

Diagnostic Accreditation Program

**ACCREDITATION STANDARDS**

Document Control

Copyright © 2024 by the Diagnostic Accreditation Program and the College of Physicians and Surgeons of British Columbia.

All rights reserved. No part of this publication may be used, reproduced or transmitted, in any form or by any means electronic, mechanical, photocopying, recording or otherwise, or stored in any retrieval system or any nature, without the prior written permission of the copyright holder, application for which shall be made to:

Diagnostic Accreditation Program  
College of Physicians and Surgeons of British Columbia  
300-669 Howe Street  
Vancouver BC V6C 0B4

The Diagnostic Accreditation Program and the College of Physicians and Surgeons of BC has used their best efforts in preparing this publication. As websites are constantly changing, some of the website addresses in this publication may have moved or no longer exist.

## Introduction

Document control involves managing and implementing processes to ensure the accuracy and appropriate use of documents. The term “document” in this context refers to paper or electronic media that provides the service with guidance or instructions, including, but not limited to, policy statements, procedures and related job aids, instructions for use, protocols, procedures, manuals, and standard operating procedures.

Document management and document control incorporates the approval, distribution, identification and routine review of documents.

## Document control

No.	Description	Risk	Reference	Change
<b>DOC1.0</b>	<b>THE SERVICE DEFINES AND MAINTAINS PROCEDURES TO CONTROL DOCUMENTS.</b> <i>Guidance: In this context, "documents" can be policy statements, procedures and related job aids, instructions for use, protocols, procedures, manuals, standard operating procedures, etc. Documents can be in any form or type of medium, such as hard copy or digital.</i>			New
<b>DOC1.1</b>	<b>The service defines and maintains document control procedures.</b>			New
DOC1.1.1	<b>M</b> Documents (internal and external) which are related to the provision of service are controlled. <i>Guidance: In this context, "documents" can be policy statements, procedures and related job aids, instructions for use, protocols, procedures, manuals, standard operating procedures, etc. Documents can be in any form or type of medium, such as hard copy or digital.</i>	L	ISO-15189	New
DOC1.1.2	<b>M</b> Documents include a unique identification.	L	ISO-15189	New
DOC1.1.3	<b>M</b> Documents include a current revision date or version.	L	ISO-15189	New
DOC1.1.4	<b>M</b> Documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy.	L	ISO-15189	New
DOC1.1.5	<b>M</b> Documents are periodically reviewed and updated as necessary.	L	ISO-15189	New
DOC1.1.6	<b>M</b> Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled.	L	ISO-15189	New
DOC1.1.7	<b>M</b> Documents are protected from unauthorized changes and any deletion or removal.	L	ISO-15189	New
DOC1.1.8	<b>M</b> Documents are protected from unauthorized access.	L	ISO-15189	New
DOC1.1.9	<b>M</b> Unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.	L	ISO-15189	New
DOC1.1.10	<b>M</b> Handwritten amendments to documents indicate an entry date and the identification of the individual.	L		New

No.	Description	Risk	Reference	Change
DOC1.1.11	<p><b>M</b> Handwritten amendments to documents do not exceed six months since entry date.</p> <p><i>Guidance: Documents are re-issued to include the amendments, as authorized.</i></p>	L		New
<b>DOC1.2</b>	<b>There are mechanisms to communicate changes to documents.</b>			New
DOC1.2.1	<p><b>M</b> New or revised documents are communicated to staff.</p> <p><i>Guidance: In this context, "documents" can be policy statements, procedures and related job aids, instructions for use, protocols, procedures, manuals, standard operating procedures, etc. Documents can be in any form or type of medium, such as hard copy or digital.</i></p>	H		New
DOC1.2.2	<p><b>M</b> The communication of documents is recorded.</p>	M		New

## References

Abbreviation	Reference
ISO-15189	International Standards Organization, ISO 15189 Medical laboratories - Requirements for quality and competence, Geneva, Switzerland: ISO; 2022 Fourth edition.