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Six Sigma Quality Design and Control

SECOND EDITION

James O. Westgard, PhD

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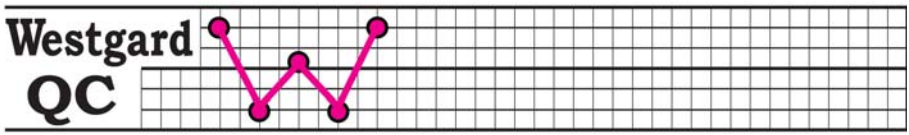

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Preface to the Second Edition

The principle of continuous improvement applies to quality management itself. The 1st edition of this book was published in 2001, when Six Sigma Quality Management was just becoming known in healthcare. At the time of this edition, there has been considerable progress in large commercial laboratories, but there is still much work to be done in most healthcare laboratories.

Six Sigma sets a quantitative goal for process performance – the tolerance limits for a product should encompass 6-sigmas of process variation. Such performance provides products that will have only a few defects per million opportunities. Low defects means high quality and low cost because there is no need for re-testing, no follow-up testing, no complaints from customers, and no time and effort needed to service those complaints!

The goal of this book is to help both manufacturers and laboratories apply the principles of Six Sigma Quality Management to the design, improvement, and control of quality of diagnostic tests. Many of you know that this isn't my first attempt to provide guidance and advice on matters of quality. This has been my life's work, as I recount in Chapter 1. And while quality means doing it right the first time, I admit that it has taken until this book to finally get the ***right approach*** with the ***right tools and technology*** at the ***right time***.

The right approach is Six Sigma! The important concepts and principles are presented in Chapters 2 and 3, adapted to analytical quality management for laboratories in Chapters 4 and 5, and forged into processes for quality design and control in Chapter 6. The 2nd edition adds a new quality design tool – the Sigma Metrics Graph – that makes it easy to get started with the selection of the right QC procedures for application in your laboratory.

The right tools and technology are described in Chapters 7 through 10. The description begins with graphical attributes of the chart of operating specifications, or OPSpecs chart. The structure of the underlying mathematical models is developed qualitatively in Chapter 8 and quantitatively in Chapter 9. Computer technology that supports the OPSpecs design tool is illustrated in Chapter 10. Not everyone will want to go through all the details and theory behind the tools and technology, but it's important for you to understand that there is a scientific basis, a quantitative framework, and a practical computer program to support your applications.

The right time is now, as demonstrated by application of the quality design and control processes to “hot” areas of laboratory testing and interest in Chapters 11-15. These applications consider complex situations, such as multi-test automated analyzers, cardiac markers for point-of-care testing, neonatal screening, and patient data for monitoring the stability of analytical systems. These applications illustrate the use of both analytical and medical tolerance limits in the form of allowable total errors and clinical decision intervals, respectively.

The illustrations of medical tolerance limits, or clinical quality requirements, are the best feature of this book and go beyond any previous applications. The ability to drive the quality design and control process directly from the test interpretation guidelines makes the concept of medical usefulness a reality. The tools and technology make it a practicality.

Finally, the last section on "Obstacles and Opportunities" has been greatly expanded to consider some important issues that may influence the success of our work in the laboratory today. Quality in healthcare is a major concern today, yet there are many competing interests that may become obstacles to our pursuit of quality. Management is always looking for the latest trends, often with little follow-through to complete earlier programs. Analytical quality is not trendy and it is often thought that problems in this area have been solved. Quality control itself has been downplayed (some may say dumbed down) by the latest US government regulations that allow laboratories to reduce QC from daily to weekly or even monthly QC (the so-called "equivalent QC" options). Cost, of course, continues to be a major concern in healthcare today and continues to take priority over quality, even though the costs of poor quality may not be recognized or understood. Quality must start with top management and that means the very top of the healthcare organization and also the top of our government. (The last chapter on Quality Leadership Today gets political – fair warning.)

Readers of our “basics” series – Basic Method Validation, Basic QC Practices, and Basic Planning for Quality – will find that this book starts where the previous works leave off. All the concepts and principles carry over, but this treatment is more advanced and makes use of advanced computer technology, rather than manual tools. Basic Planning is not a prerequisite, but it certainly is helpful and complementary.

Acknowledgments

As with our previous books, my son Sten makes it possible to develop these materials and bring them to publication. He sets a schedule that keeps new materials coming for our website and for hardcopy publications. When the first edition of Six Sigma was published, Sten and his wife Jill had just delivered a production of their own – their first child and my first grandchild, Maren Jane Westgard. Now that the second edition of Six Sigma is here, Sten and Jill, as well as my daughter Kris and her husband Gordon, have enriched our lives even more: there are now *four* grandchildren in the family, including Linnea Solbrit, Henry Nolan, and Alexander George. Grandchildren have brought real meaning to the idea that quality means exceeding customer expectations. Being a grandfather far exceeds all my expectations.

