The Metrology Handbook

The Metrology Handbook

The Measurement Quality Division, ASQ
Jay L. Bucher, Editor

ASQ Quality Press
Milwaukee, Wisconsin

The Metrology Handbook
The Measurement Quality Division

Printed in the United States of America

12 11 10 09 08 07 06 05 04   5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

The metrology handbook / The Measurement Quality Division ; Jay Bucher, editor ; [authors] Jay L. Bucher ... [et al.].-- 1st ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-87389-620-3 (hardcover : alk. paper)
1. Mensuration--Handbooks, manuals, etc. 2. Calibration--Handbooks, manuals, etc. 3. Quality assurance--Handbooks, manuals, etc. I. Bucher, Jay L., 1949- II. American Society for Quality. Measurement Quality Division. III. Title.

T50.M423 2004
620'.0044--dc22

2004003464

ISBN 0-87389-620-3

The idea for the cover picture, and the photograph of the micrometer, are by Graeme C. Payne. The image of Earth, AS17-148-22727, is courtesy of Earth Sciences and Image Analysis Center, NASA Johnson Space Center. (http://eol.jsc.nasa.gov/) This image, now known as the "Blue Marble" photograph, was taken on December 7, 1972 by the crew of Apollo 17 as they were en route to the Moon for the final landing of the 20th Century.

Publisher: William A. Tony
Acquisitions Editor: Annemieke Hytinen
Project Editor: Paul O'Mara
Production Administrator: Randall Benson
Special Marketing Representative: Matt Meinholz

Printed in the United States of America

Printed on acid-free paper

ASQ
AMERICAN SOCIETY FOR QUALITY™

Quality Press
600 N. Plankinton Avenue
Milwaukee, Wisconsin 53203
Call toll free 800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org
E-mail: authors@asq.org

Table of Contents

List of Figures and Tables

CD Contents

Foreword

My introduction to real metrology was quite rude. I was applying for a job as an analytical chemist, and the laboratory director interviewing me asked how to run an infrared spectrum. After rather proudly reciting what I had been taught in college, I was immediately deflated when he asked me how accurate the measurement result would be. As I stammered my non-answer, I realized that job was not going to happen. Oh, if I only had *The Metrology Handbook* at that time.

Over the course of the last few decades, metrology has changed significantly. Concepts have been defined more rigorously. Electronics, computers, micro-technology, lasers and many more technological developments have pushed measurement capability to almost unbelievable accuracy. The industrial world has realized that measurement is fundamental to product and process quality. Consumers demand product characteristics and functionality realizable only with today's measurement accuracy. It is the job of the metrologist to meet the need for greater measurement accuracy by using all tools now available.

The American Society for Quality has assembled in *The Metrology Handbook* the basic components of the practice of metrology as it is known today. For those who want to be part of the ever growing metrology community, it introduces the fundamental concepts in a clear and precise way. For those who are already metrology professionals, it is an ideal companion to supplement and expand your knowledge. And for those who work in or manage metrology and calibration laboratories—either today or tomorrow—*The Metrology Handbook* covers the essentials of operating a respected laboratory.

The practice of metrology is both constant and changing. Metrology is constant in that it relies on a strong sense of the fundamental. Good measurement is based on understanding what must be controlled, what must be reported and what must be done to ensure that repeated measurements continue to maintain accuracy. Metrology is always changing as scientists, engineers, and technicians learn more about how to make good measurements. In the latter part of the last century, concepts such as uncertainty, quality systems, statistics, and good metrology laboratory management underwent significant changes, resulting in better metrological practice. All this and more is covered here.

It is essential that every metrology professional be familiar with these new approaches and use them daily in his or her work. A metrology professional must continue to expand his or her knowledge through courses, conferences and study. Through the work of organizations such as the American Society of Quality and handbooks such as *The Metrology Handbook*, the task of keeping up with advances has been made much simpler.

Dr. John Rumble, Jr.
Gaithersburg, Maryland

Preface

Metrology, in one form or another, has been around from the early days of *Homo-sapiens* when they had to hunt for survival. Back then, traceable standards were not available, and unbroken chains of comparison did not exist. In an article in *Quality in Manufacturing*, Nathalie Mitard states that metrology only became important when people started making tools from metal instead of stone, bone, and wood.[1] Be that as it may, the science of measurement was alive and well, and made itself apparent with the dawning of each new day.

In order for the hunter to kill game with a weapon, what felt good or worked effectively was replicated to gain the desired results over and over again. If a bow was not of the correct length, arrows did not have enough force to penetrate fur, bone, and muscle of wild game; or it was too difficult to draw the bow for the strength and length of the arm. Through trial and error, early humans became the hunters instead of the hunted. This happened because they remembered what worked the best and disregarded what didn't! With today's sophisticated machines and technology, reproducing bows and arrows to match your specific measurements, use, and function is as easy as ordering online. And, hopefully, you don't have to worry about a saber-toothed tiger attacking you while waiting for your new weapon.

