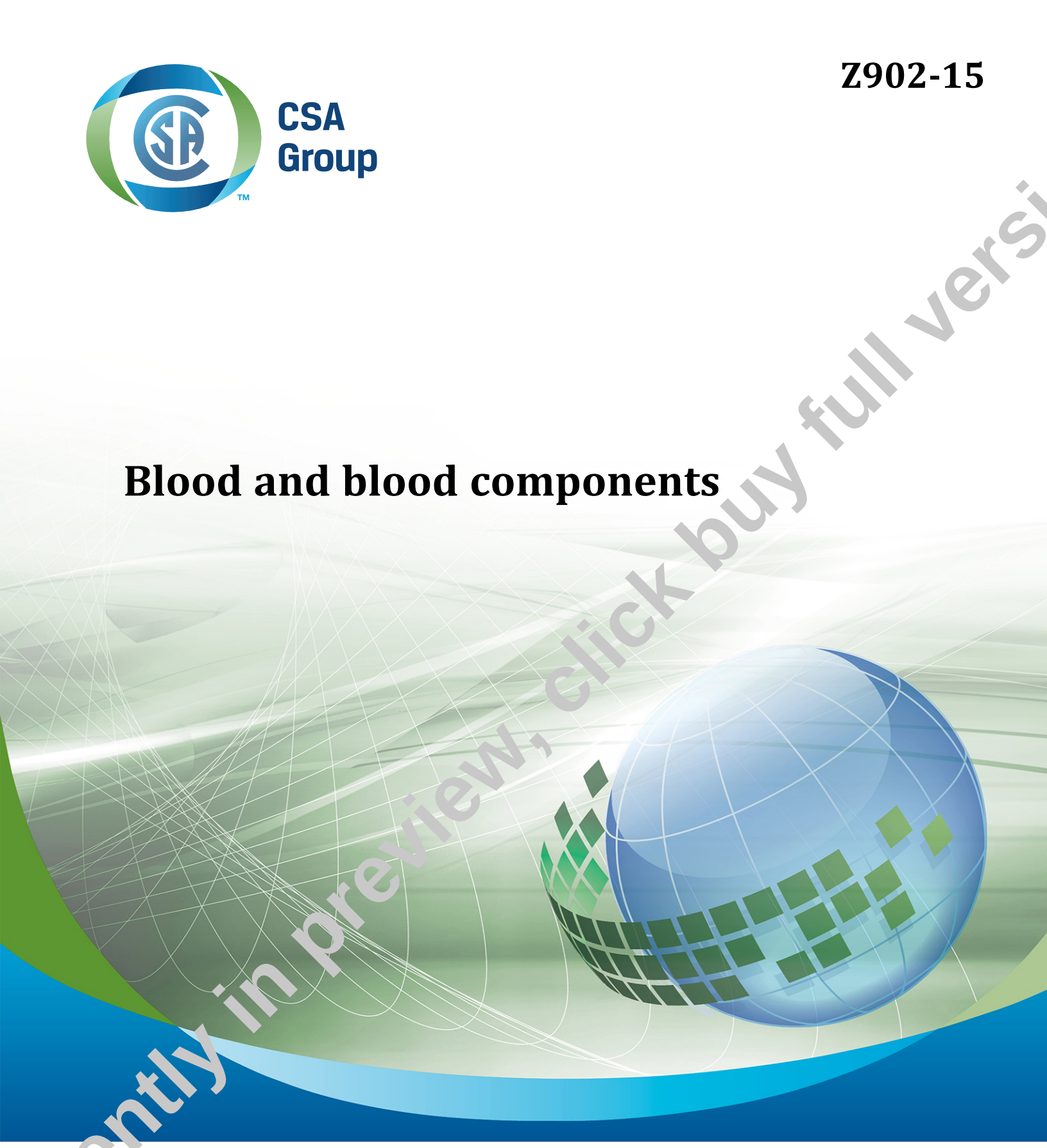
Z902-15

Blood and blood components



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Blood and blood components

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Preface

This is the third edition of CSA Z902, *Blood and blood components.* It supersedes the previous editions published in 2010 and 2004.

See Annex A for a list of major changes to this edition.

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.

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 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.*

Z902-15
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. Additional national and international standards may be used to specific activities or functions within a health care facility, for example ISO 15189.

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, freezing, or other means of separating out the desired component. The term is also applied to whole blood.

Although this Standard centres on blood components, it is recognized that some hospital transfusion services also manage blood products as part of their responsibilities. Starting with the second edition, this Standard has included requirements for transfusion services that manage blood products so that procedures are appropriately consistent between the two types of blood-derived materials. For a facility or department that manages blood products but not blood components, such as a hospital pharmacy, the requirements of this Standard may be used as a reference in developing procedures for the management of blood products.

This Standard was developed by a Technical Committee representing a balance of interests that include 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 components for transfusion. It addresses issues of safety, efficacy, and quality for recipients, safety of donors, management of blood components, and safety of facility personnel and others who are exposed to or potentially affected by 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 components for transfusion.

1.3

It also includes requirements for the storage and use of blood products, when such products are within the responsibility of on organization that is covered by this Standard.

Note: *While this Standard does not specifically apply to organizations that manage blood products but not blood components (e.g., a hospital pharmacy), these organizations are encouraged to review the relevant requirements for blood products and incorporate them as appropriate into their procedures.*

1.4

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 components for transfusion;
c) preparation of blood components;
d) testing and labelling of 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;

   Note: *This Item refers to blood products that are managed directly through the transfusion service, as opposed to those managed by other services, e.g. the pharmacy.*

k) directed donations and designated donations;
l) pre-assessed 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.

1.5

This Standard does not include requirements for activities associated with

a) the collection of plasma for use in the manufacture of plasma products; and
b) the processing, manufacture, or commercial distribution of blood products, including solvent detergent plasma.

Note: *Plasma for use in the manufacture of a drug for human use is covered under the* Blood Regulations*.*

1.6

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

Z317.10-15
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

Nuclear Safety and Control Act (1997, c.9)

Health Canada

Blood Regulations, SOR/2013-178, 2013-10-23

Guidance Document: Blood Regulations, Health Products and Foods Branch, 2014-05-12

Blood Establishment Licence Amendment Requirements for Information Technology Submissions. Biologics and Genetic Therapies Directorate. October 2002.

Guideline for Investigation of Suspected Transfusion Transmitted Bacterial Contamination. Canada Communicable Disease Report (CCDR). Supplement, Vol. 34S1, January 2008.

Infection Control Guidelines: Handwashing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report (CCDR). Supplement, vol. 24S8, December 1998.

Medical Devices Regulations, SOR/98-282

Other publications

American Association of Blood Banks

Standards for Blood Banks and Transfusion Services, 29th ed. 2014.

