TECHNOLOGICAL CHANGE AND METROLOGY SERVICES
MEDICAL METROLOGY AND ITS EFFECTS ON SOCIETY

A THESIS SUBMITTED TO
THE GRADUATE SCHOOL OF SOCIAL SCIENCES
OF
THE MIDDLE EAST TECHNICAL UNIVERSITY

BY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR
THE DEGREE OF MASTER OF SCIENCE
IN
THE DEPARTMENT OF SCIENCE AND TECHNOLOGY POLICY STUDIES

APRIL 2005

Approval of the Graduate School of Social Sciences

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ABSTRACT

TECHNOLOGICAL CHANGE AND METROLOGY SERVICES MEDICAL METROLOGY AND ITS EFFECTS ON SOCIETY

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April 2005, 76 pages

Accuracy of measurements is one of the most vital issues for industry and society as a whole. In this context, medical devices create a significant impact on the costs of health care services, such as additional medicine treatments, longer hospital stays, etc. The main aim of this thesis is to analyze and explain the use of metrology services and the socio-economic impact of medical metrology on consumers in Turkey. A framework for economic impact assessment of the calibration services for three specific medical devices, namely patient bedside monitors, ventilators and pacemakers –both of which are required for use especially after open-heart surgeries, has been developed and a cost-benefit analysis has been performed. The Benefit-to-Cost ratios of the calibration activity on patient bedside monitors, ventilators and pacemakers were calculated as 36.74, 2.22 and 1.79, respectively. Calibration services seem to have a very favorable Benefit-to-Cost ratio even based on the lower-bound estimations.

Keywords: Economic Impact Assessment, Metrology Services, Medical Metrology

ÖZ

TEKNOLOJİK DEĞİŞİM ve METROLOJİ HİZMETLERİ - MEDİKAL METROLOJİ ve TOPLUMA ETKİLERİ

Evren, Bükülmez
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Tez Yöneticisi : Prof. Dr. Erol Taymaz

Nisan 2005, 76 sayfa

Ölçümlerin doğruluğunun etkisi, endüstri ve toplumu bir bütün olarak ilgilendiren, hayati konulardan biridir. Bu çerçevede, tıbbi cihazlar, sağlık hizmetlerinin maliyetinde, ek ilaç tedavileri, artan hastane kalış süreleri vb.. gibi, ciddi etkiler yaratmaktadır. Bu tezin amacı, metroloji hizmetlerinin yararlarını ortaya koymak ve aynı zamanda medikal metrolojinin tüketiciler üzerindeki sosyo-ekonomik etkilerini Türkiye ölçeğinde yansıtmaktır. Bu kapsamda, özellikle açık kalp ameliyatlarının sonrasında kullanılmakta olan hastabaşı monitörü, sûni solunum cihazı ve de kalp pili cihazlarına yönelik gerçekleştirilen kalibrasyon uygulamalarının ekonomik etkilerinin değerlendirmesi için bir model geliştirilmiş ve bu etkiyi değerlendirmek için maliyet-yarar analizi yapılmıştır. Hastabaşı monitörü, sûni solunum cihazı ve de kalp pili cihazlarına yönelik kalibrasyon uygulamalarının Yarar/Maliyet oranları sırasıyla 36.74, 2.22 ve 1.79 olarak bulunmuştur. Analizin sonuçları incelendiğinde, söz konusu cihazlara yönelik kalibrasyon uygulamalarının alt sınır tahminlerinde bile ekonomik anlamda olumlu sonuçlar verdiği görülmektedir.

Anahtar Kelimeler: Ekonomik Etki Değerlendirmesi, Metroloji Hizmetleri, Medikal Metroloji

ACKNOWLEDGEMENTS

I express sincere appreciation Prof. Dr. Erol Taymaz for his guidance and insight throughout the research.

I offer thanks to Dr. A. Haluk Nalbanoğlu (Assistant Secretary General of TTGV), my colleagues at TTGV and the participant firms and interviewers in this study for sharing their time, thoughts and views.

My appreciations and thanks go to Asst. Prof. Dr. Erkan Erdil for his encouragement during my research. Also, I would like to thank Cenk Çakar and Mustafa Gündüz for their valuable comments.

My deepest appreciations go to Ayşe Alpagut for her significant support and encouragement during writing this thesis.

Lastly but not the least I would like to express my deepest respect and love to my family who have encouraged me during my studies.

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CHAPTER 1

INTRODUCTION

Science and technology are driving forces in modern society. They contribute to many aspects of our public and personal lives, but often in complex and unpredictable ways that make it hard to assess their importance (ETAN, 1999). Hence, in order to evaluate immediate results and long term consequences of public RTD programmes that support developments in science and technology, different methodologies are used, and direct and indirect effects of these programmes as well as unintended results are observed.

In this context, additionality has become a key component in measuring the effectiveness of policy instruments for the benefits of the industry and society. Being a strategic issue for development, governments should investigate how additionality is to be treated in their evaluation programmes, since such programmes demonstrate the effectiveness and efficiency of this individual RTD programmes via cost-benefit relation in use of resources. Thus, evaluation of reliability of measurements is one of the most interesting and vital subjects for industry and society, and the traceability issue, related to the structure of the institutional mechanisms for handling metrology services, becomes a paramount importance for reliability of measurements.

