

## Book review: “A Practical Guide to ISO 15189 in Laboratory Medicine”

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### REVIEWED BOOK

***“A Practical Guide to ISO 15189  
in Laboratory Medicine”***

by David Burnett

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### RECENSION

Laboratory accreditation is still optional in many countries but it is increasingly the path that many have volunteered to take. The ultimate beneficiary of accreditation is the patient who is the ultimate end-user of the laboratory, since the reliability of results is assured with it. Reliable results in turn contribute to patient safety and effective treatment.

This book is yet another contribution from that well known authority on laboratory accreditation, David Burnett and is a successor to his previous publications, “Understanding Accreditation in Laboratory Medicine” in 1996 and, “A Practical Guide to Accreditation in Laboratory Medicine” in 2002. The author has indicated that this will be his “third and final book”. It is primarily intended as a guide for laboratory professionals seeking to implement or renew accreditation that uses the ISO 15189:2012 standard. It should also be useful to auditors working for accreditation bodies. While other standards for the clinical laboratory, exist the ISO 15189 has been recommended by the IFCC.

This easily readable book is more than a manual for accreditation. The opening chapter is a description of the ISO 15189 standard and this is followed by one on defining and managing quality in the medical laboratory. In subsequent chapters due attention is given to organisation and management, personnel, accommodation, environmental conditions and safety.

The actual testing process is covered in three chapters, beginning with a chapter on equipment, reagents, consumables and external services. This is followed by chapters on pre- and post-examination processes and the quality of examination results. The book is replete with diagrams and tables which makes it easy to read. However, though pre-analytical errors may constitute up to 75% of laboratory errors (1), they receive a scant 18 pages of attention.

There are three useful appendices. The first is on “The ‘Ideal Standard’ and ISO 15189:2012” which is an index to the clauses of these standards and the chapters in which they are discussed. The next appendix provides some sample pages from the Quality Manual of a fictional hospital while the last appendix is a bibliography of for each chapter of the book and includes several online references.

The book is comprehensive in its coverage of the subject. Yet one is left to wonder if more could have been done. Though it discusses hazards and risk management in terms of the immediate environmental and personnel of the laboratory, the book does not address the wider impact to the environment of the laboratory’s

activities. While this topic may not be within the remit of the ISO 15189 standard, Burnett would have done us a great service had he devoted a small section to the environmental impact of laboratories and how it could be incorporated into overall quality management. This is but a suggestion and is not meant to be a criticism of what is otherwise a very useful textbook on accreditation.

A check with Google reveals that there are not many books on the ISO 15189 standard. It is usually a challenge for those new to accreditation to understand and interpret the technical jargon of manuals (the more familiar word “test”, for example, is replaced with the all-encompassing “examination” which is usually used for histopathology) which require subtlety and appreciation of nuance. Hence, there is a need for clearly written guides for the implementation of this standard. This book is an answer to that need.

## REFERENCE

1. Plebani M. Quality Indicators to Detect Pre-Analytical Errors in Laboratory Testing. *Clin Biochem Rev.* 2012; 33: 85–88.