

Using **ISO 9001** *in* **HEALTHCARE**

Applications for Quality Systems, Performance Improvement,
Clinical Integration, Accreditation, and Patient Safety

Second Edition



James M. Levett, MD and Robert G. Burney, MD

Using ISO 9001 in Healthcare, Second Edition

Also available from ASQ Quality Press:

ISO 9001:2008 Explained, Third Edition

Charles A. Cianfrani, Joseph J. Tsiakals, and John E. (Jack) West

ISO 9001:2008 Internal Audits Made Easy: Tools, Techniques, and Step-By-Step Guidelines for Successful Internal Audits, Third Edition
Ann W. Phillips

*Root Cause Analysis and Improvement in the Healthcare Sector:
A Step-by-Step Guide*

Bjørn Andersen, Tom Natland Fagerhaug, and Marti Beltz

*A Lean Guide to Transforming Healthcare: How to Implement Lean Principles
in Hospitals, Medical Offices, Clinics, and Other Healthcare Organizations*
Thomas G. Zidel

The ASQ Pocket Guide to Root Cause Analysis

Bjørn Andersen and Tom Natland Fagerhaug

The Quality Toolbox, Second Edition

Nancy R. Tague

The Certified Six Sigma Green Belt Handbook

Roderick A. Munro, Matthew J. Maio, Mohamed B. Nawaz,
Govindarajan Ramu, and Daniel J. Zrymiak

*The Certified Manager of Quality/Organizational Excellence Handbook,
Fourth Edition*

Russell T. Westcott, editor

The Certified Six Sigma Black Belt Handbook, Second Edition

T.M. Kubiak and Donald W. Benbow

The ASQ Auditing Handbook, Fourth Edition

J.P. Russell, editor

*The Internal Auditing Pocket Guide: Preparing, Performing, Reporting and
Follow-up, Second Edition*

J.P. Russell

Root Cause Analysis: Simplified Tools and Techniques, Second Edition

Bjørn Andersen and Tom Fagerhaug

To request a complimentary catalog of ASQ Quality Press publications, call
800-248-1946, or visit our Web site at <http://www.asq.org/quality-press>.

Using ISO 9001 in Healthcare, Second Edition

Applications for Quality Systems,
Performance Improvement,
Clinical Integration, Accreditation,
and Patient Safety

James M. Levett, MD
Robert G. Burney, MD

ASQ Quality Press
Milwaukee, Wisconsin

American Society for Quality, Quality Press, Milwaukee, WI 53203
© 2014 by ASQ
All rights reserved. Published 2014.
Printed in the United States of America.

19 18 17 16 15 14 13 5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

Levett, James M., 1949-

Using ISO 9001 in healthcare: applications for quality systems, performance improvement, clinical integration, accreditation, and patient safety / James M. Levett, MD, Robert G. Burney, MD.

pages cm

Includes bibliographical references and index.

ISBN 978-0-87389-885-0 (hardcover: alk. paper)

1. Medical care—Standards. 2. Medical care—Quality control. 3. Total quality management. I. Burney, Robert G., 1936- II. Title.

RA399.A1L48 2014

362.1068—dc23

2014006620

No part of this book may be reproduced in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher.

Acquisitions Editor: Matt T. Meinholz

Managing Editor: Paul Daniel O'Mara

Production Administrator: Randall Benson

ASQ Mission: The American Society for Quality advances individual, organizational, and community excellence worldwide through learning, quality improvement, and knowledge exchange.

Attention Bookstores, Wholesalers, Schools, and Corporations: ASQ Quality Press books, video, audio, and software are available at quantity discounts with bulk purchases for business, educational, or instructional use. For information, please contact ASQ Quality Press at 800-248-1946, or write to ASQ Quality Press, P.O. Box 3005, Milwaukee, WI 53201-3005.

To place orders or to request ASQ membership information, call 800-248-1946. Visit our Web site at www.asq.org/quality-press.

♾ Printed on acid-free paper



Quality Press
600 N. Plankinton Ave.
Milwaukee, WI 53203-2914
E-mail: authors@asq.org

The Global Voice of Quality™

Dedication

*This book is again dedicated to all healthcare providers
who are striving to improve our delivery system.*

(This page intentionally left blank.)