One of the key service sectors, which get directly affected from reliability of the measurements, is the medical sector. Medical devices used in treatment of patients, create a significant impact on the costs of health care services, such as additional medicine treatments, longer hospital stays, and etc. In order to reduce such costs, the device should operate efficient and properly, and they need to be under maintenance for calibration in periods varying with the usage frequencies. Potential social benefits of the calibration measurement activities in this sector can be summarized as reduced number of deaths from preventable illness, reduced incidence of illness' and accidents due to better safety standards, improvements in the quality of the environment, reductions in the incidence of disease in the food chain, and etc. (Spencer and Williams, 2002)

In this respect, the aim of this thesis is to analyze and explain the use of metrology services and demonstrate the socio-economic impact of medical metrology on consumers in Turkey. For this purpose, a framework for economic impact assessment of the calibration activity for three specific medical devices, namely as patient bedside monitors, ventilators and pacemakers have been developed. A model for cost-benefit analysis has been put forward to show the impact of calibration activity. Data and statistics utilized in the model, are obtained from State Institute of Statistics, Ministry of Health, some authorities of public and private biomedical calibration laboratories and finally, from hospitals via interviews. Results of the analysis performed for all aforementioned medical devices indicate that calibration activity seems very favorable even based on the lower-bound estimations.

Chapter 2 gives brief explanations on the concept of additionality and its evaluation. In this scope, RTD Evaluation Programmes and impact assessment methods and their role for the society at large are clarified. Also, this chapter includes the concept of metrology with the institutional mechanisms that are bounded upon each other via traceability concerns, as well as the medical metrology concept, its importance for the society and the institutional structure of Turkey's Metrology System. In Chapter 3, country experiences of impact assessments on metrology services are put forward for USA, UK, Turkey and for some other European countries. In Chapter 4, the related cost-benefit model is introduced, putting forward the general framework and background for the research procedure. Via the cost-benefit model, effects of calibrating medical devices and possible impacts of calibration on society are economically estimated. Chapter 5 concludes the results obtained from this analysis of medical testing calibration.

CHAPTER 2

THEORETICAL BACKGROUND

Metrology is a broad term and its importance cannot be disregarded for successful industrial development as well as its degree of reliability for society considering its effects on consumers. This chapter starts with the concept of additionality and economic impact assessment and describes the different dimensions of metrology and its importance for the industry and society. In addition, the roles of the National Metrology Institute (UME), the Turkish Standards Institute (TSE) and the National Accreditation Council (TÜRKAK) are described.

2.1 Concept of Additionality

Additionality refers to the amount of additional activity and outcomes that arise as a result of a policy compared with what would have occurred without government intervention, or indeed, had the investment been directed elsewhere. (Simmonds et al., 2002) Demonstrating the effectiveness of public spending on research, technology, development and innovation (RTDI) helps to justify such spending, provides a chance for policymakers to learn from experience and also, helps society realize the complex nature of innovation (ETAN, 1999).

‘‘Additionality has become a key component in measuring the effectiveness of policy instruments for stimulating improvements in RTDI.’’ (TAFTIE, 2004) Therefore, the government agencies around the world should understand the strategic role of additionality considering their improvement in planning, implementation and evaluation of their policy actions.

The concept of additionality has been widely used by policy-makers and administrators to justify and rationalize public funding for RTDI. In this context, additionality measures to which extent the public support makes a difference in stimulating new RTDI initiatives at the funding recipients and in the economy as a whole. (TAFTIE, 2004) Typical additionality measures comprise of added/new investments in RTDI (input additionality), new patents, publications, innovations etc. (output additionality) and improved development processes, collaboration patterns etc. (behavioral additionality). (TAFTIE, 2004)

In the recent years, studies on evaluation and impact assessment have become widespread in the European Union (EU). The funding criteria set out in EU's proposals and, in particular, the shift towards broader socio-economic targets, consequently require a strengthening of the current mechanisms for assessment and data provision. (Bach & Georghiou, 1998) The more the RTD objectives are expressed in terms of expected socio-economic impacts, the wider the scope of the assessment will have to be. As well as input data such as RTD expenditure and the characteristics of participants, more attention must be paid to gathering and assessing output and impact data. To reflect the full scope of potential socio-economic impacts, impact data need to be collected over a relatively long period of time after the completion of the project. (Bükülmez, 2004)

2.1.1 Additionality and Impact Assessments

‘‘Evaluation of additionality involves comparison with the null hypothesis or counterfactual – what would have happened if the policy measure or funding had not been implemented?’’ (TAFTIE, 2004) However, there is almost no data on counterfactual in practice. Current efforts have therefore been focused mostly on ex-post measurements of input additionality since data and indicators on increased R&D are relatively easy to collect. The methods used to evaluate additionality try to find a strong correlation between the input indicators and the government intervention, e.g. through econometric studies. ‘‘This focus on input additionality has also been motivated by the linear model in which input and output additionality are supposed to be closely correlated.’’ (TAFTIE, 2004) These types of evaluations are being done for many institutes around the world and there is a continuous research to develop better mechanisms applied for economic impact analysis in this field.

Evaluation of a policy instrument comprises its effectiveness (goal achievement), its efficiency (cost-benefit relation in use of resources) and coherence (strategic fit in the policy portfolio) (Larosse, 2004).

The purpose of an economic impact assessment of a RTDI activity is to evaluate, both qualitatively and quantitatively, the benefits to industry and to compare those benefits, in a systematic matter, to the costs of conducting the RTDI project. (Link, 1996) Industry is not the only sector that benefits from RTDI programs. Economic impact studies are also in the service of consumers and the public at a large scale. However, potential users of program outputs within industrial sectors are of primary importance to the government institutions. Table 2.1 demonstrates the impact dimensions of public RTD spending.