I continue to have much help and support from my wife Joan. She has her own antique business, Pieces of Time, but she always finds time for me and Westgard QC. We trade time, and it's certainly quality time. What more could be better!

A special thank you to Carmen Ricos for allowing us to include her table of biologic goals and calculated biologic total errors. And also to Robert Kennedy, who developed the computer programs illustrated in this book. EZ Rules® 3 particularly owes its user interface to Robert's idea for making Validator® easier to operate for the user who is not a QC specialist.

James O. Westgard
Madison, Wisconsin

Author's Note:

I have spent the last 30 years of my career advocating the improvement of quality control in the healthcare laboratory. During that time, I've discovered that it's not enough to talk about the need for quality improvement; people need tools and techniques to make improvements. So I developed statistical tools to help identify poor quality control practices and I also developed planning processes to guide quality improvements. Then I discovered it wasn't enough to demonstrate those quality improvement tools; people needed these tools to be practical, fast, and easy to use. So I collaborated with others on the creation of software that automated the tools and techniques and provided a simple, graphic interface for users. Even then, I discovered that having the theory and tools and software wasn't enough; people need a quick and convenient way to learn and access these things. So I started publishing books, offering online courses, and posting articles on the Internet.

Throughout this book, you'll see that I mention Westgard QC products. You may be tempted to say this book is therefore commercially biased. I admit to several biases: I am biased against the "status quo" compliance mentality of current QC practices in healthcare. I am biased against the idea that we should abandon statistical QC for unproven, less capable QC techniques. I am biased against the short-sighted, short-term impulse to slash costs in every area of healthcare laboratories and eliminate any investment in quality control. These very biases, and my unwillingness to accept the decline of quality control practices, led me to found a company that would create products to enable and enhance the improvement of quality control.

I'm happy to admit that I'm proud of every book that has been published by Westgard QC and that I'm proud of all the software packages we've released. In the text, where possible, I note some of the other products available on the market that provide the same quality improvement tools or techniques. In many cases, however, there is no other software or book out there on the market – for instance, our software may remain the only software in the world that provides automatic QC selection for quite some time. I look forward to the day when this market is crowded with competitors and I have to provide a third edition of this book.

Table of Contents

Metrics and Methods

Tools and Technology

Application Strategies

Obstacles and Opportunities

Appendices

Talking about Quality

About the Author

James O. Westgard, PhD, is a Professor in the Department of Pathology and Laboratory Medicine at the University of Wisconsin Medical School, where he teaches in the Clinical Laboratory Science program. He is the Faculty Director of Quality Management Services at the Clinical Laboratories, University of Wisconsin Hospital and Clinics. He is also President of Westgard QC, Inc.

A complete profile of him is available at
http://www.westgard.com/jimbio.htm

Talking about Quality

There isn't a single laboratory, hospital, company, or manufacturer that doesn't claim to have *excellent* quality. And no one disagrees with the concepts of quality, quality design, quality improvement, and quality control. So why is it so hard to get people to *improve* quality? Isn't everyone in healthcare concerned about quality assurance, trained in quality control, and working on quality improvement? Doesn't the healthcare organization have a high profile Quality Assurance Program? Isn't the laboratory inspected and accredited?

And yet healthcare isn't a quality experience. What happened on your last visit to your doctor, clinic, or hospital? Was your appointment on-time, or did they just move you from one waiting room to a smaller waiting room at the actual time of your appointment? It's almost like airline departures – it's officially considered "on-time" if you leave the gate at the listed time of departure. When you actually leave the ground doesn't matter to them.

The truth is that quality can be a difficult fight in healthcare organizations. What people say and what people do are not always consistent. There's a saying amongst fast-food restauranteurs: "People talk fit and eat fat." While the news is replete with fad diets and health warnings and the shelves are full of low-fat, no-fat foods, the incidence of obesity in Americans is still rising at a frightening rate. In the same vein, every company in business projects the image that they are working hard at quality, but behind the mask, they are often hardly working at quality at all. They're just *talking* about quality – they're *doing* nothing about it.

That's the point of these short discussions on "Talking about Quality." As you read through the book, we're going to analyze, dissect and dispel much of the common "talk" about quality. And we're going to show how **you can DO quality.**

Talking about Quality: "But we're different!"