Designing and/or manufacturing has made giant leaps throughout history due to improvements in measurement within agriculture, building construction, tool making, clothing, food, and transportation, to name a few (see Chapter 1). From sowing wild oats to cultivating genetically modified organisms; living in a cave to building the world's tallest structures that are designed to be earthquake resistant; from using the original hammer, a rock, to crafting specialty tools that work in deep space and at the bottom of the sea; going from the fig leaf to donning fire retardant clothes, from walking to space shuttles: Metrology affects everyone on a daily basis, whether we realize it or not. These, of course, are only general examples in the long history of *metrology*, the science of measurement.

Our purpose in writing this handbook was to develop a practical metrology reference for calibration professionals. We have intentionally focused on information for the vast majority of practicing professionals providing calibration/testing services, realizing that to do justice to the immense volumes of graduate and postgraduate level published metrology work would not be practical in a single handbook.

Whether you're changing disciplines in your career field; helping to becoming certified to a new or different standard; accepting more responsibilities as a supervisor or manager; training your fellow calibration practitioners; or using it to prepare for ASQ's

Certified Calibration Technician (CCT) exam . . . we hope this handbook provides the information, guidance, and/or knowledge to help you achieve your goals.

Endnote

1. Mitard, Nathalie. 2001. From the cubit to optical inspection. *Quality in Manufacturing* (September/October). www.manufacturingcenter.com/qm/archives/0901/0901gaging_suppl.asp

Acknowledgments

This handbook is a synthesis of the education, training, experience, and hard work of several individuals.The authors acknowledge and are grateful for the support of our faiths, our families, and our employers during this project. This book has touched the lives of friends, coworkers, supervisors, clients, and families. We would be remiss if we did not acknowledge their part in allowing us to do our part. Their patience and understanding made this task a great deal easier and, in some cases, turned an insurmountable job into just a bump in the road. To all of you, we collectively say, "Thank you from the bottom of our hearts. We could not have done this without your understanding and support."

To Annemieke Hytinen of ASQ, our acquisitions editor . . . the English language does not have enough words to express our gratitude. Your patience, understanding, and continual support during the easy and hard times have provided a bright light at the end of that long tunnel the team has traveled for the past year. We hope you will think kindly of calibration practitioners, consultants, and metrologists.

To Ann Benjamin of ASQ, for providing valuable collaborative resources and timely support in helping to make the handbook come to fruition.

To the metrology community . . . this book was written with your needs and requirements in mind. On behalf of ASQ's Measurement Quality Division, we solicit your observations, comments, and suggestions for making this a better book in the future. Calibration and metrology are living entities that continue to grow and evolve. What we do would not be much fun if they didn't.

And finally, to this unique team of coauthors—thank you. Two simple words that say it all. This book is the result of cooperation, understanding, and devotion to the calibration/metrology community and a burning desire to share what we have learned, experienced, and accomplished in our individual careers. I thank you, the rest of the team thanks you, and the metrology community surely will thank you.

Jay L. Bucher, MSgt, USAF (Ret), ASQ CCT
Editor, *The Metrology Handbook*

Primary authorship responsibility for *The Metrology Handbook* is as follows:

Keith Bennett:	Chapter 1
Hershal Brewer:	Chapters 8 and 17
David Brown:	Chapter 24, 25, 26, 27, 28, and Appendices E, IV, and V
Jay L. Bucher:	Chapters 2, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 35, 36, 37, 39, 40, 41, 42, and Appendix A
Christopher Grachanen:	Chapter 19, 20, 38, and Appendices A, B, VII, and VIII
Emil Hazarian:	Chapters 33 and 34
Graeme C. Payne:	Chapter 3, 17, 21, 22, 30, 31, 32, and Appendices A, C, D, I, II, and VI
Dilip Shah:	Chapters 23 and 29, and Appendix III

The following individuals in addition to their contribution as coauthors also provided invaluable review of *The Metrology Handbook* contents: Jay L. Bucher, Christopher Grachanen, Graeme C. Payne, and Dilip Shah.

A CALIBRATION TECHNICIAN . . .

. . . tests, calibrates, and maintains electronic, electrical, mechanical, electromechanical, analytical, physical inspection measuring and test equipment (IM&TE) using calibration standards and calibration procedures based on accepted metrological practices derived from fundamental theories of physics, chemistry, mathematics, and so on. In some organizations calibration technicians perform IM&TE repairs as well as maintaining calibration standards.