Table 2.1. Impact Dimensions of Public RTD Spending

Main Domains of Impact of Public RTD Spending	Direct Impacts		Indirect Impacts	
	Short Term	Long Term	Short Term	Long Term
Science	Scientific finding	Knowledge	Improved Teaching	Industrial Spillovers
Economy and Society	Improved Technology	Improved Technical Know-How	Increased Productivity	Improved Competitiveness
Policy	Improved Understanding	Problem-Solving	Increased Problem Awareness	Increased General Satisfaction

Source: ETAN, 1999

Economic impact assessments give an outline and basis for both internal institutional planning and external communication with industry clients, industry partners and policy-makers. It is important to state that formulating a strategy for the economic impact assessment to be carried out is a critical stage, since the methodology to be applied and the scope of qualitative and quantitative information to be collected are determined after this stage. Increase in problem awareness by the institutions and general satisfaction by the society is obtained by the experience and knowledge generated after the impact studies.

Benefit/cost (B/C) analysis is a method of comparing the benefits from a single project to the costs incurred to conduct the project (i.e., the costs to achieve the benefits). (Link, 1996) The ratio of benefits –to-costs is the ratio of the present value of all measured benefits to the present value of all costs. Both benefits and costs are referenced to the initial time period, t=0, as:

$$\left[\sum_{t=0}^{t=n} B_t / (1 + r)^t\right] / \left[\sum_{t=0}^{t=n} C_t / (1 + r)^t\right]$$

where r is the discount rate, representing the opportunity cost for public funds and it could differ across a portfolio of public investments. B/C ratio of 1 implies a break-even project and B/C > 1 is a relatively successful project. (Blank, 1995)

2.1.2 RTD Programme Evaluation in Europe

Evaluation is a key tool in the process of clarifying and managing RTDI policy. Table 2.2 gives an overview of the spread of the evaluation culture in Europe, in the mid 1990s. (Arnold, 1997)

Table 2.2 European Science and Technology Evaluation Practices, Selected Countries

Country	Start of Evaluation	Evaluation Responsibility	Focus	Evaln Community
France	1982/90	CNE: Universities CNER: Other Report to President	Mainly institutions Increasingly programmes	◧
Germany	1970s	Wissenschaftsrat: Universities BMBF etc: Other BMBF includes internal evaluation group	Programmes Institutions	■
UK	Mid-80s	HEFCE: Universities Policy Departments: Other DTI includes internal evaluation group	Universities Programmes	■
Nether-lands	1982/86	Universities' Association Policy Departments	Scientific disciplines Institutes Programmes	◧
Austria	Late-80s	Policy departments	Some university and programme activities	□
Ireland	Late-80s	Universities: None Other: Forfás; Department of Enterprise & Employment	Structural Funds programmes	□
Greece	1990	Universities: None Other: Policy departments	Structural Funds programmes	□
Italy	1994	Universities: Internal Other: Little	Little evaluation done	□
Spain	-	Universities: Not required Other: Little	Little evaluation done	□
Portugal	-	Legal basis exists, but apparently little practice	Structural Funds programmes	□
Sweden	Mid-80s	Research Councils	All institutions, programmes	□
Norway	Early-80s	Research Council of Norway	All institutions, programmes	◧
Finland	Late-80s	Academy of Finland TEKES	Most institutions, programmes	□

Key □ 0 - 5 professionals ◧ 6 - 10 professionals ■ >10 professionals

Source: Arnold, 1997

In many European countries the evaluation culture was first established in universities as a part of internal quality control procedures implemented by the scientists.

> ‘‘Evaluation has become a routine part of science and technology policy making in the northern part of Europe, while there is still less interest and practice in the south. A useful indicator of the state of development is the number of professional RTD evaluators based in a country. However, it is clear that there are particularly strong cultures in the UK, Germany, the Netherlands, France and Norway.’’ (Arnold, 1997)

In the UK, RTD evaluation was promoted in the 1980s for proving the success of technology funding (UK’s major Information Technology R&D programme of the 1980s) by the Department of Trade and Industry Department. In Sweden, in the early 1990s, the government forced its agencies to demonstrate their effectiveness on using the public money. ‘‘In the USA, the Government Performance and Results Act (GPRA) of 1993 has provided a similar pressure.’’ (Arnold, 1997)

2.2 The Concept of Metrology

Metrology is the science of measurement. It is the key to sustainable industrial growth; moreover, it is a requirement for successful implementation of environmental, health and safety policies in order to meet the needs of society.

An important term is in metrology is calibration. It means the sequence of procedures, which establishes, under certain circumstances, the relation between the values indicated by a measuring instrument or measuring system or the values given by a measuring tool or a reference material and the corresponding values obtained from measuring standards. One of the most significant factors in production and quality control is the reliability of measurements. Reliability can only be achieved by calibrating the measuring devices, e.g. determining the magnitude of their measurement error with a better, more accurate, instrument. However, this more accurate instrument also needs to be calibrated, and in this way a chain is established where at the highest level, national measurement studies are compared with each other to set the international standards. Thus, an important concept in metrology is that of traceability.

> ‘‘It refers to the property of a measurement or of the value of a standard, to be related to established references, normally national or international standards, through a continuous chain of comparisons, all of them with known uncertainties. The possibility of determining traceability in any measurement relies on the concept and the actions of calibration and on the hierarchical structure of the standards.’’ (Rocío, Marbán & Pellecer, 2002)

Via this chain, all measurements are connected to the 7 base International System of Units (SI Units); the Meter, Kilogram, Second, Kelvin, Ampere, Candela, and Mol, as defined by BIPM (Bureau International des Poids et Mesures - International Office of Weights and Measures).

