.25	Microbial growth is established and disinfection is ineffective
>50	Disinfection program is ineffective, especially if fungi and/or yeast is present	>0.25	Microbial growth is substantial

In patients treated with high flux membranes, a risk of pyrogen transfer due to backfiltration (a movement of dialysis fluid into the blood pathway of the device due to an inverted pressure gradient rather than the diffusion gradient discussed above) may exist. Lonneman et al, however, concluded that diffusion rather than convection is the predominant mechanism of transmembrane transport of pyrogens and backfiltration across pyrogen adsorbing membranes does not necessarily increase their passage⁽⁴⁾. It should be emphasised that the adsorption capacity of the synthetic membranes is not infinite and that a breakthrough of pyrogenic substances can occur in the event of excessive water contamination.

A raised C-reactive protein (a sensitive marker of activation of the acute phase response) is associated with a significantly increased risk of death^(5,6) and has led to speculation that micro-inflammation associated with transmembrane transfer of endotoxins and bacterial fragments may contribute to raised serum levels of CRP in patients undergoing regular haemodialysis. Impure dialysis fluid has also been implicated in the pathogenesis of dialysis-related amyloidosis and an increased rate of loss of residual renal function. Ultrapure dialysis fluid is produced by additional ultrafiltration of dialysis fluid in dialysis machines and used as an online substitution fluid in convective therapies such as haemodiafiltration or haemofiltration. It may also be used in high flux haemodialysis. A number of clinical studies have shown that the use of ultrapure dialysis fluid is associated with a range of clinical benefits⁽⁷⁻¹⁰⁾. Its use for haemodialysis has been associated with lower indices of inflammatory response (serum CRP and IL-6), with better preservation of residual renal function, nutritional status and correction of anaemia and may reduce the risk of complications due to dialysis-related amyloidosis. In a prospective 30 month observational study patients with combined high levels of CRP and pro-inflammatory cytokines showed an increase in all-cause mortality (RR =2.57, p < 0.001) and cardiovascular death (RR = 1.9, p < 0.001)⁽⁹⁾. Although the clinical benefit of ultrapure dialysis fluid has not been established in a large scale randomized trial it would seem prudent to ensure that water is as pure as reasonably possible and the European Best Practice Guidelines recommend the use of ultrapure water for all dialysis treatments⁽¹¹⁾.

The concentrations of microbial contaminants and endotoxin in ultrapure dialysis fluid shall be < 0.1 CFU/mL and < 0.03EU/mL respectively when used for high flux haemodialysis. However the ultrapure dialysis water requires further treatment if it is to be used as infusion fluid in convective therapies. In some dialysis units up to 100% of treatments are now performed with such convective techniques. Modern dialysis machines permit the production of substitution fluid on site and on-line allowing large reinfusion volumes to be used. This on-line process shall be validated to produce fluid that is sterile and non-pyrogenic. Compliance of on-line produced fluid with the requirements of BS ISO 11663 cannot be demonstrated with traditional test procedures. For this reason, compliance with this standard shall be ensured by proper operation of a validated system, verified according to the manufacturer's instructions at the time of installation, and confirmed by the user with a regular monitoring and maintenance schedule. The user shall follow the manufacturer's instructions for use of the validated system, and the user's monitoring and maintenance schedule shall be designed to confirm that the water and concentrates used to prepare the substitution fluid continue to meet the specifications of BS ISO 13958 and BS ISO 13959.

The test procedures used for monitoring microbial contamination of water for dialysis should be appropriate to the type of organisms found in water and need to be adhered to stringently. Membrane filtration using a filter pore diameter of 0.45 microns or less and a filtration volume between 10-1000ml are required⁽¹²⁾. A low nutrient agar, such as Tryptone Glucose Extract Agar (TGEA) or Reasoner's Agar 2A, should be used⁽¹³⁻¹⁶⁾ and samples should be incubated for at least 7 days at 17-23°C^(13,17). These conditions have been shown to give good recovery for most environmental bacteria found in purified water. Some species are better adapted for growth at a higher temperature and/or on richer media, but the long incubation time will allow most of these to grow. Details of methods for sampling and culturing of water for dialysis are available in the Appendix of European Best Practice Guidelines for Haemodialysis Part 1⁽¹¹⁾ and in the EDTNA/ERCA Guidelines on Control and Monitoring of Microbiological Contamination in Water for Dialysis⁽¹⁷⁾, which also gives specific test conditions for fungi. Detailed procedures for the collection and analysis of samples of water and dialysis solution for microbiological analysis also form part of ISO 23500⁽¹²⁾.

