CSA Group

Z364.5-17

Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting

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Contents

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Preface

This is the second edition of CSA Z364.5, *Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting.* It supersedes the previous edition, published in 2010.

Home hemodialysis and peritoneal dialysis (home dialysis) are installed and carried out through a variety of practices. While the basic requirements are fundamentally similar among organizations, the methodology varies. This Standard has been developed to provide nephrology personnel with a Standard for improving the quality of home hemodialysis and peritoneal dialysis treatment and providing expert guidance to Canadians undergoing these treatments.

The major differences between this edition and the previous edition include

a) moving quality management content to the new CSA Group Standard Z364.6; and
b) updates to current practices and health record requirements for home dialysis.

CSA Group acknowledges that the development of the second edition of this Standard was made possible, in part, by the financial support of Charles River, Baxter, and Mar Cor Purification, as well the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Québec, Saskatchewan, and Yukon as administered by the Canadian Agency for Drugs and Technologies in Health (CADTH).

This Standard was prepared by the Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the Technical Committee on Kidney Dialysis and the Strategic Steering Committee on Health Care Technology & Systems, and has been formally approved by the Technical Committee.

Notes:

1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*
2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*
3) *This Standard was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*
4) *To submit a request for interpretation of this Standard, please send the following information to* ***inquiries@csagroup.org*** *and include "Request for interpretation" in the subject line:*
   a) *define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;*
   b) *provide an explanation of circumstances surrounding the actual field condition; and*
   c) *where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.*

   Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*
5) *This Standard is subject to review within five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to* ***inquiries@csagroup.org*** *and include "Proposal for change" in the subject line:*
   a) *Standard designation (number);*
   b) *relevant clause, table, and/or figure number;*
   c) *wording of the proposed change; and*
   d) *rationale for the change.*

Z364.5-17
Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting

0 Introduction

Since the introduction of home hemodialysis and peritoneal dialysis (home dialysis) to Canada more than thirty years ago, these technologies have developed into an increasingly important treatment option for clients with renal disease. The benefits of home dialysis for the client are many and include greater flexibility and convenience, more time with family, a greater sense of independence and control, fewer transportation issues, fewer admissions to hospital, and mounting evidence of improvements in long-term clinical outcomes.

Although in most cases home dialysis is taking place safely, it has become apparent that, as the number of Canadians needing renal replacement therapy grows, the industry needs a common home dialysis Standard to provide consistent requirements and practices. While the basic set-up requirements are fundamentally similar among dialysis providers, the methodology varies, and as a result the outcomes can be inconsistent. This Standard was developed to resolve these inconsistencies and improve the use of best practices across Canada.

1 Scope

1.1

This Standard specifies requirements for the safe installation and operation of hemodialysis and peritoneal dialysis performed in a home setting. It is intended for use by dialysis providers, including health care workers and professionals who perform technical and operational functions associated with home dialysis, as well as stakeholders who have an interest in safety or related quality assurance (e.g., professional associations, regulators, and consumers).

This Standard is intended to provide a comprehensive, integrated, and consistent management framework to ensure that a completed home dialysis set-up and its major systems meet the necessary technical and operational requirements. The major systems covered include

a) quality management;
b) home assessment;
c) physical space requirements;
d) plumbing requirements;
e) water requirements;
f) electrical requirements;
g) supply storage and waste management;
h) emergency preparedness;
i) client and caregiver training; and
j) documentation and records.

1.2
This Standard is not intended to apply to hemodialysis or peritoneal dialysis performed in a hospital or a regional dialysis clinic setting, or a long-term care facility.

1.3
In this Standard, “shall” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the Standard; “should” is used to express a recommendation or that which is advised but not required; and “may” is used to express an option or that which is permissible within the limits of the Standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

2 Reference publications
This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below, including all amendments published thereto.

CSA Group

C22.1-15
Canadian Electrical Code, Part I

Z32-15
Electrical safety and essential electrical systems in health care facilities

Z364.6-17
Quality management for kidney dialysis providers

Z1600-14
Emergency and continuity management program

CAN/CSA-ISO 11663:15
Quality of dialysis fluid for haemodialysis and related therapies

CAN/CSA-ISO 13958:15
Concentrates for haemodialysis and related therapies

CAN/CSA-ISO 13959:15
Water for haemodialysis and related therapies

CAN/CSA-ISO 26722:16
Water treatment equipment for haemodialysis applications and related therapies

ESA (Electrical Safety Authority)

Ontario Electrical Safety Code — Bulletin 24-7-4, Issued May 2016
Dialysis units located in residential occupancies — Rule 24-106

Health Canada

Good Manufacturing Practices (GMP) Guidelines (2009)
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0001-eng.php

Workplace Hazardous Materials Information System (WHMIS)
http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php

Other publications

Lancaster, K. 2001. Planning a curriculum and learning programme. In M. Meyer, et al., eds., *ETD practices in South Africa.* Durban: Butterworths.

3 Definitions

The following definitions shall apply in this Standard:

Accessory equipment (electrical) — additional equipment used in a medical treatment procedure (e.g., an infusion pump).

Air gap — an unobstructed vertical space ensuring that there is no physical connection between a fluid outlet and a drain.

Aseptic technique — practices designed to reduce the number and transfer of pathogens.

Battery backup power equipment — equipment providing electrical power to medical equipment during a power outage or when power from a local electrical utility is not available.

Caregiver — an individual responsible for meeting the physical, medical, and psychological needs of a dependent person (i.e., a home dialysis client). The caregiver can be a related or unrelated person.

Cleanliness — the absence of dirt (e.g., dust, stains, and garbage) and dirt-related odours.

Clotting — the transformation of blood from a liquid into a soft, semi-solid, or solid mass.

Note: *Clotting can be shown by the inability of a solidified mass of blood to flow freely in tubing or by an inability to remove dark red coloration from a dialyzer.*

Concentrate — a mixture of electrolytes and/or compounds that, when diluted with dialysis water in the ratio listed on the concentrate label, yields dialysis fluid.

Continuous ambulatory peritoneal dialysis (CAPD) — a form of continuous peritoneal dialysis.

Continuous cycling peritoneal dialysis (CCPD) — a form of intermittent peritoneal dialysis.

Dialysis fluid — aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during dialysis.

Notes:

1) *The term "dialysis fluid" is used throughout this Standard to mean fluid made from dialysis water and concentrates that is delivered to a dialyzer by a dialysis fluid delivery system. In this Standard, "dialysis fluid" is used to refer to what is alternatively called "dialysate", "dialysis solution", or "dialyzing fluid".*