The progress of nations is dependent on their progress in their measurements. Measurement systems not only facilitate and regulate commercial transactions, but also are they fundamental for governments, for enterprises and for the population at large, due to the provision of quality assurance of the products and services offered to consumers.

Metrology has become even more important as a result of the relationship between metrology and quality, measurements and quality control, calibration, laboratory accreditation, traceability, and certification. (Rocío, Marbán & Pellecer, 2002) There should be an infrastructure required to support the establishment of policies and regulations for manufacturing products and for services produced locally or imported from foreign countries. (Measurement capabilities of a country determine its level of technological development not only for manufacturing but also for health, education and environment fields.

2.2.1 Institutional Structures of Metrology Services

Metrology generally determines the precise definitions and appropriate techniques to carry out the measures. In this regard, there are several bodies, autonomous or governmental, responsible for metrology related activities in a country. They are classified into two categories, Scientific, Legal/Industrial Metrology, according to their scope and their field of application. Scientific metrology is responsible for the research needed to produce standards with a sound scientific basis, and it promotes their acceptance and international equivalence.

> ‘‘The field of Legal Metrology relates to commercial transactions; it seeks to ensure that the client who buys something is effectively receiving the amount agreed upon. For its part, the aim of Industrial Metrology is to promote competitiveness in manufacturing and service industries, through permanent improvement of the measurements that influence quality.’’ (Rocío, Marbán & Pellecer, 2002)

It is essential to have a technical infrastructure that can act as the framework for global coordination and order. Therefore, the adoption and recognition of an international system of measurement units is required.

The first serious formal step for an international order on measurements was the international Metre Convention or Treaty of the Meter (May 20, 1875), which gave birth to the BIPM. (Harasic, 2002) Almost all developed and developing countries have a national center, having relations with BIPM. The main objectives of these centers are to build and maintain national standards for all measurements carried out within that country, and to calibrate the measurement standards and devices of lower level laboratories. This chain extends to production, quality control and to all scientific, commercial and military devices, which are used for measurements. In this way, all measurements are then traceable to the national standards. National standards are linked to the standards in other countries or those of BIPM by a process of international comparisons. This is called traceability as mentioned in Section 2.2.

Figure 2.2 demonstrates the schematic representation of the various types of standards that exist in a particular area of metrology, and how the level of precision decreases along the chain of responsibility.

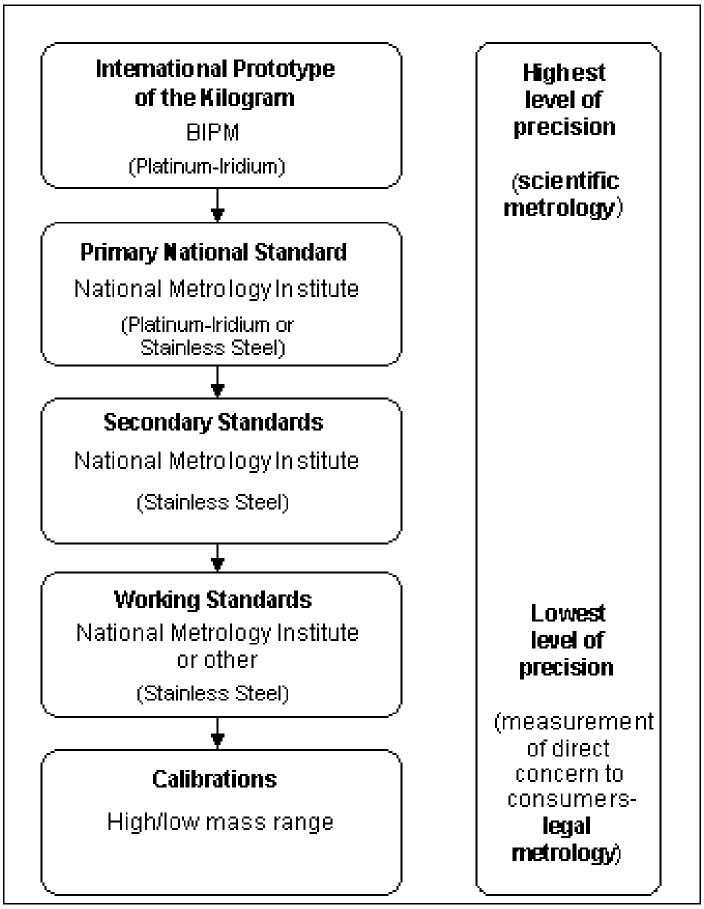

Figure 2.1. Chain of Traceability

(Source: BIPM, 2005)

Legal metrology, as represented by the work of the International Organization of Legal Metrology (OIML, established in 1955) is an intergovernmental organization whose principal aim is to harmonize the regulations and metrological controls applied by the national metrology services of its national members. It is concerned with the chain of measurement traceability that directly affects consumers, and has the backing of national laws which protect the consumer from, for example, shopkeepers whose weighing or other measuring devices may not be calibrated correctly. This means that regulations issued by the OIML are often incorporated directly into national and international laws and regulations concerned with consumer protection.

Both scientific and legal metrology are essential in ensuring consistent national measurement systems and traceable to international standards, so that there are no significant differences in measurements and tests made in different countries.

2.2.2 The Socio-Economic Role of Measurements

Metrology has a significant direct impact not only on industrial enterprises, but also on people by watching over the contents, the quality and the safety of consumer products.

