CSA Group

Z7000-18
National Standard of Canada

General requirements for quality management and safety in perioperative settings

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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 to judge its suitability for their particular purpose.

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Preface

This is the first edition of CSA Z7000, *General requirements for quality management and safety in perioperative settings*.

CSA acknowledges that the development of this Standard was made possible, in part, by the financial support of 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 Technical Committee on Perioperative Safety under the jurisdiction of the Strategic Steering Committee on Health Care Technology, and has been formally approved by the Technical Committee.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

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.*
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   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.*

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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.*

Z7000-18
General requirements for quality management and safety in perioperative settings

0 Introduction

0.1

Perioperative environments are found in the traditional acute care hospital, but are also increasingly common in a variety of health care organizations (HCOs) including but not limited to

a) surgical centres;
b) vision correction centres;
c) physician's offices;
d) dental offices; and
e) education centres (e.g., dental, ophthalmology).

0.2

The perioperative environment contains numerous hazards that can affect the safety of patients, personnel, and visitors. The types of risk specific to the perioperative environment can include but are not limited to

a) biological;
b) ergonomic;
c) physical; and
d) psychosocial.

This Standard provides strategies and guidance for safety within the perioperative environment.

0.3

This Standard introduces new language related to quality management systems (QMS). QMS is a framework for establishing policies and standard operating procedures (SOPs), management accountability, and occupational health and safety (OHS) — including psychological health — with the goal of promoting a safer working environment. These policies and SOPs are based on several inputs, including government regulations, national standards, and the specific requirements that make up the quality system of the individual HCO. All health care professionals and ancillary personnel are responsible for following safety policies and SOPs. This responsibility includes identifying, reporting, and resolving any safety hazards.

To lead and manage a safe perioperative environment, it is necessary to adopt a systematic and transparent approach. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing a perioperative environment in an HCO encompasses quality management along with other management strategies.

1 Scope

1.1

This Standard includes requirements for establishing a quality management system (QMS) that addresses safety of patients, personnel, families, vendors, third parties, and visitors in a perioperative environment including requirements for

a) establishing a QMS;
b) occupational health and safety (OHS);
c) policies and standard operating procedures (SOPs), clinical practice standards, and documentation;
d) personnel qualifications and training;
e) work areas and equipment;
f) infection prevention and control;
g) evaluation and purchase of medical devices; and
h) management and prevention of patient safety incidents.

1.2

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 amendments published thereto.

CSA Group

CAN/CSA-C22.2 No. 60601 series
Medical electrical equipment

Z305.13-13
Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings

Z314 (under development)
Canadian medical device reprocessing

CAN/CSA-Z317.2-15
Special requirements for heating, ventilation, and air-conditioning (HVAC) systems in health care facilities