CANADIAN STANDARDS ASSOCIATION

CAN/CSA-Z902-10

A National Standard of Canada

Blood and blood components

Standards Council of Canada
Conseil canadien des normes

Legal Notice for Standards

Canadian Standards Association (CSA) standards are developed through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document's fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party's intellectual property rights. CSA does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA makes no representations or warranties regarding this document's compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA is a private not-for-profit company that publishes voluntary standards and related documents. CSA has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA and the users of this document (whether it be in printed or electronic form), CSA is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA's and/or others' intellectual property and may give rise to a right in CSA and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by licence or by law, CSA reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:
- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF format.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to
- alter this document in any way or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.

CANADIAN STANDARDS ASSOCIATION

CSA Standards Update Service

CAN/CSA-Z902-10
February 2010

Title: *Blood and blood components*
Pagination: 116 pages (x preliminary and 106 text), each dated **February 2010**

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

- go to **www.ShopCSA.ca**
- click on **E-mail Services** under **MY ACCOUNT**
- click on **CSA Standards Update Service**

The **List ID** that you will need to register for updates to this publication is **2020704**.

If you require assistance, please e-mail **techsupport@csa.ca** or call 416-747-2233.

Visit CSA's policy on privacy at **www.csagroup.org/legal** to find out how we protect your personal information.

The Canadian Standards Association (CSA), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities.

CSA standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

Individuals, companies, and associations across Canada indicate their support for CSA's standards development by volunteering their time and skills to CSA Committee work and supporting the Association's objectives through sustaining memberships. The more than 7000 committee volunteers and the 2000 sustaining memberships together form CSA's total membership from which its Directors are chosen. Sustaining memberships represent a major source of income for CSA's standards development activities.

The Association offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, the Association regularly and continually audits and inspects products that bear the CSA Mark.

In addition to its head office and laboratory complex in Toronto, CSA has regional branch offices in major centres across Canada and inspection and testing agencies in eight countries. Since 1919, the Association has developed the necessary expertise to meet its corporate mission: CSA is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

For further information on CSA services, write to
Canadian Standards Association
5060 Spectrum Way, Suite 100
Mississauga, Ontario, L4W 5N6
Canada

CANADIAN STANDARDS ASSOCIATION

The Standards Council of Canada (SCC) is the coordinating body of the National Standards System, a coalition of independent, autonomous organizations working towards the further development and improvement of voluntary standardization in the national interest.

The principal objects of the SCC are to foster and promote voluntary standardization as a means of advancing the national economy, benefiting the health, safety, and welfare of the public, assisting and protecting the consumer, facilitating domestic and international trade, and furthering international cooperation in the field of standards.

A National Standard of Canada (NSC) is a standard prepared or reviewed by an accredited Standards Development Organization (SDO) and approved by the SCC according to the requirements of CAN-P-2. Approval does not refer to the technical content of the standard; this remains the continuing responsibility of the SDO. An NSC reflects a consensus of a number of capable individuals whose collective interests provide, to the greatest practicable extent, a balance of representation of general interests, producers, regulators, users (including consumers), and others with relevant interests, as may be appropriate to the subject in hand. It normally is a standard which is capable of making a significant and timely contribution to the national interest.

Those who have a need to apply standards are encouraged to use NSCs. These standards are subject to periodic review. Users of NSCs are cautioned to obtain the latest edition from the SDO which publishes the standard.

The responsibility for approving standards as National Standards of Canada rests with the
Standards Council of Canada
270 Albert Street, Suite 200
Ottawa, Ontario, K1P 6N7
Canada

Standards Council of Canada
Conseil canadien des normes

Cette Norme nationale du Canada est offerte en anglais et en français.

National Standard of Canada

CAN/CSA-Z902-10
Blood and blood components

Prepared by

CANADIAN STANDARDS ASSOCIATION

Approved by
Standards Council of Canada

Published in February 2010 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

The Canadian Standards Association (CSA) prints its publications on Rolland Enviro100, which contains 100% recycled post-consumer fibre, is EcoLogo and Processed Chlorine Free certified, and was manufactured using biogas energy.

To purchase CSA Standards and related publications, visit CSA's Online Store at ***www.ShopCSA.ca*** *or call toll-free 1-800-463-6727 or 416-747-4044.*

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

Contents

Technical Committee on Blood and Blood Components

G. Delage	Héma-Québec, Saint-Laurent, Québec	*Chair*
J.L. Freedman	St. Michael's Hospital, Toronto, Ontario	*Vice-Chair*
F. Agbanyo	Blood, Tissues, Organs and Xenografts Division, Centre for Biologics Evaluation, Ottawa, Ontario	*Associate*
R. Berger	Blood Advisory Group, Niagara Falls, Ontario	
H. Dunlop	Blood, Tissues, Organs and Vaccines Division, Office of Regulatory Affairs, Ottawa, Ontario	*Associate*
N. Garneau	Ministère de la Santé et des Services Sociaux, Québec, Québec	
M. Hamilton	Department of Health Acute and Tertiary Care, *Representing CBS — P/T Blood Liaison Committee*	
N. Heddle	Transfusion Research Program McMaster University, Hamilton, Ontario *Representing CBS — P/T Blood Liaison Committee*	
H. Hume	Canadian Blood Services, Ottawa, Ontario	
C. Hyson	Blood Safety Surveillance and Health Care Acquired Infections Division, Centre for Communicable Diseases and Infection Control, Ottawa, Ontario	*Associate*
D. Lepine	Medical Devices Bureau In Vitro Diagnostic Devices, Ottawa, Ontario	*Associate*
J. Lobo-Dale	Office of Policy and International Collaboration, Ottawa, Ontario	*Associate*
A. Maguire	Canadian Society for Transfusion Medicine, Kamloops, British Columbia *Representing Canadian Society for Transfusion Medicine*	
G. Nayeri	BTOX Compliance Unit, Compliance, Enforcement and Coordination Division, Ottawa, Ontario	

S. O'Brien	Canadian Blood Services, Ottawa, Ontario	
D. Page	Canadian Hemophilia Society, La Durantaye, Québec	
G. Polnicky	Blood, Tissues, Organs and Xenografts Division Centre for Biologics Evaluation, Ottawa, Ontario	
S. Rémy	Héma-Québec, Saint-Laurent, Québec	
K. Robinson	Marketed Biologicals, Biotechnology and Natural Health Products Bureau, Ottawa, Ontario	*Associate*
G. Rock	Canadian Hematology Society, Ottawa, Ontario	
M. Silva	American Association of Blood Banks, Encino, California, USA	*Associate*
L. Stevens	Neutropenia Support Association, Winnipeg, Manitoba	
M. Tang	Office of Policy and International Collaboration, Ottawa, Ontario	*Associate*
M. Tremblay	Héma-Québec, Saint-Laurent, Québec	
T. Walker	Canadian Blood Services, Ottawa, Ontario	
J. Kraegel	Canadian Standards Association, Mississauga, Ontario	*Project Manager*

Preface

This is the second edition of CAN/CSA-Z902, *Blood and blood components.* It supersedes the first edition, published in 2004. This Standard is intended to ensure that the critical elements and methods of blood safety, efficacy, and quality are incorporated into facility procedures.

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.

February 2010

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.*

CAN/CSA-Z902-10
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;