In this respect, ‘‘quality of life’’ is a term to emphasize the non-economic benefits of assessment of measurement system of a country. Governments should provide their populations not only trade and consumer protections, but also, health and environmental safety. ‘‘Accurate and widely accepted measurements are important in ensuring that market transactions can take place and that consumers can feel confident that the goods they buy are of the quantity and quality they require.'' (Temple, Slembeck & Williams, 2002)

Consumers use measurement as a guide to the qualities as well as the quantities of the things they purchase. Familiarity and confidence in measurement are essential to the proper functioning of efficient markets. (Spencer & Williams, 2002)

The role of measurement and testing in society is very important and it is somewhat greater than its use in industry. However, the social benefits of the use of accurate measurement within society are not easily quantifiable. There are many externalities affecting the measurement activities.

''Since, measurement techniques have little saleable benefit of their own accord it is likely one of the main sources of benefit will be due to the externalities and spillovers to other forms of production.'' (Temple, Slembeck & Williams, 2002)

In selecting outcome metrics for quantitative measurement of economic impacts, the ideal approach is to choose those metrics that represent the "final" impact of the diffusion of the technology infrastructure on the relevant supply chain segment. However, final or ultimate outcomes can require complex metrics, such a "quality of life index" for medical technologies and services. Such final outcome metrics represent measures of the social objectives of broad government programs, and many analysts separate government programs into those with social and those with economic objectives. (Tassey, 2003)

2.2.3 Medical Metrology

One of the most important concepts in metrology is the medical metrology, since it has a vital impact on the well being of the population. The products or testing devices should be in accordance with health and safety standards and specifications.

As mentioned earlier, the social benefits of the use of accurate measurement within society is quantitatively hard to determine, as a result of arising externalities. Somehow, these benefits are larger than the benefits arising in the industry. They depend on where and how measurement is applied.

Potential social benefits of the medical metrology are as follows:

- Reduced deaths from preventable illness
- Reduced incidence of illness and accidents due to better safety standards
- Improvements in the quality of the environment
- Reductions in the incidence of disease in the food chain
- Protection from fraud and other sharp practices in trading and many others

(Spencer & Williams, 2002)

Measurement systems generate significant non-economic benefits in the form of improvements to many aspects of ‘‘quality of life’’ for example in health and safety, environment, trade and consumer protection. For example, an individual is greatly reassured by knowing that the X-Ray they must have to help mend a broken arm is done from a calibrated machine so they will not receive a damaging excessive radiation. (Bowns, 1999)

Another example can be given from the potential hazards of genetically modified food and beef safety.

One of the important areas for the social use of measurement services is the health care service. There is variety of measurements applied for medical testing in a range from simple ‘‘blood pressure tests’’ to HIV/AIDS testing. Besides, there is variety of medical testing devices, those of which the decisions on human lives are taken based on the results taken from. There could be certainly some errors in measurement results of these devices as they age with years and cause some terrible results, which may be called as medical accidents. [*]

In this regard, there appears a responsibility of governmental health institutions/officials and the professional users of medical testing devices. Beginning from the procurement of mentioned devices to the hospital, that hospital is liable to any defect, disorganization and patient safety that may come out in the operation of these testing devices. The application of periodical calibration procedures on medical testing devices during their operation life-times, leads to not only the higher quality and reliability of service to the patients but also increase in the benefit-to-cost ratio for the applied tests on patients, and also the minimization of risks such as patient deaths, incidence or extension of illnesses, etc.

In the framework of health care services in Europe, the European Commission has financed several projects on economic impact assessments of country specific metrology issues. The reason for financing those impact

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[*] On December 7th, 1999, American President has stated some remarks on Health Care The Rose Garden: ‘‘Last week the Institute of Medicine released a disturbing report about patient safety and medical errors in our nation’s health care system. According to the study, as many as 98,000 Americans lose their lives each year as a result of preventable medical errors. Up to 7,000 die because of errors in prescribing medicine. And the cost of all these errors add as much as $29 billion to our medical bills.’’

assessment projects was the characteristics of the EU. It is necessary to have in mind that, the EU is a single market, which has free movement of goods through out the Community of more than 350 million people and which is still expanding. The freedom of movement in the EU has certainly become possible by implementing technical harmonization directives. For the product range of medical devices there are three directives: Active Implantable Medical Devices, Medical Devices and In Vitro Diagnostic Medical Devices. Medical Devices Directive 93/42/EEC (MDD) covers the majority of all medical devices. When a Notified Body is needed in conformity assessment under the MDD, some authorized and accredited bodies can provide the manufacturers with the passport to the European market. Figure 2.3 demonstrates the conceptual view of European Medical Device Directive:

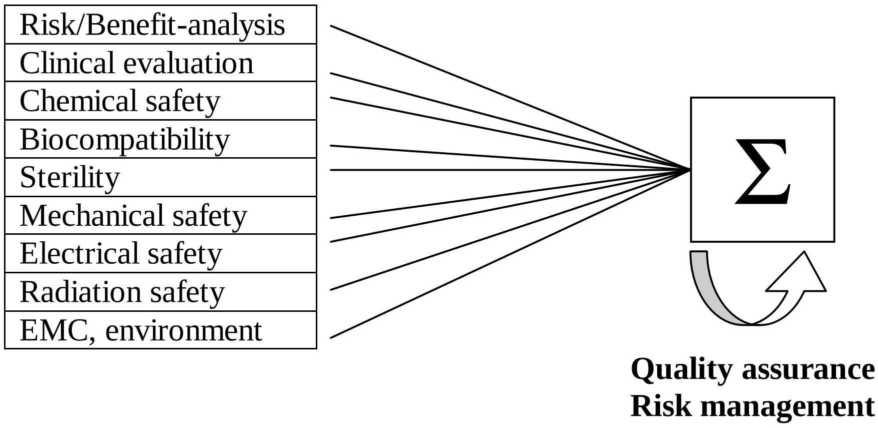

Figure 2.2. Medical Device Directive (98/79/EC)
(Source: VTT, 2005)