A Calibration Technician typically:

- has a working knowledge of applied mathematics, basic algebra, and basic statistics
- has in-depth knowledge of at least one field of metrology and at least basic familiarity with others
- is a graduate from a technical trade school, military training school, or has at least a two year associates degree
- possesses good written and oral communication skills
- has basic computer skills

Part I
Background

Chapter 1

History and Philosophy of Metrology/Calibration

Weights and measures may be ranked among the necessaries of life to every individual of human society. They enter into the economical arrangements and daily concerns of every family. They are necessary to every occupation of human industry; to the distribution and security of every species of property; to every transaction of trade and commerce; to the labors of the husbandman; to the ingenuity of the artificer; to the studies of the philosopher; to the researches of the antiquarian; to the navigation of the mariner; and the marches of the soldier; to all the exchanges of peace, and all the operations of war. The knowledge of them, as in established use, is among the first elements of education, and is often learned by those who learn nothing else, not even to read and write. This knowledge is riveted in the memory by the habitual application of it to the employments of men throughout life.

John Quincy Adams, Report to the Congress, 1821

ANCIENT MEASUREMENT

Weights and measures were some of the earliest tools invented. From the beginning of mankind there were needs to standardize measurements used in everyday life, such as construction of weapons used for hunting and protection, gathering and trading of food and clothing, and territorial divisions. The units of specific measurements, such as length, were defined as the length of an individual's arm (other parts of the human anatomy were also used). Weight probably would have been defined as the amount a man could lift or the weight of a stone the size of a hand. Time was defined by the length of a day and days between the cycles of the moon. Cycles of the moon were used to determine seasons. Although definitions of these measurements were rudimentary, they were sufficient to meet local requirements. Little is known about the details of any of these measurements, but artifacts over 20,000 years old indicate some form of timekeeping.

The earliest Egyptian calendar was based on the moon's cycles, but later the Egyptians realized that the Dog Star in Canis Major, which we call Sirius, rose next to the sun every 365 days, about when the annual inundation of the Nile began. Based on this knowledge, they devised a 365-day calendar that seems to have begun in 4236 B.C., which appears to be one of the earliest years recorded in history.

As civilizations grew they became more sophisticated and better definitions for measurement were required. The history of Egypt begins at approximately 3000 B.C. This is when Upper and Lower Egypt became unified under one ruler, Menes, and when the first pyramids were being built. At this time trade of goods was common as well as levies or taxes on them. Definitions for liquid and dry measures were important. Length was also an important measure as well as time. Some key Babylonian units were the *Kush* (cubit) for length, *Sar* (garden-plot) for area and volume, *Sila* for capacity, and *Mana* for weight. At the base of the system is the barleycorn (*She*), used for the smallest unit in length, area, volume, and weight.

Length

The smallest unit of length is the *She* (barleycorn), which equals about ¹⁄₃₆₀ meter.

6 *She*	=	1 *Shu-Si* (finger)
30 *Shu-Si*	=	1 *Kush* (cubit—about ½ m.)
6 *Kush*	=	1 *Gi / Ganu* (reed)
12 *Kush*	=	1 *Nindan / GAR* (rod—6 m.)
10 *Nindan*	=	1 *Eshe* (rope)
60 *Nindan*	=	1 *USH* (360 m.)
30 *USH*	=	1 *Beru* (10.8 km.)

Area and Volume

The basic area unit is the *Sar*, an area of 1 square *Nindan*, or about 36 square meters. The area *She* and *Gin* are used as generalized fractions of this basic unit.

180 *She*	=	1 *Gin*
60 *Gin*	=	1 *Sar* (garden plot 1 sq. *Nindan*—36 sq. m.)
50 *Sar*	=	1 *Ubu*
100 *Sar*	=	1 *Iku* (1 sq. *eshe*—0.9 acre, 0.36 *Ha*.)
6 *Iku*	=	1 *Eshe*
18 *Iku*	=	1 *Bur*

Capacity

These units were used for measuring volumes of grain, oil, beer, and so on. The basic unit is the *Sila*, about 1 liter. The semistandard Old Babylonian system used in mathematical texts is derived from the ferociously complex mensuration systems used in the Sumerian period.

180 *She*	=	1 *Gin*
60 *Gin*	=	1 *Sila* (1 liter)
10 *Sila*	=	1 *Ban*
6 *Ban*	=	1 *Bariga*
5 *Bariga*	=	1 *Gur*

Weight

The basic unit of weight is the *Mana*, about ½ kilogram.

180 *She*	=	1 *Gin/Shiqlu* (Shekel)
60 *Gin*	=	1 *Mana* (*Mina*—500 gm.)
60 *Mana*	=	1 *Gu/Biltu* (talent, load—30 kg.)

Royal Cubit Stick

The *royal cubit* (524 millimeters or 20.62 inches) was subdivided in an extraordinarily complicated way. The basic subunit was the *digit*, doubtlessly a finger's breadth, of which there were 28 in the royal cubit.