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Guideline 5.3 – Preparation and composition of dialysis fluid

Dialysis fluid is produced by the mixing of dialysis water with acid and bicarbonate concentrates and the microbiological contaminant levels for acid and bicarbonate concentrates are defined in BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies*. For dialysis fluid thus produced or if non bicarbonate buffered or modified bicarbonate buffered dialysis fluid is used, we recommend that the microbiological contaminant levels of the dialysis fluid should not exceed those cited in BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* (1B)

Rationale

Whilst standardisation of the concentrations of electrolyte components of the dialysis fluid is desirable, it is recognised that patients' clinical requirements vary and individualization of the composition of the dialysis fluid may be required, most notably in terms of potassium, calcium and magnesium concentrations. In addition, centralised delivery of concentrate for the preparation of one or two dialysis fluid prescriptions is used by some haemodialysis units. Although such dialysis fluids are suitable for most patients and the sodium and bicarbonate concentrations can be adjusted via the haemodialysis machine, individualisation of dialysis fluid electrolyte concentrations, especially potassium, calcium and magnesium cannot be easily achieved.

One of the critical functions of dialysis is the correction of the metabolic acidosis caused by the failure of the diseased kidneys to excrete non-volatile acids and to regenerate bicarbonate. Bicarbonate is the natural buffer normally regenerated by the kidneys and was the initial choice as dialysate buffer. If, however, sodium bicarbonate is added to a calcium- or magnesium-containing dialysis fluid, carbonate salts will precipitate unless the dialysis fluid is maintained at a low pH level. Acetate does not precipitate calcium or magnesium, and is rapidly converted to bicarbonate in the liver. It became widely used with the introduction of single patient proportionating systems⁽¹⁾. In the late 1970s and early 1980s, a number of studies suggested that some of the morbidity associated with haemodialysis could be attributed to the acetate component of the dialysate^(2, 3). This appears to have been unmasked by the introduction of high-efficiency and short-duration dialysis, using membranes with large surface areas. Acetate intolerance led to the reappraisal of bicarbonate as a dialysis buffer in the early 1980s and technical solutions to the problem of precipitation of calcium carbonate led to its replacement of acetate as the buffer of choice. It should be noted, however, that even 'bicarbonate' dialysis fluid contains moderate amounts of acetate⁽⁴⁾.

A systematic review of 18 randomised trials indicated a reduction in the number of treatments complicated by headaches, nausea/vomiting and symptomatic hypotension when bicarbonate was used⁽⁵⁾. Economic evaluations showed the cost of self-mix bicarbonate buffer to be similar to that of acetate. Although bicarbonate remains the buffer of choice for the majority of dialysis patients, non bicarbonate buffered dialysis fluids are available for use in specific situations. The NxStage machine, intended for home haemodialysis, uses lactate as a buffer. A concentrate for bicarbonate haemodialysis acidified with citrate instead of acetate is also available. The small amount of citrate used (one-fifth of the concentration adopted in regional anticoagulation) protects against intra dialyser clotting, increases dialysis efficiency while minimally affecting the calcium concentration^(6,7).