Whatever your business, company, or institution, we're all organizations of people who have missions to accomplish. Quality management has to do with planning the activities of our people to achieve the mission of our organization.

If we are different, it's only that the quality of medical services is *more* important than the quality of most other goods and services! Customer expectations and requirements are higher for healthcare services. The need for quality is greater. The need for better quality management is paramount!

A close analogy to the workings of a healthcare organization is "just in time" (JIT) industrial production, where a component is produced or delivered just-in-time for assembly. There is no inventory of materials because inventory itself represents waste in materials, space, time, etc. JIT forces the highest level of quality because there is no room for mistakes or errors. If an item or service is not satisfactory, the whole process comes to a stop. JIT demands quality.

In healthcare organizations, every patient is an individual with special problems that must be diagnosed and treated. The process requires highly individualized treatment. On the basis of one finding, often a laboratory test, another procedure is required – now, immediately, just-in-time for diagnosis and treatment. The delivery of healthcare demands the highest level of quality and the most advanced quality management system.

How can healthcare organizations NOT implement Six Sigma? Six Sigma provides a universal methodology for characterizing process performance in terms of defects and defect rates. Right now healthcare organizations have no measure of the quality of their processes, in spite of JCAHO, CQI, IOP, ORYX, and other ineffective acronyms.

1: Quality in the new millennium

When we hit the *official* start of the new millennium, the year 2001, we reached an interesting milestone. I'm not the first one to tell you that it was the same year as Stanley Kubrick's film *2001: A Space Odyssey*. This seminal film (and novel by Arthur C. Clarke) came out in 1968 and had an extraordinary vision of the year 2001. Kubrick and Clarke predicted:

- Space travel would be so commonplace it would be run by traditional airlines like Pan Am.
- Space stations would be large and there would be numerous manned bases on the moon.
- Computers would become so powerful, so advanced, that they could reason, conspire, and even have nervous breakdowns.

Our year 2001 didn't quite fulfill those expectations.

- Pan Am is no longer around and our airlines are a disaster, at least for the traveler.
- We have a space station (just barely) but space travel is a rare event and a contentious political issue.
- We have not returned to the Moon since the Apollo landings. Few people in 1968 – in the heat of the US Space Program – would have believed that once we reached the Moon, we would turn our back on it. But we did.
- Computers have indeed grown quite powerful, complex, and widespread, but true artificial intelligence has not been achieved – unless you interpret the propensity of some computers to crash at critical moments as an evil form of sentience.

I have to admit that in 1968 I was too busy to pay any attention to Clarke's book or Kubrick's film. I had just finished graduate school at the University of Wisconsin in January 1968 and was

beginning my first job as a Clinical Chemist at the University of Wisconsin Hospital. I finished my studies at the end of the first semester and needed a temporary job while my wife completed her teaching year in the Madison Public School system.

Having been trained to do research, I never doubted I had that capability. But, I didn't know whether or not I had the skills to do practical and useful work. To me, that was the biggest challenge that I had to demonstrate to myself. The University reminded me that I also had to demonstrate *academic excellence* and I was told that I should "write down some of the things" I was learning and doing. To that end, I began to write about method evaluation and quality control. I'm still writing about those subjects, which demonstrates that I'm still learning some new things and better ways of doing them.

I will also admit that I had no intention of staying at the University for these thirty-some years. It just happened that the clinical laboratory was the ideal workplace to apply my training in analytical chemistry, the work was truly satisfying, and also very challenging.

Laboratory 1968

I began as a Clinical Chemist in February 1968. The first wave of laboratory automation was in progress – Technicon AutoAnalyzers and multichannel systems were being installed for as many of the tests as possible. One of the first computer information systems was being developed in our laboratory, therefore we were one of the few laboratories that had online data acquisition. It was a new world of automation and computerization!

Clinical laboratories were at the beginning of a long period of growth and development, but it was very difficult to maintain staffing – not unlike the period we are entering today. What differed was that we had no problem getting the hospital administration to provide us with new positions. The problem was that we could never keep our positions fully staffed. There was a shortage of Medical Technologists and a high turnover in staff.

Emergency medicine was beginning to develop. Physicians who served in the Vietnam War were beginning to provide more aggressive emergency room treatments. The first blood gas instruments appeared, making it possible to provide critical laboratory tests that were of much value in emergency services. Micro analyses were also improving, which increased the demand for services for pediatrics and neonates. Renal dialysis and kidney transplantation were becoming significant services at our hospital. All of these led to increased demand for stat tests and around the clock service.