Contents

<i>List of Figures and Tables</i>	<i>xi</i>
<i>Foreword</i>	<i>xiii</i>
<i>Preface</i>	<i>xvii</i>
<i>Acknowledgements</i>	<i>xix</i>
<i>Introduction</i>	<i>xxi</i>
Chapter 1 Quality Management Systems in Healthcare: What Are They and Why Are They Useful?	1
The Process Approach	2
Building the System	3
Managing the Key Processes	4
Improving the Key Processes	5
Putting It Together: The Quality Management System	6
The Value of a Quality Management System	7
Additional Features of a QMS	8
Chapter 2 Background and Introduction to the ISO Family of Standards	9
Overview and Key Tenets of ISO 9001	10
Principles for Healthcare	11
Individual Standards	14
Customer Focus	19
Summary	21

Chapter 3 Practical Aspects of Setting up a Quality Management System: How-to-do-it	23
Choosing a Registrar	23
Management/Leadership Commitment	24
Writing a Quality Policy, Quality Manual, and Quality Objectives	25
Identifying and Mapping Key Processes	26
Establishing a Controlled Document System	30
Writing Procedures	34
Auditing	35
Staff and Physician Involvement and Education	35
Chapter 4 ISO and the Culture of a Healthcare Organization ..	41
Understanding and Defining Culture	41
Why Culture Matters	44
Assessing the Culture	45
Establishing a Culture	46
ISO 9001 as a Culture	49
Chapter 5 Incorporating Quality Tools and Techniques into an ISO QMS	51
ISO and Other Systems	51
Incorporating Tools	52
Malcolm Baldrige National Quality Award	54
Lean	55
Six Sigma	57
Other Tools	58
Summary	58
Chapter 6 Clinical Integration and Care Coordination Facilitated by a Quality Management System	59
Start Simple: Align a Few Key Documents/Processes	59
Other Components of Clinical Integration	61
Specific Features of the ISO 9001 Standard Related to Clinical Integration	62
Barriers to Clinical Integration	63
Care Coordination	64
Summary	66

Chapter 7 Using ISO 9001 as the Foundation for a Performance Improvement System	67
The ISO 9001 Standard and Performance Improvement	67
Using an ISO QMS to Support Data Collection for the Physician Quality Reporting System (PQRS)	69
The ISO QMS and the Balanced Scorecard/Strategy Map	73
Patient Safety and Reporting	75
Risk Assessment	76
Meaningful Use	78
Chapter 8 Experience with ISO 9001 in a Multi-specialty Clinic	81
ISO 9001 Background and Requirements	81
ISO Implementation and Costs	82
Cost Savings Attributed to ISO Implementation	84
Community Benefits of ISO Implementation	87
Additional Clinic Benefits of ISO Implementation	88
Summary	90
Chapter 9 ISO 9001 at the State Department	91
The Setting	91
The Beginning	92
The Decision	93
The Journey	94
Success	95
The Future	96
Fast Forward	97
Moving it Overseas	98
Summary	98
Chapter 10 Experience with ISO 9001 in Healthcare Organizations	99
Accreditation Standards	99
Enter ISO 9001	99
Hospitals	100
Recognizing the Problem	101
A New Paradigm	101
Rehabilitation Facilities	103
Advantages of ISO 9001	104

Chapter 11 Utilization of ISO 9001 Concepts in Community and Hospital Settings to Enhance Clinical Care and Patient Safety	107
Community Anticoagulation Therapy (CAT) Clinic and the Cedar Rapids Healthcare Alliance	107
A Lean Project for the Community	110
Health Information Exchanges: The Future of Healthcare IT	114
Patient Safety Organizations and Patient Safety Evaluation Systems	115
AHRQ Common Formats	118
ISO 9001 as a Framework for Accountable Care Organizations and Population Health Management	119
Moving Toward a Quality System at the Community Level	123
Appendix Case Study: Hospitals and ISO 9001	125
History	125
Results	127
Summary	127
<i>Index</i>	129