It is not possible to set evidence-based standards for the other components of the dialysis fluid. However there is evidence that non-diabetic haemodialysis patients using glucose-free dialysis fluid have a surprisingly high rate of asymptomatic hypoglycaemia without an associated counter-regulatory response^(8,9). The long-term effects of repeated dialysis-induced hypoglycaemia are uncertain. Hypoglycaemia is not observed if the dialysis fluid contains glucose, but glucose-containing dialysis fluid is slightly more expensive. In elderly and diabetic patients higher insulin levels coupled with higher dialysis fluid glucose levels (2g/L) impair potassium removal during haemodialysis. Hyperglycaemia also activates inflammatory pathways and contributes to the pro-inflammatory state of haemodialysis patients. The recent study by Burgmeister et al suggested that a level of around 1g/L would be appropriate for both diabetic and non-diabetic patients⁽¹⁰⁾. For these reasons the use of dialysis fluid containing a more physiological glucose concentration is now routine clinical practice.

References

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Guideline 5.4 – Quality of dialysis fluid

We recommend that dialysis fluid production uses dialysis water produced by compliance with the requirements of BS ISO 13959; 2009: *Water for haemodialysis and related therapies*. The dialysis fluid thus produced should additionally comply with the requirements of BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*.

Standard dialysis fluid is considered as the minimum quality, ultrapure dialysis fluid is recommended for routine haemodialysis and ultrapure dialysis fluid is mandatory for creating on-line prepared substitution fluid used in convective therapies such as on-line haemodiafiltration. The process used for the production of on-line prepared substitution fluid shall be validated to produce fluid that is sterile and non-pyrogenic. (1B)

Rationale

Haemodialysis patients are directly exposed to large volumes of dialysis fluid with the dialyser membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. To minimize this hazard, BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies* and BS ISO 13959; 2009: *Water for haemodialysis and related therapies*, set out the quality requirements for the water and concentrates used to prepare dialysis fluid^(1,2). However, dialysis fluid could contain unacceptable levels of contaminants even though it is prepared from water and concentrates meeting the requirements of the above standards. Furthermore, the dialysis fluid might be used as the starting material for the on-line preparation of fluids intended for infusion into the patient, for example, in therapies such as on-line haemodiafiltration. For these reasons, BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* outlines the acceptable limits for microbiological contaminants of the dialysis fluid. BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* defines three levels of quality of dialysis fluid: standard dialysis fluid, ultrapure dialysis fluid, and online prepared substitution fluid⁽³⁾.

a) Standard dialysis fluid shall contain a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml. The action level for the total viable microbial count in dialysis fluid should be 50 CFU/ml. If microbial counts exceeding the action levels are observed in the dialysis fluid, corrective measures, such as disinfection and retesting, should be taken promptly to reduce the levels.

b) Ultrapure dialysis fluid shall contain a total viable microbial count of less than 0.1 CFU/ml and an endotoxin concentration less than 0.03 EU/ml. As for standard dialysis fluid, if the limits are exceeded corrective measures should be taken to reduce the levels to an acceptable range.

c) Microbiological requirements for online prepared substitution fluid

Substitution fluid for convective therapies, such as haemodiafiltration and haemofiltration, may be produced on-line by a process of ultrafiltration with bacteria and endotoxin retentive filters. This on-line process shall be validated to produce fluid that is sterile and non-pyrogenic. Compliance of online produced fluid with the requirements of BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* cannot be demonstrated with traditional test procedures. For this reason, compliance with BS ISO 11663;2009: *Quality of dialysis fluid for haemodialysis and related therapies* shall be ensured by proper operation of a validated system, verified according to the manufacturer's instructions on installation, and confirmed by a regular monitoring and maintenance schedule.

1. BS ISO 13958; 2009: *Concentrates for haemodialysis and related therapies*
2. BS ISO 13959; 2009: *Water for haemodialysis and related therapies*
3. BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*

Guideline 5.5 - Responsibility for policies for monitoring and recording of quality of dialysis water

We recommend that the senior renal technologist shall be the person responsible for ensuring concordance with policies for monitoring and recording of the quality of dialysis water and dialysis fluid. If this person is absent from work, procedures shall be in place to ensure continuance of policies. (not graded)

Rationale

Responsibility for the policies for monitoring and recording of quality of dialysis water shall be part of the job plan of the senior renal technologist in the renal unit. The senior renal technologist should be accountable to the Clinical Director of the renal unit for monitoring and recording of the quality of dialysis water and should report immediately to the Clinical Director whenever action limits are exceeded.

