CANADIAN STANDARDS ASSOCIATION

Z902-09

Blood and blood components

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CSA Standards Update Service

Z902-09
November 2009

Title: *Blood and blood components*
Pagination: 115 pages (x preliminary and 105 text), each dated **November 2009**

To register for e-mail notification about any updates to this publication

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CSA Standard

Z902-09
Blood and blood components

Published in November 2009 by Canadian Standards Association
A not-for-profit private sector organization
5060 Spectrum Way, Suite 100, Mississauga, Ontario, Canada L4W 5N6
1-800-463-6727 • 416-747-4044

100%

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ISBN 978-1-55491-297-1
Technical Editor: *Jeffrey Kraegel*

Contents

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Preface

This is the second edition of CSA Z902, *Blood and blood components.* It supersedes the first edition, published in 2004.

This Standard was prepared by the Technical Committee on Blood and Blood Components, 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 approved as a National Standard of Canada by the Standards Council of Canada.

November 2009

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 publication 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 publication.*

(4) *CSA Standards are subject to periodic review, and suggestions for their improvement will be referred to the appropriate committee.*

(5) *All enquiries regarding this Standard, including requests for interpretation, should be addressed to Canadian Standards Association, 5060 Spectrum Way, Suite 100, Mississauga, Ontario, Canada L4W 5N6.*

Requests for interpretation should

(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) be phrased where possible to permit a specific "yes" or "no" answer.

Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are published in CSA's periodical* Info Update*, which is available on the CSA Web site at www.csa.ca.*

Z902-09
Blood and blood components

0 Introduction

This Standard has been prepared to maintain and enhance the safety, efficacy, and quality of blood collection, storage, processing, and transfusion. The requirements set out in this Standard are the minimum criteria for acceptable performance and may be exceeded in practice. It should be noted that activities covered within this Standard can also be subject to federal, provincial, territorial, or local laws and regulations.

This Standard is not intended to replace detailed specifications and operating procedures; rather, the principles and criteria outlined in this Standard should be used in maintaining and preparing specifications and operating procedures.

Throughout this Standard, the term "blood component" refers to a therapeutic component of blood intended for transfusion (e.g., red cells, granulocytes, platelets, plasma) that can be prepared using conventional blood bank methodology. Such methods may include centrifugation, filtration, or freezing. The term "blood and blood components" comprises whole blood along with blood components, as described in this paragraph.

This Standard was developed by a balanced Technical Committee that includes health care professionals as well as representatives of the federal, provincial, and territorial governments, user groups, and blood centres. In developing this Standard, the Technical Committee extensively consulted equivalent standards in Canada and other jurisdictions, including the American Association of Blood Banks' *Standards for Blood Banks and Transfusion Services* and the Canadian Society for Transfusion Medicine's *Standards for Hospital Transfusion Services*. Differences from these standards, where they occur, represent the Technical Committee's decisions based on Canadian practice and current scientific knowledge.

1 Scope

1.1

This Standard provides management requirements for facilities that collect, process, store, and use human blood and blood components for transfusion. It addresses issues of safety, efficacy, and quality for recipients, safety of donors, management of blood and blood components, and safety of facility personnel and others who are exposed to or potentially affected by blood and blood components.

1.2

This Standard applies to blood centres and transfusion services and to any other organization that collects, processes, stores, or uses human blood or blood components for transfusion.

1.3

As a management standard, this Standard is not intended to replace detailed specifications and operating procedures; rather, it is intended for use in their preparation. It includes requirements for policies and procedures, quality management, personnel, physical plant, and equipment. In addition, this Standard outlines specific requirements to be included in the facility's operating procedures for the following activities:

(a) donor selection for allogeneic blood collection;
(b) collection of blood and blood components for transfusion;
(c) preparation of blood components;
(d) testing and labelling of blood and blood components;

(e) release, storage, packing, and transportation;
(f) requests, pre-transfusion testing, selection of components, and acceptance criteria;
(g) transfusion;
(h) autologous blood collection and transfusion;
(i) apheresis donation;
(j) transfusion service responsibilities regarding blood products used in the facility;
(k) directed donations and designated donations;
(l) walking donor programs;
(m) home transfusion;
(n) adverse event monitoring and corrective action;
(o) removal of unsafe components and donors from the blood supply;
(p) record management; and
(q) validation and maintenance of computer systems.

1.4

This Standard does not include requirements for activities associated with
(a) the collection of source plasma; and
(b) the processing, manufacture, or commercial distribution of plasma derivatives and related blood products, including solvent detergent plasma.

Note: *Source plasma is covered under the* Food and Drug Regulations *for human plasma collected by plasmapheresis (i.e., Sections C.04.400 through C.04.423, Division 4, Part C).*

1.5

In CSA Standards, "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

Note: *A bibliography is provided in Annex A.*

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 (Canadian Standards Association)

CAN/CSA-C22.2 No. 60601-1-08
Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

Z317.10-09
Handling of waste materials in health care facilities and veterinary health care facilities

Government of Canada

Food and Drugs Act, Chapter F-27 of the Revised Statutes of Canada, 1985

Food and Drugs Regulations, Chapter 870 of the Consolidated Regulations of Canada, 1978

Part C (Drugs), Division 1A, Establishment Licensing