- Four digits equaled a *palm*, five *a hand*.
- Twelve digits, or three palms, equaled *a small span*.
- Fourteen digits, or one-half a cubit, equaled *a large span*.
- Sixteen digits, or four palms, made *one t'ser*.
- Twenty-four digits, or six palms, were a *small cubit*.

The Egyptians studied the science of geometry to assist them in the construction of the pyramids. The royal Egyptian cubit was decreed to be equal to the length of the forearm from the bent elbow to the tip of the extended middle finger plus the width of the palm of the hand of the pharaoh or king ruling at that time.

The royal cubit master was carved out of a block of granite to endure for all times. Workers engaged in building tombs, temples, pyramids, and so on were supplied with cubits made of wood or granite. The royal architect or foreman of the construction site was responsible for maintaining and transferring the unit of length to workers instruments. They were required to bring back their cubit sticks at each full moon to be compared to the royal cubit master. Failure to do so was punishable by death. Though the punishment prescribed was severe, the Egyptians had anticipated the spirit of the present day system of legal metrology, standards, traceability, and calibration recall.

With this standardization and uniformity of length, the Egyptians achieved surprising accuracy. Thousands of workers were engaged in building the Great Pyramid of Giza. Through the use of cubit sticks, they achieved an accuracy of 0.05%. In roughly 756 feet or 9,069.4 inches, they were within 4 ½ inches.

Digit

The digit was in turn subdivided. Reading from right to left in the upper register, the 14th digit on a cubit stick was marked off into 16 equal parts. The next digit was divided into 15 parts, and so on, to the 28th digit, which was divided into two equal parts. Thus, measurement could be made to digit fractions with any denominator from two through 16. The smallest division, $\frac{1}{16}$ of a digit, was equal to $\frac{1}{448}$ part of a royal cubit.

Although the Egyptians achieved very good standardization of length, this standardization was regional. There were multiple standards for the cubit, which varied greatly due to the standard they were based on, the length from the tip of the middle finger to the elbow. Variations of the cubit are as follows:

- Arabian (black) cubit of 21.3 inches
- Arabian (hashimi) cubit of 25.6 inches
- Assyrian cubit of 21.6 inches
- Ancient Egyptian cubit of 20.6 inches
- Ancient Israeli cubit of 17.6 inches
- Ancient Grecian cubit of 18.3 inches
- Ancient Roman cubit of 17.5 inches

Of these seven cubits the variation from the longest to the shortest was 8.1 inches, with an average value of 20.36 inches. These variations made trade difficult between different regions. As time evolved there became greater need for trade on a regional basis. The need for more sophistication and accuracy became greater.

MEASUREMENT PROGRESS IN THE LAST 2000 YEARS

Efforts at standardizing measurement evolved around the world, not just in Egypt. English, French, and American leaders strived to bring order to their marketplaces and governments.

732 King of Kent—The measurement of an acre is in common use.

960 Edgar the Peaceful decree, “All measure must agree with standards kept in London and Winchester.”

1215 King John agrees to have national standards of weights and measures incorporated into the Magna Carta.

1266 Henry III declares in an act that:

- One penny should weigh the same as 32 grains of wheat.
- There would be 20 pennies to the ounce.
- There would be 12 ounces to the pound.
- There would be eight pounds to the weight of one gallon of wine.

1304 Edward I declares in a statute that:

- For medicines, one pound equals 12 ounces (apothecaries, still used in United States).
- For all other liquid and dry measures one pound equaled 15 ounces.
- One ounce still equals 20 pennies.

1585 In his book *The Tenth,* Simon Stevin suggests that a decimal system should be used for weights and measures, coinage, and divisions of the degree of arc.

1670 Authorities give credit for originating the metric system to Gabriel Mouton, a French vicar.

1790 Thomas Jefferson proposes a decimal-based measurement system for the United States. France's Louis XVI authorizes scientific investigations aimed at a reform of French weights and measures. These investigations lead to the development of the first metric system.

1792 The U.S. Mint is formed to produce the world's first decimal currency (the U.S. dollar consisting of 100 cents).

1795 France officially adopts the metric system.

1812 Napoleon temporarily suspends the compulsory provisions of the 1795 metric system adoption.

1824 George IV, in a Weights and Measures Act (5 GEO IV c 74) establishes the "Imperial System of Weights and Measures," which is still used.

1840 The metric system is reinstated as the compulsory system in France.

1866 The use of the metric system is made legal (but not mandatory) in the United States by the (Kasson) Metric Act of 1866. This law also makes it unlawful to refuse to trade or deal in metric quantities.