6. Water treatment facilities for home haemodialysis

Guideline 6.1 – Maintenance of the water and power supply

We recommend that the utility companies providing water and power to the patient's home be notified that home dialysis is being performed, and that they have details of patients' addresses on their risk register to ensure that patients are notified of any proposed interruption of supply and that restoration of supply is a priority. (not graded)

Guideline 6.2 – Training of the patient and/or helper

We recommend that the patient and/or helper in the home should be formally trained in the correct operation and maintenance of the water treatment equipment by an appropriately trained technologist. There should be a record of the training, and the patient and /or helper should keep a log of the maintenance and monitoring procedures. (not graded)

Guideline 6.3 – Home haemodialysis installations

We recommend that all installations for home haemodialysis should include carbon filters/beds with built in redundancy, heat disinfection portable reverse osmosis and point of use ultrafiltration. (1C)

Guideline 6.4 – Frequency of monitoring of feed and product water used for home haemodialysis

Guideline 6.4.1 – Frequency of monitoring of feed water used for home haemodialysis

We recommend that feed water from a private well should be tested for chemical and microbial quality at least every six months whereas the chemical and microbial quality of feed water from municipal suppliers should be assessed annually using data obtained from the supplier. (1C)

Guideline 6.4.2 – Frequency of monitoring of product water used for the preparation of dialysis fluid for home haemodialysis

We recommend that the chemical and microbial quality of the water used for the preparation of dialysis fluid for home haemodialysis should be monitored at least every six months. (1C)

Rationale for 6.1-6.4

The general considerations described in the previous sections of this document are equally applicable to home haemodialysis installations. To incorporate a haemodialysis machine in a home the home will need a water supply, a drain connection, and a power source.

If the feed water to the home is from a private well an annual analysis of the quality of the product water may not be sufficient to ensure that the treatment system installed will remove contaminants present and a more frequent analysis may be needed, particularly if the well is subject to seasonal changes or liable to contamination from sources such as septic tanks, underground fuel storage tanks or agricultural waste and chemicals.

The equipment selected for home haemodialysis should be as simple as possible to operate. The equipment selected should comply with the requirements BS ISO 26722; 2009: Water treatment equipment for haemodialysis and related therapies ⁽¹⁾, and the dialysis water produced should meet the requirements of BS ISO 13959; 2009: *Water for haemodialysis and related therapies*. As such equipment may be in a different area to where dialysis is being undertaken. Any alarm associated with a component of the water treatment system which does not invoke alarms on the proportionating system should be audible and visible in the patient treatment area.

There are a number of specific points pertinent to home installations ⁽²⁾:

a) Carbon beds/filters

Carbon beds or carbon block filters are used to effect removal of chlorine/chloramine from the feed water and if the water is derived from a well, to also remove organic contaminants from ground water. Where practical, two carbon beds in series, which together provide a minimum of 10 min Empty Bed Contact Time (EBCT) provide a degree of safety over a single carbon bed.

If carbon blocks are used, it should be recognised that the size, configuration and exchange frequency of the blocks will be critically dependent upon the level of chlorine/chloramine and organic contaminants in the feed water and a well defined schedule of replacement should be in place. Experience in the use of such blocks in the treatment of acute renal failure suggests that two carbon block filters in series rated according to the NSF International (Ann Arbor, MI, USA) for a minimum chlorine reduction capacity of 40 000 gal (approximately 150 000 litres) at a flow rate of 2 gal/min (7.7 l/min) and an incoming free chlorine concentration of 2 mg/l can be used. When used carbon block filters should not compromise the feed water requirements specified by the manufacturer of the reverse osmosis system.

b) The distribution system for the product water at home

Because systems used for home haemodialysis operate intermittently, the distribution system should be designed and maintained to minimize bacterial proliferation. The system should allow regular sanitisation of the distribution loop up to the point where it connects to the machine. The use of heat sanitization is preferable to eliminate the use of disinfecting chemicals by the home haemodialysis patient, reducing the associated exposure risk.