List of Figures and Tables

Figure 1.1	The process approach	2
Figure 1.2	Mission, vision, values, and strategy	3
Figure 1.3	Defining the key processes	4
Figure 1.4	Managing the key processes	4
Figure 1.5	Improving the key processes	5
Figure 1.6	The PDCA cycle	6
Figure 1.7	The quality management system	7
Figure 2.1	Interaction of key processes with other aspects of the management system	16
Table 3.1	Healthcare service delivery processes	27
Table 3.2	Healthcare support processes	28
Figure 3.1	Clinical patient flow, process 1	29
Figure 3.2	Clinical patient flow, process 2	30
Figure 3.3	Document example 1	31
Figure 3.4	Document example 2	32
Figure 3.5	Components of a controlled document system	33
Table 3.3	ISO 9001:2000 matrix of responsibility	36
Table 5.1	Seven types of waste	55
Table 5.2	A simple table to track patient stay in recovery room	58
Figure 6.1	Comparison of the registration processes at a hospital and a clinic	60
Table 6.1	Components of clinical integration related to features of the ISO 9001 QMS	61
Figure 7.1	PCI document of 2014 PQRS perioperative measures	70
Figure 7.2	Medical Group of the Upper Midwest strategy map	74
Table 7.1	Risk assessment of Medical Group of the Upper Midwest	77
Figure 8.1	PCI days in accounts receivable	84
Figure 8.2	PCI purchasing process	85
Figure 8.3	PCI workers' compensation claims	86
Figure 8.4	SIP orthopedic indicators in Cedar Rapids	88
Figure 8.5	PCI clinical patient flow process	89

Figure 11.1	An anticoagulation clinic document in ISO format	108
Figure 11.2	Common healthcare processes	111
Figure 11.3	Developing a community “system of care”	112
Table 11.1	Comparing ISO 9001 and population health management principles	120
Figure 11.4	A quality management system for population health	122
Figure 11.5	A community healthcare quality system	124

Foreword

Plus ça change, plus c'est la même chose. (The more things change, the more they stay the same).

It has now been several years since the publication of the first edition of this book. In the interim we have witnessed the problematic roll out of the Affordable Care Act (ACA), the near complete shut-down of the United States government with its sequester activity, and the rise (and perhaps fall) of the accountable care organization (ACO). Also in that time patient safety has only marginally improved and we have learned that the way we collect, validate, and analyze data about hospital acquired infections (HAIs) is seriously flawed.¹ In addition, the billions of dollars spent by the federal government and others on “healthcare improvement projects” has resulted in precious few tangible and measureable results in true quality improvement and waste/cost reductions in healthcare.

Why are we in this dark place despite having the benefit of Drs. Levett and Burney’s well thought out, proven approach to healthcare quality improvement in their first edition of this book?

It may be because decision making with regard to healthcare quality and cost reduction in the United States is still dominated by those shackled to the centuries old “medical model” of thinking. Their emphasis seems to be on the clinical dimension of quality in healthcare; it either doesn’t recognize or diminishes the importance of the other dimensions of healthcare quality such as operations, culture, and financial measures. It is as if they view healthcare quality as being dependent only on clinical performance. Given the backgrounds of those influencing quality decisions in healthcare at the national and institutional levels, this is not surprising. Quite simply, it is what they know best. Sadly, however, their approach seems to come close to meeting a definition of insanity typically attributed to Einstein: “The definition of insanity is doing the same thing over and over again and expecting different results.”

Drs. Levett and Burney, to their credit, are keenly aware of the trend in healthcare away from its roots as a cottage industry (where the “Captain of the Ship” rule applied) toward the new reality of healthcare as a corporate enterprise with resulting and necessary changes in the cultures, values, and methods of those in charge at all levels and a much greater awareness of and reliance upon systems thinking to identify and overcome the problems healthcare faces.²

With this new orientation, it seems likely that those with operational, cultural, and fiscal responsibilities for the delivery of high-quality, cost-efficient, and consumer-acceptable healthcare will begin to adopt and master the techniques and quality systems that have made it possible for other industries and service organizations worldwide to make stunning advances in products, services, and organizational culture.