STANDARDS, COMMERCE, AND METROLOGY

Standards of measurement before the 1700s were local and often arbitrary, making trade between countries—and even cities—difficult. The need for standardization as an aid to commerce became apparent during the Industrial Revolution. Early standardization and metrology needs were based on military requirements, especially those of large maritime powers such as Great Britain and the United States. A major task of navies in the eighteenth and nineteenth centuries was protection of their country's international trade, much of which was carried by merchant ships. Warships would sail with groups of merchant ships to give protection from pirates, privateers, and ships of enemy nations; or they would sail independently to "show the flag" and enforce the right of free passage on the seas. A typical ship is the frigate USS *Constitution.* She was launched in 1797 and armed with 34 24-pound cannon and 20 32-pound cannon. (The size of cannon in that era was determined by the mass, and therefore the diameter, of the spherical cast-iron shot that would fit in the bore.) For reasons related to accuracy, efficiency, and economy, the bores of any particular size of cannon all had to be the same diameter. Likewise, the iron shot had to be the same size. If a cannonball was too large, it would not fit into the muzzle; too small, and it would follow an unpredictable trajectory when fired. The requirements of ensuring that dimensions were the same led to the early stages of a modern metrology system, with master gages, transfer standards, and regular comparisons. Figure 1.1 is an example of a length standard that probably dates from this era. This one, mounted on the wall of the Royal Observatory at Greenwich, England, is one of several that were placed in public places by the British government for the purpose of standardizing dimensional measurements. It has standards for three and six inches, one and two feet, and one yard. In use, a transfer standard would be placed on the supports, and presumably it should fit snugly between the flats of the large posts. The actual age of this standard is now unknown.

Figure 1.1 Early dimensional standard at the Royal Observatory, Greenwich, England. (Photo by Graeme C. Payne.)

Over time, as measurements became standardized within countries, the need arose to standardize measurements between countries. A significant milestone in this effort was the adoption of the Convention of the Metre treaty in 1875. This treaty set the framework for and still governs the international system of weights and measures. It can be viewed as one of the first voluntary standards with international acceptance, and possibly the most important to science, industry, and commerce. The United States was one of the first nations to adopt the Metre Convention.

1875 The Convention of the Metre is signed in Paris by 18 nations, including the United States. The Meter Convention, often called the Treaty of the Meter in the United States, provides for improved metric weights and measures and the establishment of the General Conference on Weights and Measures (CGPM) devoted to international agreement on matters of weights and measures.

1878 Queen Victoria declares the Troy pound illegal. Commercial weights could only be of the quantity of 56 lb, 28 lb, 14 lb, 7 lb, 4 lb, 2 lb, 1 lb, 8 oz, 4 oz, 2 oz, and so on.

1889 As a result of the Meter Convention, the United States receives a prototype meter and kilogram to be used as measurement standards.

1916 The Metric Association is formed as a nonprofit organization advocating adoption of the metric system in U.S. commerce and education. The organizational name started as the American Metric Association and was changed to the U.S. Metric Association (USMA) in 1974.

1954 The International System of Units (SI) begins its development at the tenth CGPM. Six of the new metric base units are adopted.

1958 A conference of English-speaking nations agrees to unify their standards of length and mass, and define them in terms of metric measures. The American yard was shortened and the imperial yard was lengthened as a result. The new conversion factors are announced in 1959 in the *Federal Register*.

HISTORY OF QUALITY STANDARDS

In some respects, the concept we call *quality* has been with humankind through the ages. Originally aspects of quality were passed on by word of mouth, from parent to child, and later from craftsman to apprentice. As the growth of agriculture progressed, people started settling in villages and resources were available to support people who were skilled at crafts other than farming and hunting. These craftsmen and artisans would improve their skill by doing the same work repeatedly and make improvements based on feedback from customers. The main pressure for quality was social because the communities were small and trade was local. A person's welfare was rooted in his or her reputation as an honest person who delivered a quality product—and the customers were all neighbors, friends, or family.

The importance and growth of quality and measurement probably increased with the development of the first cities and towns, on the order of 6000 to 7000 years ago. Astronomy, mathematics, and surveying were important trades. Standard weights and measures were all developed as needed. All of these were important for at least three activities: commerce, construction, and taxation. The systems of measuring also represented an important advance in human thought because it is an advance from simple counting to representing units that can be subdivided at least to the resolution available to the unaided eye. In Egypt, systems of measurement were good enough 5000 years ago to survey and construct the pyramids at Giza with dimensional inaccuracies on the order of 0.05%. This was made possible by the use of regular calibration and traceability. Remember, the cubit rules used by the builders were required to be periodically compared to the Pharaoh's granite master cubit. Juran mentions evidence of written specifications for products about 3500 years ago, and Bernard Grun notes regulations about the sale of products (beer, in this case) about the same time. Standardization of measurements increased gradually as well, reaching a peak in the later years of the Roman Empire. (It is often said, humorously, that the standard-gauge spacing of railway tracks in Europe and North America is directly traceable to the wheel spacing of Roman war chariots.)

