

Disclaimer for Documents Released to TraQ

Disclaimer for Provincial Laboratory Quality Manual Model Documents and for Transfusion Medicine Operations Manual documents: Process Maps, Procedures and Training & Competence templates

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The process maps and Training & Competence templates are the result of input and review by British Columbia Transfusion Medicine technical specialists, but may contain errors or omissions for which the BC Provincial Blood Coordinating Office is not liable.

The Provincial Laboratory Quality Manual Model Documents are the result of the work and review of British Columbia Laboratory Quality Managers, working as members of the Quality Management Working Group. Work was coordinated and facilitated by the Provincial Laboratory Coordinating Office (PLCO) and the BC Provincial Blood Coordinating Office (PBCO).

These documents must be reviewed, customized and validated prior to use in the user's organization.

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Background

Documents

Provincial Laboratory Quality Manual Model Documents Ver 1.0

Released	April 1, 2007
Developed by	A working group of British Columbia (BC) laboratory quality managers Representatives from all BC Health Authorities, and from both the public and private sector Quality Management Working Group (QMWG)
Facilitated by	Provincial Laboratory Coordinating Office Provincial Blood Coordinating Office Lucia Berte, consultant
Goal	Develop model documents that could be used by all laboratories in BC to write a facility specific laboratory quality manual
Basis of Model	Clinical and Laboratory Standards Institute (CLSI)¹ guidelines: HS1-A2 (Second Edition) GP26-A3(Third Edition) Standard: ISO 15189 Medical laboratories – Particular requirements for quality and competence 2003-07-15

Provincial Standardized Technical Operations Manual Verification Drafts to be Reviewed, Customized and Validated by User

Released	December 2006
Developed by	A network of blood transfusion technical specialists Representatives from all BC Health Authorities Compliance Working Group (CWG)
Facilitated by	Provincial Blood Coordinating Office Lucia Berte, consultant
Goal	Develop a CAN/CSA Z902-04 compliant transfusion medicine operations manual to provide optimal practice procedures that could be used in different service levels of facilities across a region.

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Basis of Model CLSI guidelines¹:

HS1-A2 (Second Edition)
GP26-A3 (Third Edition)
GP2-A4 (Fourth Edition)
GP21-A2 (Second Edition)

Standards:

CAN/CSA Z902-04 Standards for Blood and Blood
Components
ISO 15189 Medical laboratories – Particular requirements
for quality and competence 2003-07-15

Other Documents

TraQ manual and Competency Companion
Facility SOPs
Technical references
Manufacturer's package inserts

¹ Current versions of the guidelines can be purchased from CLSI at:

Title: GP02-A5 (Electronic Document) Laboratory Documents: Development and
Control

Publication Date: 03/14/2006

Edition: Fifth Edition

Click [here](#) for more detail on this document

Title: GP21-A3 (Electronic Document) Training and Competence Assessment

Publication Date: 02/05/2009

Edition: Third Edition

Click [here](#) for more detail on this document

Title: GP26-A3 (Electronic Document) Application of a Quality Management System
Model for Laboratory Services

Publication Date: 11/20/2004

Edition: Third Edition

Click [here](#) for more detail on this document

Title: HS01-A2 (Electronic Document) A Quality Management System Model for
Health Care

Publication Date: 11/20/2004

Edition: Second Edition

Click [here](#) for more detail on this document

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The Development Model

Lucia Berte facilitated the paradigm shift that organized the work of both working groups to a single quality management model. Both groups followed a common model, with common language, and focus.

The CLSI model proposes that work is done in a sequential path, from process to process, and from procedure to procedure within a process. The rules of work are the policies, and they are linked to the step in a procedure where they occur. Work is supported by the quality management system. The quality management system is organized into 12 elements, called the quality system essentials (QSEs). The QMWG focused on the high level policies for the quality management system for a laboratory. The CWG focused on the QSE of Process Control, specifically organizing Transfusion Medicine work as processes, then writing procedures for those processes, and embedding policies into procedures. Training and Competence packages were developed for each process. In some cases, single procedures had a Direct Observation Checklist developed.

This work is a massive paradigm shift from the existing one of large SOPs with many subsections of critical information hidden in notes or sections at the beginning or end of the actual work. Procedures have been written as work instructions that begin immediately, and do not include training information. Training and Competence is a separate section of the laboratory quality system, located within the Personnel QSE. "If/Then" tables were used to enable clear organization and speedy retrieval of information for the user. Procedures that occurred in more than one process were called "Common Procedures" that were subdivided into 3 categories. The team did not develop policies, processes and procedures that are part of the daily lab operations, such as Maintenance, Daily QC or Work-station Setup procedures.

Lucia Berte presented some of the work produced by the CWG in the AABB publication: *Transfusion Service Manual, 2nd Edition, Lucia Berte (author)*. The book explains the rationale behind the change and information related to the development of the documents.

These documents are linked to a profound culture change that must occur for sustainability of this work. We highly recommend that you read the referenced CLSI guidelines to provide background and assistance as you develop these documents.

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The following documents are included:

Provincial Laboratory Quality Manual	Model documents for high-level policies for each of the 12 CLSI QSEs	
For each Transfusion Medicine Laboratory process: Verified Drafts to be reviewed, customized and validated by the user	Process map Associated procedures for each process Associated Training and Competence package for each process Master Log of Questions for T&C (Excel workbook with separate worksheet per process)	
(organized by document type, then by process)		
"The Rules"	CWG Styleguide 2006 Flowchart Symbols Flowchart Rules	
Templates	Process	Lab Process Legend Visio Process Template Word Process Template
	Procedure	Computer Template Computer Procedure Writer Job-aid General Procedure General Procedure Writer Job-aid Procedure tracking List (Blank)
	Training and Competence	Training and Competence Terms /Glossary 12 T&C templates
	Quality Manual	Policy Template