Not only must the medical device technically compete with the other devices, but it must also compete with the latest technology findings. The medical devices create a significant impact on the costs of health care services, such as additional medicine treatments, longer hospital stays, and etc. In order to reduce these costs the device should operate efficient and proper, and they need to be under maintenance for calibration in periods varying with the usage frequencies.

2.3 The Structure of Metrology System In Turkey

The national system of innovation contains all institutions necessary for creation and maintenance of the abilities such as technical and financial R&D support, knowledge dissemination, accreditation, certification, and etc. The system certainly includes institutions related to standards and quality control, national metrology system and national notification-accreditation-certification system.

National metrology centers, with the secondary level accredited laboratories, form the national measurement system and coordinate their activities. The national center proves its proficiency via comparisons with other national centers with international comparisons, which are frequently being observed by BIPM with the information relayed to other national centers through various publications.

In Turkey, first studies related to international measurement system started on 25 May 1875 when Miralay Hüsnü Bey had signed the Meter Convention on behalf of the Ottoman Empire. Though the Ottoman Empire was one of the 20 states that were the founders of the Meter Convention, there was no significant development in this field until the law of Weights and Measures (law no 1781) has been put in act on 26 March 1931. After the World War II, the need for an integrated system of metrology was felt strongly in Turkey. Turkish Standards Institute (TSE) has been established by the law numbered 132 dated 18.11.1960 for the purpose of preparing standards for every kind of products, processes and services. However, the volume of the market for calibrations was not large enough to justify a major investment in keeping national standards until 1980. The Prime Ministry of Turkey asked TÜBİTAK (Scientific and Technical Research Council of Turkey) to establish the national measurement system in the early 1980s. Initial studies began in 1982, the feasibility study was accepted by all the relevant parties, and the UME was founded in 1992, as part of TÜBİTAK.

On the other hand, in 1998, a working group has been formed by the Undersecretariat of Foreign Trade for drafting a law on National Accreditation System and the law establishing TÜRKAK (No. 4457) was approved on 27 October 1999.

UME maintains the traceability of its National Standards by intercomparisons with the BIPM and other National Metrology Institutes. TSE represents the main secondary laboratory in Turkey that provide various calibration, analysis and services. Also TSE's another major task is to prepare standards for every kind of product and to inspect the given standards. TÜRKAK is the legal entity to accredit the local and international bodies laboratory for certification and inspection services, ensure them to operate in accordance with the international standards.

2.3.1 National Metrology Institute (UME)

The establishment of measurement standards and strengthening national measurement services are regarded as a fundamental step to provide the basis for equity in trade, to promote the development of industry, to develop and manage modern measurement systems. The conversion of science into a major productive force is inevitably accompanied with growing interest in increasing measurement accuracy. (NPL, 1998)

UME, established in 1992, is a non-profit government entity that also falls under the jurisdiction of the TÜBİTAK organization and is governed by its laws and regulations. A large part of its financing is received from budget allocations (%85), while the rest comes from the private sector. It is expected that this trend will change somewhat over the next several years and that UME will depend less on budget allocations for its sustainability.

There are 43 laboratories, each of which has environmental control and all the parameters such as temperature, humidity and air pressure are measured and recorded by a fully automated computerized environmental control center. The most sensitive laboratories are underground and special precautions are taken in order to minimize vibrations.

Objectives of UME are listed as follows:

- To establish and maintain national measurements standards in accordance with the SI Units.
- To ensure the traceability of national measurement standards to international standards.
- To establish a national measurement system and provide services to the laboratories within this system in terms of calibration, training, consultancy and other areas.
- To ensure the suitability of the laboratories which wish to join to the Turkish Calibration Service and to organize their accreditation.
- To contribute to research and development in the areas of measurement techniques, calibration and basic metrology at an international level.

- To develop high technology products and to disseminate them via its developed infrastructure.
- To increase the quality of products produced in Turkey by means of a national measurement system.
- To represent Turkey at an international level in the field of metrology.

(UME, 2005)

Services provided by UME are summarized in Table 2. 3.

Table 2.3. Services Provided by UME

Measurements Calibration Tests Analysis On-site measurements	***Training*** Programmed (Regular) On Demand Special
Consultancy Measurements Quality Systems Accreditation New Labs Feasibility Equipment Requirements Training Requirements Quality Handbook Uncertainty Calculations On Site Problem Solving New Diagnostic Techniques	***Information Dissemination*** Publications (mostly guidance) Technical Meetings (not regular) Scentific Activities (meetings, presentations) Technical Committees (on specific subjects) UMBA (National Measurement Information Network)
Infrastructure Support Machine Shop Services Electronic Shop Services Optical Shop Services Repair/Maintenance Liquid Nitrogen and Liquid Helium	***Device Control Software*** IEEE 488, RS 232, Bi-centronics Visual Basic, Labview, Pascal, C++, etc.
Accreditation (until TURKAK)	***Equipment, Prototype Production***

Source: UME, 2005

UME provides industrial calibration services to the secondary level and other laboratories, making use of closely monitored, temperature controlled and vibration isolated laboratories. UME organizes training seminars in response to requests from companies. It provides consultancy in the areas of general metrology, accreditation of laboratories, general uncertainty calculation, as well as the setting up of laboratories including control of environmental conditions, choice of equipment, laboratory layout etc. Also, UME conducts R&D activities to produce and to develop new measurement systems and devices.