Measurement science and quality experienced a resurgence as Europe emerged from the Dark Ages. Again, some of the driving forces were commerce, construction, and taxation. Added to these were military requirements and the needs of the emerging fields of science. Many of the quality aspects were assumed by trade and craft guilds. The guilds set specifications and standards for their trades, and developed a training system that persists to this day: the system of apprentices, journeymen, and master craftsmen. Guilds exercised quality control through inspection, but often stifled quality improvement and product innovation.

The Industrial Revolution accelerated the growth of both quality and measurement. Quantities of manufactured items increased, but each part was still essentially custom made. Even while referring to a master template, it was difficult to construct parts that could be randomly selected and assembled into a functioning device. By the mid-1700s the capability of a craftsman to produce substantially identical parts was demonstrated in France. In 1789, Eli Whitney used this capability in the United States when he won a government contract to provide 10,000 muskets with interchangeable parts, but it took him 10 years to fill the contract. By 1850 it was possible for a skilled machinist to make hundreds of repeated parts with dimensional uncertainties of no more than ±0.002 inch. Those parts were still largely handmade, one at a time.

MEASUREMENT AND THE INDUSTRIAL REVOLUTION

The Industrial Revolution began around 1750. Technology began to progress quickly with materials, energy, time, architecture, and man's relationship with the earth. Industry began to quickly evolve. With a growing population the need for clothing, transportation, medicines, and food drove industry to find better, more efficient methods to support this need. Technology had evolved sufficiently to support this growth.

During this time there was tremendous growth of discoveries in quantum mechanics and molecular, atomic, nuclear, and particle physics. These discoveries laid the groundwork for much of the seven base units of the current International System of Units (SI). These seven units are well-defined and dimensionally independent. These units are the meter (M), kilogram (kg), second (s), ampere (A), kelvin (K), mole (mol), and candela (cd).

During the middle 1800s there was a lot of progress with temperature and thermodynamics. Note the speed of discovery.

1714 Mercury and alcohol thermometer are invented by Daniel Gabriel Fahrenheit.

1821 Thermocouples are invented by Thomas Johann Seebeck. The discovery that metals have a positive temperature coefficient of resistance, which led to the use of platinum as a temperature indicator (PRT) is made by Humphrey Davy.

1834 Lord Kelvin formulates of the Second Law of Thermodynamics.

1843 Discovers the mechanical equivalent of heat.

1848 Lord Kelvin discovers the absolute zero point of temperature (0 K).

1889 Platinum thermometers are defined by many different freezing points and boiling points of ultra pure substances such as the freezing point of H_2O at 0ºC, the boiling point of H_2O at 100ºC, and the boiling point of sulfur at 444.5ºC.

1900 The Blackbody radiation law is formulated by Max Planck.

1927 The Seventh CGPM adopted the International Temperature Scale of 1927.

There were many more discoveries during this period that covered electromagnetic emissions, radioactivity, nuclear chain reactions, superconductivity, and others. The following is a list of some of the properties and quantities of electricity that were defined.

1752 Benjamin Franklin proves that lightning and the spark from amber are the same thing.

1792 Alessandro Volta shows that when moisture comes between two different metals electricity is created. This led him to invent the first electric battery, the voltaic pile, which he made from thin sheets of copper and zinc separated by moist pasteboard. The unit of electrical potential, the *volt*, is named after Volta.

1826 George Simon Ohm states Ohm's law of electrical resistance.

1831 Michael Faraday discovers the first method of generating electricity by means of motion in a magnetic field.

1832 Faraday discovers the laws of electrolysis.

1882 A New York street is lit by electric lamps.

1887 The photoelectric effect is discovered by Heinrich R. Hertz.

1897 J. J. Thomson discovers the electrons.

1930 Paul A. M. Dirac introduces the electron hole theory.

With the advancement in the discoveries of these physical phenomena, technology took advantage and developed products around these discoveries. With these advancements better measurements were needed. To build a single machine, an inventor could probably get by without much standardization of his measurements, but to build multiple machines, using parts from multiple suppliers, measurements had to be standardized to a common entity.

Metrology is keeping up with physics and industry. Recent successes in the industry that wouldn't be possible without metrology include the following: Fission and fusion are being refined for both weapons and as a source of energy. Semiconductors are being developed, refined, and applied on a larger scale with the invention of the integrated circuit, solar cells, light-emitting diodes, and liquid crystal displays. Communication technology has developed through application of satellites and fiber optics. Lasers have been invented and applied in useful technology to include communication, medicine, and industrial applications. The ability to place a humanmade object outside the Earth's atmosphere started the space race and has led to placing a man on the moon, satellites used for multiple purposes, probes to other planets, the space shuttle, and space stations. A few spacecraft have passed beyond the farthest known planets and are headed into interstellar space. One thing is certain: as technology continues to grow, measurement challenges will grow proportionally.

MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY

From the beginnings of civilization people have been concerned about the quality and safety of foods and medicines. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with such ingredients as ground peas or beans. Regulation of food in the United States dates from early colonial times. Federal controls over the drug supply began with inspection of imported drugs in 1848. The following chronology describes some of the milestones in the history of food and drug regulation in the United States.

1820 Eleven physicians meet in Washington, D.C., to establish the U.S. Pharmacopeia, the first compendium of standard drugs for the United States.

1848 Drug Importation Act passed by Congress requires U.S. Customs Service inspection to stop entry of adulterated drugs from overseas.

1862 President Lincoln appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.

1880 Peter Collier, chief chemist, U.S. Department of Agriculture, recommends passage of a national food and drug law, following his own food adulteration investigations. The bill was defeated, but during the next 25 years more than 100 food and drug bills were introduced in Congress.

1883 Dr. Harvey W. Wiley becomes chief chemist, expanding the Bureau of Chemistry's food adulteration studies. Campaigning for a federal law, Wiley is called the Crusading Chemist and Father of the Pure Food and Drugs Act. He retired from government service in 1912 and died in 1930.

1902 The Biologics Control Act is passed to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans.

Congress appropriates $5,000 to the Bureau of Chemistry to study Chemical Perservatives and Colors and their effects on digestion and health. Wiley's studies draw widespread attention to the problem of food adulteration. Public support for passage of a federal food and drug law grows.

1906 The original Food and Drugs Act is passed by Congress on June 30 and signed by President Theodore Roosevelt. It prohibits interstate commerce in misbranded and adulterated foods, drinks and drugs. The Meat Inspection Act is passed the same day. Shocking disclosures of unsanitary conditions in meat packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines were the major problems leading to the enactment of these laws.

1927 The Bureau of Chemistry is reorganized into two separate entities. Regulatory functions are located in the Food, Drug, and Insecticide Administration, and nonregulatory research is located in the Bureau of Chemistry and Soils.

1930 The name of the Food, Drug, and Insecticide Administration is shortened to Food and Drug Administration (FDA) under an agricultural appropriations act.

1933 FDA recommends a complete revision of the obsolete 1906 Food and Drugs Act. The first bill is introduced into the Senate, launching a five-year legislative battle.

1937 Elixir of Sulfanilamide, containing the poisonous solvent diethylene glycol, kills 107 persons, many of whom are children, dramatizing the need to establish drug safety before marketing and to enact the pending food and drug law.

1938 The Federal Food, Drug, and Cosmetic (FDC) Act of 1938 is passed by Congress, containing new provisions:

- Extending control to cosmetics and therapeutic devices
- Requiring new drugs to be shown safe before marketing—starting a new system of drug regulation
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases
- Providing that safe tolerances be set for unavoidable poisonous substances
- Authorizing standards of identity, quality, and fill-of-container for foods
- Authorizing factory inspection
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions

Under the Wheeler-Lea Act, the Federal Trade Commission is charged with overseeing advertising associated with products otherwise regulated by FDA, with the exception of prescription drugs.

1943 In *U.S. v. Dotterweich*, the Supreme Court rules that the responsible officials of a corporation, as well as the corporation itself, may be prosecuted for violations. It need not be proven that the officials intended, or even knew of, the violations.

1949 FDA publishes Guidance to Industry for the first time. This guidance, "Procedures for the Appraisal of the Toxicity of Chemicals in Food," came to be known as the black book.

1951 Durham-Humphrey Amendment defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner.

1958 Food Additives Amendment enacted, requiring manufacturers of new food additives to establish safety. The Delaney proviso prohibits the approval of any food additive shown to induce cancer in humans or animals.

FDA publishes in the Federal Register the first list of Substances generally recognized as safe (GRAS). The list contains nearly 200 substances.

1959 U.S. Cranberry crop recalled three weeks before Thanksgiving for FDA tests to check for aminotriazole, a weed killer found to cause cancer in laboratory animals. Cleared berries were allowed a label stating that they had been tested and had passed FDA inspection, the only such endorsement ever allowed by FDA on a food product.

1962 Thalidomide, a new sleeping pill, is found to have caused birth defects in thousands of babies born in western Europe. News reports on the role of

Dr. Frances Kelsey, FDA medical officer, in keeping the drug off the U.S. market, arouse public support for stronger drug regulation.

Kefauver-Harris Drug Amendments passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them. The new law also exempts from the Delaney proviso animal drugs and animal feed additives shown to induce cancer, but which leave no detectable levels of residue in the human food supply.

