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# **Quality management for kidney dialysis providers**

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# Preface

This is the first edition of CSA Z364.6, *Quality management for kidney dialysis providers*. It is the core Standard in a series of CSA Group Standards for a quality management system (QMS) for kidney dialysis processes and equipment.

The function of a QMS is to establish consistency in, and control of, required processes and documentation in order to provide quality products and services. The main audience of this Standard comprises health care providers involved in kidney dialysis services, and the users and clients of the dialysis service.

CSA Group acknowledges that the development of this Standard was made possible, in part, by the financial support of Charles River, Baxter, and Mar Cor Purification, as well as 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](mailto: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](http://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](mailto: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.*

# Z364.6-17

## ***Quality management for kidney dialysis providers***

### **1 Scope**

#### **1.1**

This Standard is intended to form the basis of a QMS within a health care or home setting for the purpose of providing safe, reliable kidney dialysis treatments.

**Note:** *A comprehensive QMS can be achieved when this Standard is used in combination with the following related Standards:*

- a) CAN/CSA-C22.2 No. 60601-1;
- b) CAN/CSA-C22.2 No. 60601-2-16;
- c) CAN/CSA-C22.2 No. 60601-2-39;
- d) CAN/CSA-ISO 8637;
- e) CAN/CSA-ISO 8638;
- f) CAN/CSA-ISO 11663;
- g) CAN/CSA-ISO 13958;
- h) CAN/CSA-ISO 13959;
- i) CAN/CSA-ISO 26722;
- j) CAN/CSA-Z364.1.3;
- k) CAN/CSA-Z23500;
- l) CSA Z364.2.1; and
- m) CSA Z364.5.

#### **1.2**

As part of a QMS, this Standard includes requirements for

- a) quality management, including
  - i) policies and procedures;
  - ii) documentation;
  - iii) roles and responsibilities;
  - iv) management review;
  - v) personnel qualifications and training; and
  - vi) adverse event management (e.g., recalls);
- b) occupational health and safety;
- c) evaluation and purchase of dialysis equipment and medical devices;
- d) infection prevention and control;
- e) work areas and equipment;
- f) environmental conditions; and
- g) utilities (e.g., power supply and water quality).

#### **1.3**

This Standard applies to health care or home settings where kidney dialysis therapies occur, including but not limited to

- a) hospital dialysis centres;

- b) regional dialysis clinics;
- c) trauma centres;
- d) emergency care facilities;
- e) medical clinics, with or without overnight stay or observation;
- f) nursing homes;
- g) long-term care facilities;
- h) assisted-living facilities;
- i) mental health facilities;
- j) rehabilitation facilities;
- k) chronic care facilities;
- l) group homes;
- m) hospice care facilities;
- n) stand-alone dialysis clinics; and
- o) client homes.

## 1.4

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

CAN/CSA-C22.2 No. 60601-1:14

*Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

CAN/CSA-C22.2 No. 60601-2-16:14

*Medical electrical equipment — Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration, and haemofiltration equipment*

CAN/CSA-C22.2 No. 60601-2-39:09 (R2014)

*Medical electrical equipment — Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment*

CAN/CSA-ISO 8637:12 (R2017)

*Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*