Up till this time, most after-hours service was provided by a few senior technologists, usually the laboratory supervisors. As the demand for after-hours chemistry tests grew, we established "call programs" to provide 24 hour service. Within another year or two, we had to establish full-time staffing for 24 hour service in clinical chemistry. Night positions were, of course, not very desirable hours for most people, and we had to staff those positions with the least senior personnel, usually new Medical Technologists and Medical Laboratory Technicians.

Quality issues

Given the changes in technology, the increased demands for services, and the difficulty in maintaining adequate staffing, the quality of laboratory tests was a big concern. Dr. Roy Barnett, a clinical pathologist at Norwalk Hospital, was the leading authority on quality management in laboratory testing. Barnett published his first recommendations on the medical significance of laboratory tests in 1968 [1] and a landmark paper on method validation in 1970 [2]. Quantitative techniques for analytical quality management were just beginning to be used.

My first job assignment was to evaluate the performance of a new Technicon multichannel analyzer. This was the beginning of a long learning experience about experimental approaches and statistical techniques for method validation studies [3,4]. Of course, once a method was evaluated and implemented, then statistical QC became a big concern. My life's work lay before me, though I didn't know it at the time.

Quality management principles

By 1974, I had enough practical experience and common sense to formulate the management approach that I thought was needed to maintain a high-quality service laboratory. Working with Marion Hunt, who was the Chief Technologist in the Clinical Chemistry laboratory, we wrote the paper that has defined my life's work. That paper, **Quality is everyone's job** [5], describes the philosophy and approach to quality management that has guided me throughout my career. The paper is not well-known because it was published in a "throw-away" journal, so I'll provide a summary of some of the principles here. You'll see that many of these principles are as valid today as they were thirty years ago.

Commit to quality as a management strategy:

- To achieve quality, it is necessary to view quality management as a system that permeates all activities in the laboratory.
- Management's commitment to quality is central to the whole system.
- Management must communicate the goals to the analysts and must be willing to share the responsibilities with the analysts.
- If management encourages quality, well-qualified and conscientious people will provide quality, in spite of obstacles that may confront them.

Put everyone to work on quality:

- The laboratory should permit each analyst to contribute to the development and maintenance of the quality system; one approach is specific method or instrument responsibilities.
- It is essential that each technologist understand the QC system and that its purpose is to help him/her perform their work.
- Each technologist must understand that the most important response to an "out-of-control" indicator is to question the validity of the laboratory results.

Focus on processes and process improvement:

- Careful selection of methodology and instrument systems and proper standardization is essential to institute methods, or processes, which have a chance of providing reliable results.
- When a problem is identified, a solution must be implemented to achieve acceptable performance.

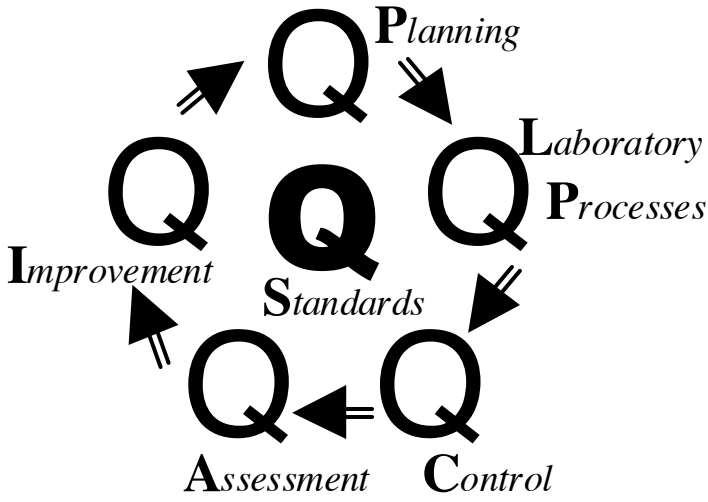
Institute on-the-job education and training:

- The in-service training program provides a mechanism for change that can be used to institutionalize process improvements.
- Through in-service training and careful and periodic evaluation of personnel, the laboratory can maintain the capabilities of each analyst.
- In-service training is the mechanism for providing the transfer of new methods from method validation to routine operation.

Although the outline we developed in the early 70s needs to be expanded to include new problem solving mechanisms and tools, the principles still apply today.

Development of a Quality Management Process

Over the years, we have continued working on these ideas. At the time we developed our approach, Total Quality Management (TQM) was popular, so we called our approach a TQM process. Today, the fads and terminology have changed, even though the fundamentals haven't. We still need a process that adapts quality management principles for practical implementation in a laboratory. This quality management process can be pictured (as shown on the following page). It identifies the important components as quality laboratory processes, quality control, quality assessment, quality planning, and quality goals [6].