Consumer Bill of Rights is proclaimed by President John F. Kennedy in a message to Congress. Included are the right to safety, the right to be informed, the right to choose, and the right to be heard.

1972 Over-the-counter drug review begun to enhance the safety, effectiveness and appropriate labeling of drugs sold without prescription.

Regulation of biologics—including serums, vaccines, and blood products-is transferred from NIH to FDA.

1976 Medical Device Amendments passed to ensure safety and effectiveness of medical devices, including diagnostic products. The amendments require manufacturers to register with FDA and follow quality control procedures. Some products must have premarket approval by FDA; others must meet performance standards before marketing.

Vitamins and Minerals Amendments (Proxmire Amendments) stop FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency.

1978 Good manufacturing practices become effective.

1979 Good laboratory practices become effective.[3]

1983 Orphan Drug Act passed, enabling FDA to promote research and marketing of drugs needed for treating rare diseases.

1984 Fines Enhancement Laws of 1984 and 1987 amend the U.S. Code to greatly increase penalties for all federal offenses. The maximum fine for individuals is now $100,000 for each offense and $250,000 if the violation is a felony or causes death. For corporations, the amounts are doubled.

1988 Food and Drug Administration Act of 1988 officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner of Food and Drugs appointed by the president with the advice and consent of the Senate and broadly spells out the responsibilities of the secretary and the commissioner for research, enforcement, education, and information.

The Prescription Drug Marketing Act bans the diversion of prescription drugs from legitimate commercial channels. Congress finds that the resale of such drugs leads to the distribution of mislabeled, adulterated, subpotent, and counterfeit drugs to the public. The new law requires drug wholesalers to be licensed by the states; restricts reimportation from other countries; and bans sale, trade, or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.

1990 Safe Medical Devices Act is passed, requiring nursing homes, hospitals, and other facilities that use medical devices to report to FDA incidents that suggest that a medical device probably caused or contributed to the death, serious illness, or serious injury of a patient. Manufacturers are required to conduct postmarket surveillance on permanently implanted devices whose failure might cause serious harm or death, and to establish methods for tracing and locating patients depending on such devices. The act authorizes FDA to order device product recalls and other actions.

1995 FDA declares Cigarettes to be drug delivery devices. Restrictions are proposed on marketing and sales to reduce smoking by young people.

1996 Federal Tea Tasters Repeal Act repeals the Tea Importation Act of 1897 to eliminate the Board of Tea Experts and user fees for FDA's testing of all imported tea. Tea itself is still regulated by FDA.

1997 Food and Drug Administration Modernization Act reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods.

1998 First phase to Consolidate FDA Laboratories nationwide from 19 facilities to nine by 2014 includes dedication of the first of five new regional laboratories.

References

BIPM (International Bureau of Weights and Measures). 2000. The Convention of the Metre. www.bipm.fr/enus/1_Convention/foreword.html

Bertermann, Ralph E. 2002. *Understanding current regulations and international standards; Calibration compliance in FDA regulated companies.* Mt. Prospect, IL: Lighthouse Training Group.

Columbia Encyclopedia. 2003. "Measurement" Expanded Columbia Electronic Encyclopedia, Columbia University Press. Accessed through the History Channel, www.historychannel.com/perl/print_book.pl?ID-100597

Evans, James R. and William M. Lindsay. 1993. *The management and control of quality*, 2nd ed. St. Paul, MN: West Publishing Company.

Juran, Joseph M. 1997. Early SQC: A historical supplement. *Quality Progress*, 30, (September): 73–81.

Juran, Joseph M. 1999. *Juran's quality handbook*. Wilton, CT: McGraw-Hill.

NBS (National Bureau of Standards). 1975. *The International Bureau of Weights and Measures 1875–1975.* NBS Special Publication 420. Washington, DC: U.S. Government Printing Office.

NCSL International (NCSLI). 2003. "The Royal Egyptian Cubit." www.ncsli.org/misc/cubit.cfm

NIST (National Institute of Standards and Technology). 2003. Frequently asked questions about the Malcolm Baldrige National Quality Award. www.nist.gov/public_affairs/factsheet/baldfaqs.htm

Swade, Doron. 2000. *The Difference Engine: Charles Babbage and the quest to build the first computer.* London: Viking Penguin Books.

U. S. Navy. 1966. *Why calibrate?* Washington, DC: Department of the Navy. Training film number MN-10105.

U. S. Navy. 2003. "United States Ship Constitution." Washington, DC: Department of the Navy www.ussconstitution.navy.mil/statpage.htm

Index

Note: Page numbers in italics refer to illustrations; a *t* following a page number refers to a table.

A

B

D

E

J

K

Q

R

S

T

U