Such are the universal systems and tools discussed and described in great detail in this book: the general concepts of a quality management system and the ISO 9000 family of standards. I believe them to be even more applicable and relevant today than when the first edition of this book was published. Healthcare organizations of any type that are compliant with these standards are effectively deploying process improvement tools such as statistical process control, Lean, and Six Sigma while also changing their values, beliefs, and cultures to maximize their ability to provide world-class services and products in accordance with customer demand. In truth, in order to succeed in the “new-order healthcare system,” each organization will have to embark on a continuous journey to improve its quality, processes, and culture. Healthcare organizations, being “complex adaptive systems,” will have to adopt and utilize the systems approach to survive and flourish.³

Unfortunately, the positive culture shift to continuous improvement and systems thinking in healthcare has been slow to develop. Hospitals and healthcare organizations in the main are still relying on older, less current models for quality improvement and cost reduction and on having those who have always done “quality” continue to do it. It is a rare healthcare institution that advertises for a professional-level quality engineer to manage its quality department, preferring instead someone with clinical credentials and some training in Lean. The result is much like that of a coach who knowingly leaves his younger, more talented and credentialed “first string” players on the bench, preferring instead to field those better known to the fans.^{4,5}

Drs. Burney and Levett have provided in-depth explanations of the theory and science behind these systems while at the same time citing practical examples from their own experiences of the necessary considerations, methodologies, metrics, successes, failures, and benefits attendant to the use of the ISO 9001 quality management system.

In essence they have, in this work, achieved the following goals and objectives:

- They have made the case exquisitely for the adoption of ISO in healthcare.
- They have made a strong case for its effectiveness in sustainably changing the culture in healthcare to one of continuous improvement.
- They have demonstrated how it can be used effectively to address some of the most serious challenges we face in healthcare: marginally and slowly improving patient safety, controlling runaway healthcare costs complicated by perennial and pervasive waste, and improving consistently poor population health outcomes as compared to other industrialized countries.
- They have skillfully acknowledged that ISO is a foreign concept (language) for healthcare providers.
- They have effectively taught us by example how ISO can be and is being implemented.
- And finally, they have explained the likely detrimental consequences of not engaging in its use. As time has gone on, one such potential consequence could be financial insolvency for the United States!

We are, indeed, indebted to these two pioneers for skillfully and understandably bringing this methodology for effective, needed, and sustainable change to healthcare.

Almost ten years ago, the Institute of Medicine (IOM) and the National Academy of Engineering (NAE) published the third in a series of Institute of Medicine reports on the sorry state of our healthcare system.⁶ This report noted that “a real impact on quality, efficiency and sustainability of the health care system can be achieved only by using health care delivery engineering.” Although this report was all but ignored, I believe that Drs. Burney and Levett have reminded us of the importance of utilizing the kinds of quality tools and systems described in the IOM-NAE recommendation and that we should all join in thanking them!

*Joseph A. Fortuna, MD
CEO, Prism, Michigan, USA and
Chair, ASQ Healthcare Division*

References

1. J.A. Fortuna, W.A. Brenneman, S. Storli, D. Birnbaum, and K. L. Brown, "The Current State of Validating the Accuracy of Clinical Data Reporting: Lessons to Be Learned from Quality and Process Improvement Scientists," *Infection Control and Hospital Epidemiology* 34(6): 611-614, June 2013.
2. J.C. Robinson., "The Corporate Practice of Medicine," *California/Milbank Books on Health and the Public*, ISBN: 9780520220768, 1999.
3. J.W. Begun, B. Zimmerman, and K. Dooley, "Health Care Organizations as Complex Adaptive Systems," chapter published in: S.M. Mick and M. Wytenbach (eds.), *Advances in Health Care Organization Theory*, pp. 253-288, 2003.
4. J. Fortuna, K. Merrill, M. Hones-Burr, C. Elm, R. Munro, H. Shay, and B. Sherman, "The ASQ Healthcare Division Marshall Plan: Put Me In The Game, Coach!" *The Quality Management Forum*, 39(4): 4-6, Winter 2014.
5. J. Fortuna, K. Merrill, M. Hones-Burr, C. Elm, R. Munro, H. Shay, and B. Sherman, "The ASQ Healthcare Division Marshall Plan: Put Me In The Game, Coach!" *The Quality Management Forum*, 39(4): 1-27, Winter 2014. <http://asqhcd.org/wp-content/uploads/2014/01/MarshallPlanArticleFinalASOF1-13-14.pdf>
6. P.P. Reid, W.D. Compton, J.H. Grossman, and G. Fanjiang (eds.) *Building a Better Delivery System: A New Engineering/Health Care Partnership*. National Academy of Engineering and Institute of Medicine: National Academies Press, 2005.