Quality Laboratory Processes (QLP) define how the work gets done. This includes all the policies and procedures by which the laboratory prescribes the detailed operation of any work process.

Quality Control (QC) refers to the statistical QC that is commonly used in laboratories to monitor the routine performance of testing processes, detect possible errors, and correct problems before test results are reported.

Quality Assessment (QA) provides broader monitoring of laboratory performance, including such characteristics as the adequacy of patient preparation, validity of specimens, satisfactory turnaround times, etc.

Quality Improvement (QI) provides the mechanism to determine the root causes of the problems identified by QC and QA. A team problem-solving model is often needed, along with tools such as flow charts, data collection sheets, Pareto charts, cause and effect diagrams, force field analysis, etc. [7,8].

Quality Planning (QP) is concerned with establishing and validating processes that meet customer needs.

Quality Goals (QG) represent the customer needs defined in both qualitative and quantitative terms.

Implementation of a Quality Management System is a huge undertaking in any laboratory. Here's where education and training become so important for making quality everyone's job [9,10].

Analytical Quality Management

These principles can also be applied directly to the management of the analytical quality of laboratory testing processes. Analytical testing processes are still the core processes in any laboratory! It's absolutely critical that the test results meet the quality requirements of the physicians who order the tests and the patients whose very existence may depend on those test results.

I've worked on "generic" quality management principles for laboratory management, as well as the specific application of those principles to analytical testing processes. An early adaptation of the principles was described in the book *Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes*, which was published in 1986 [11]. The theme of that book is Deming's premise that improvements in quality lead to improvements in productivity and reductions in cost [12]. Experimental studies later documented that thesis in an application for laboratory tests performed on a multitest clinical chemistry system [13,14].

The quality-planning process that was applied to analytical testing processes has since been further improved by the development of new graphic tools and computer technology, eventually resulting in the efficient quality-planning process now available in *Basic Planning for Quality* [15] and in this book, in an even more advanced form.

Laboratory 2006

Laboratories today are in the midst of many changes, much like when I started in clinical chemisty in 1968. Mergers at all levels have had a profound effect on how the laboratory functions today. There has been an explosion of new methods, instruments, and technology. A severe shortage of qualified clinical laboratory scientists has again occurred. An unrelenting focus on profit and the bottom line has made quality seem like an "extra" instead of a fundamental. All this and much, much more has happened.

Perhaps the main difference between 1968 and 2006 is that while quality is still a concern in the laboratory, the reason is different. Back in 1968, we were just beginning to develop the tools and techniques needed to manage quality. Today we have many of the tools and even the technology to manage quality in a better way. However, in 2006, many laboratories pay little attention to quality management, instead assuming that all that quality stuff has been dealt with and we can move on to newer things, like Evidence-Based Medicine, bench-marking, international quality standards, pay-for-performance, etc. The truth is, since the US government passed the CLIA regulations most laboratories only do the minimum necessary to be in "compliance" with the regulations. And the minimums themselves have been repeatedly reduced by the "Final" CLIA rules and the accompanying State Operators Manual.

Compliance to the regulatory minimums does not assure quality! It only means that, at best, you're going to be average, just like all the other laboratories that are doing the minimum needed to get by. Today's compliance mentality is evidence that we've turned our back on quality.

Six Sigma Quality Management

One might be tempted to give up on quality altogether! However, a new opportunity presented itself at the start of this millennium – Six Sigma Quality Management. There is a new wave of interest and enthusiasm for Six Sigma in healthcare throughout the world. We have an opportunity to take advantage of this interest. True, Six Sigma might be just another management fad, but we don't think

so. We've studied the literature and identified the key improvements embodied in Six Sigma. And, it turns out that laboratories can readily tap into the Six Sigma principles, philosophy, process performance goals, and measurement approaches.

The purpose of this book is to bring you practical tools and training to implement Six Sigma quality design and control in your laboratories. These are special resources that can be applied to any laboratory and any analytical testing process, even those in other industries. These resources include quantitative tools that are not available in standard off-the-shelf Six Sigma training programs, therefore they will supplement any quality management program.

We'll first review some of the "basics" of Six Sigma in the next few chapters and show how the concepts apply to analytical processes in the laboratory. Then we'll get into detail about the tools and technology that can be used to design quality into laboratory testing processes and make improvements in the quality control procedures used with those processes. Finally, we'll show how to apply the theory and tools to a variety of testing processes. These are illustrative examples, some of which are very complicated, such as high-volume automated analyses, neonatal screening applications, and cardiac markers.

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