c) Point of use ultrafiltration

Installation of a point-of-use ultrafilter in either the dialysis water or dialysis fluid path to remove endotoxin and other microbial contaminants is desirable. If installed the ultrafilter should be maintained and replaced according to the manufacturer's instructions.

d) Monitoring of water and dialysis fluid quality

Routine monitoring of each treatment

A log sheet should be provided by the renal unit and used to record all measures of water treatment system performance. Measurements should be made at least 15 minutes after the water treatment system has been set in operation and before dialysis is initiated. To ensure that dialysis is not undertaken with suboptimal water quality, prior to each treatment, the performance of the reverse osmosis system should be monitored and recorded by checking the product water conductivity and percent rejection. If the reverse osmosis system is found to be outside its acceptable range, the renal unit responsible for the patient should be notified. If the water treatment includes a stand alone softener, the water hardness should be monitored prior to each treatment using a sample obtained through a labelled sample port located between the softener and the reverse osmosis system. For hardness tests requiring colour differentiation, the person performing the analysis should be able to distinguish between the colours of blue, purple, and red. If the person cannot differentiate these colours an automated meter should be used. The results obtained should be recorded on the log sheet and reviewed by the renal technologist as part of the maintenance and service of the home haemodialysis installation.

Monitoring for chemical and microbiological quality

The chemical quality of the product water used for dialysis should be analyzed at least every six months to ensure it meets the requirements of BS ISO 13959; 2009: *Water for haemodialysis and related therapies* ⁽³⁾. A more frequent analysis may be needed if there are seasonal variations in source water quality or if the source water is supplied from a well. When any repairs or component replacements are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if indicated.

The microbiological quality of the dialysis fluid should be analyzed at least every six months using the appropriate techniques to ensure it meets the requirements of BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies* ⁽⁴⁾. However if daily dialysis schedules are being practiced this frequency may be insufficient.

If the interval between sample testing exceeds six months documentation should be in place to demonstrate that the sampling schedule used has been based on trend analysis. The operating procedures should include details of the procedures to be followed if the prescribed limits are exceeded.

Sampling should be prior to any disinfection of the water treatment system and dialysis machine and a system should be in place to ensure proper collection of the samples and their timely submission to the testing laboratory. If patients or helpers are expected to perform sampling they should have received adequate training to do so and this training should be appropriately documented.

References

1. BS ISO 26722; 2009: *Water treatment equipment for haemodialysis and related therapies*
2. ISO 23500; 2011: *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies. Annex F: Special considerations for home haemodialysis*
3. BS ISO 13959; 2009: *Water for haemodialysis and related therapies*,
4. BS ISO 11663; 2009: *Quality of dialysis fluid for haemodialysis and related therapies*

Appendix 1

Haemodialysis units in UK hospitals which have reported problems with the design, installation, validation, operation and/or maintenance of new water treatment facilities

This summary has been prepared by Maurice Harrington on behalf of the Association of Renal Technologists and Renal Association to provide supporting evidence for the need for this guideline. 70 renal units responded to a questionnaire enquiring if they had encountered significant problems with the specification, installation, validation and/or maintenance of any of their main or satellite haemodialysis facilities. 30 of the units had one or more recent PFI built haemodialysis facilities. All of the haemodialysis units listed below reported delays in clinical use, additional cost and/or patient risk when commissioned in the past few years.

Broomfield, Chelmsford
Burnley Haemodialysis Unit, Royal Preston
Childrens Hospital, Bristol University Trust
Cumberland Infirmary, Cockermouth
Dorset County Hospital, Bournemouth
Forth Valley Royal Hospital, Larbert, NHS Forth valley
Freeman Hospital, Newcastle
Guy's & St Thomas's Hospitals, London
Hope Hospital, Salford, Manchester
Manchester Royal Infirmary
New Stobhill Hospital, NHS Greater Glasgow & Clyde
New Victoria Infirmary, Glasgow Greater Glasgow & Clyde
North Cumbria University Hospitals, Carlisle
Royal Infirmary of Edinburgh
Sunderland Royal (University Hospital of North Durham)
Taunton Satellite Dialysis Unit, Devon
The Royal London Hospital