2.3.2 Turkish Standards Institute (TSE)

TSE has been established in 1960 with the aim of preparing standards for every kind of item and products together with procedure and service. The Institute, responsible to the Prime Ministry, is a public founding whose abbreviation and trademark is also TSE.

The major tasks of TSE (TSE, 2005) are listed in the following:

- To prepare and to get every kind of standard
- To inspect the standards which have been prepared within or out of the Institution and to accept them as Turkish Standards if approved
- To perform the technical inspections and researches about standards, to follow up the resembling studies done in foreign countries, to establish relations with international and foreign companies of standard and to collaborate with them.
- To collaborate with universities and other scientific and technical associations and institutions, to make publications on standardization,
- To conduct research on standards and to establish laboratories in order to check the application of voluntary standards, to perform

technical studies requested by public or private sector and report about them.

- To perform studies on research and development about metrology and calibration and to establish necessary laboratories

As a result of these tasks, TSE services comprise of quality and system certification, product and service site certification, personnel certification, laboratories, calibration, standard preparation, and consumer services within the country.

2.3.3 National Accreditation Council (TÜRKAK)

Accreditation Agency of Turkey (TÜRKAK) is established in 1999, related with the Prime Ministry, subject to private law provisions, with its headquarters in Ankara, to perform the tasks such as (TÜRKAK, 2005):

- Establishing the criteria and measures related with accreditation, implement and, when required, modify, revise and annul the same,
- Evaluating the private and/or public agencies and organisations, which carry out activities on laboratory, product/service, system, personnel and similar certification issues, applying for accreditation according to relevant standards and criteria and deciding whether to accredit such organisation as a result of this evaluation, monitoring accreditted organisations, suspending the decision of accreditation temporarily or permanently, when required, and providing coordination among all agencies and organisations that will carry out activities in these fields,
- Making arrangements encouraging the use of markings and certificates issued by accredited organisations,
- Establishing relationships and cooperate with international and regional accreditation bodies and those of other countries,

- Carrying out trainings and activities promoting the importance of accreditation and the consciousness of quality

In Figure 2.3 the direct users of accreditation services, i.e. the clients of TÜRKAK services are demonstrated. In the figure the two-sided arrow with number (1) implies the protocols between TÜRKAK and the ministries responsible for safety of products on assessment of conformity assessment bodies working in the regulated area. In addition, the two-sided arrow with number (2) implies the process of certification of measuring equipment of testing laboratories by accredited calibration laboratories.

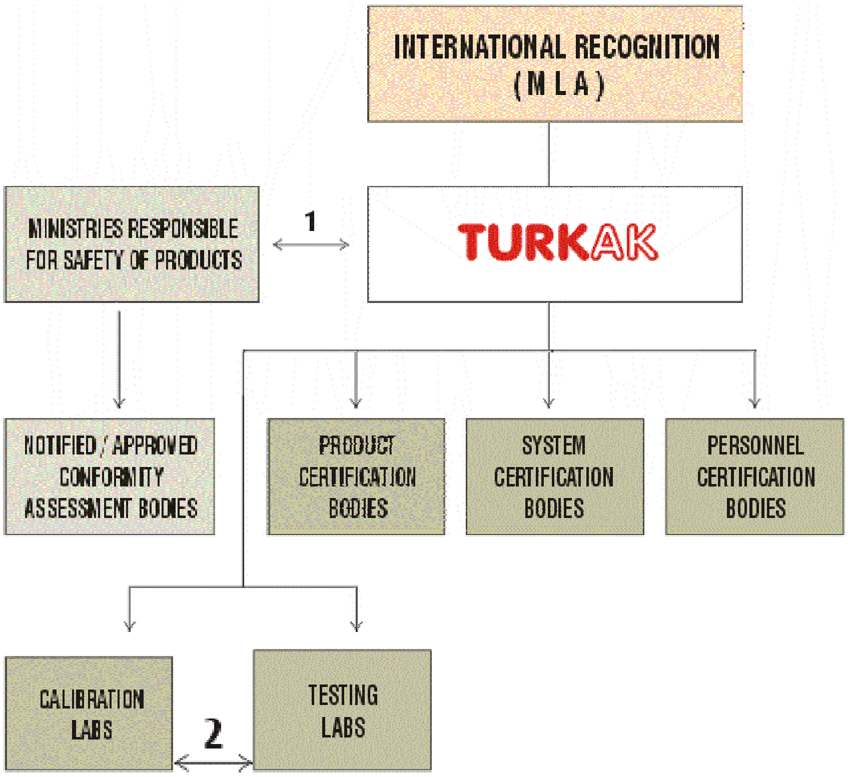

Figure 2.3. Direct Users of Accreditation Service
(Source: TÜRKAK, 2005)

There is a cooperation protocol between TÜRKAK and UME, which was signed on 15 February 2002. According to the Article 4 of the Protocol, the definitions and regulations of the following standards has been taken as the basis for the required activities implemented by TÜRKAK and UME:

- TS EN 45020: April 1997: General terms and their definitions concerning standardization and related activities.
- TS EN ISO 9000: 2001: Quality Management Systems – Fundamentals and Vocabulary
- TS EN ISO/IEC: 17025: 2000: General requirements for Competence of Testing and Calibration Laboratories.
- TS 5798: November 1998: International Vocabulary of Basic and General Terms in Metrology (VIM)
- TS EN 45003: April 1997: Calibration and Testing Laboratory Accreditation Systems – General Requirements for Operation and Recognition

CHAPTER 3

IMPACT ASSESSMENTS ON METROLOGY

Pressures have increased on government agencies that support industrial growth to demonstrate economic rationales for the existence of specific public investment and/or R&D programs. (Tassey, 1999) In this direction, economic impact assessments focus on the changes in financial and strategic aspects within public or industrial organizations in order to ensure accountability, to document value and to enhance the overall management effectiveness. (Link, 1996) In more recent years, impact assessment projects about metrology infrastructures have become more frequent in several countries.

As noted earlier, the metrology system as a part of the national innovation system plays an important role in the process of technological development and productivity growth. Figure 3.1 demonstrates the main stakeholders within a country affecting and affected by the metrology system.

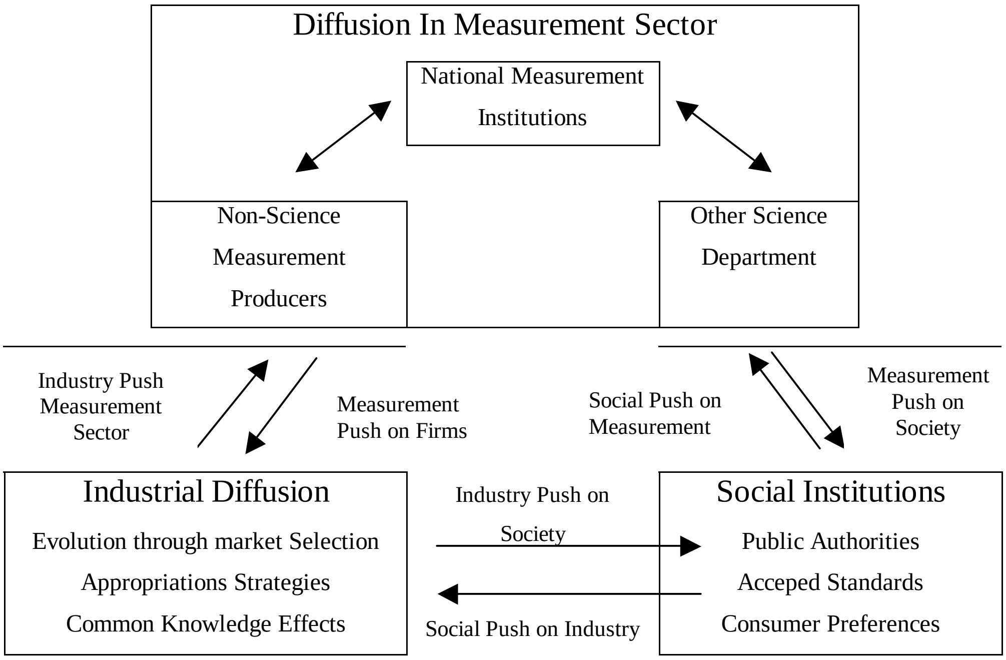

Figure 3.1. The interactions in the creation and diffusion of measurement technology (Source: Temple, Slembeck & Williams, 2002)

All stakeholders interact with each other. For example, society provides a push on the measurement sector in case of legal metrology, and consumers can demand measurement information to judge quality or safety. Industry pushes on the measurement sector to obtain more accurate and correct measurements for being more competitive. Measurement push on industry can be explained in terms of the consequences of an R&D project implemented by the measurement sector. This push can be useful for new product innovations, which will be supplied by industry.

In the following sections of this chapter, several case studies on impact assessment will be explained. Since there are a large number of studies, we focus on three countries, the USA, the UK and Turkey, and study some cases from the EU as well. Table 3.1 presents the data on the annual budget of NMIs in these countries. As shown in the table, the USA has the highest for its NMI as being the largest country in our sample. UME has a lower budget than the countries listed as follows:

Table 3.1. Comparison of NMI Budgets (Modified Version)

Country	**National Measurement Institutions**	**Budget (£- *November 1999 Exchange Rates*)**
UK	NMS	£38 MM
Germany	PTB	£82 MM
USA	NIST	£400 MM
France	BNM	£29 MM
Italy	Uffucio Centrale Metrico	£16 MM
Turkey	UME	£7.5 MM

Source: Bowns, 1999

3.1 European Experiences About Impact Assessment on Measurement Activities

Measurement activities vary widely across Europe due to different economic structure within each country. However, at a basic level, aggregate measurement activity can be determined from the data of activity so as to quantify the size and scope of measurement in the following sectors:

- National Metrology Institutions
- Legal/Industrial Metrology Institutions
- Accreditation Agencies
- Calibration and Testing Laboratories and Companies
- Producers of measurement and testing equipment
- Industrial use of measurement
- Indicators of social use of measurement

Main features of a typical measurement infrastructure in European Union includes:

A statutory basis: Every country has a statutory basis for measurement infrastructure, in the form of legislation, regulation, or as national standards. However, at the top level EU Directives, such as the Measurement Instrument Directive (MID), provide direct requirement for standardization.

National Measurement Institutes (NMI): NMIs are designed to develop and maintain national standards for one or several quantities. In all countries, at least one NMI is given responsibility for the legal metrology, the most common form of which is regulation of weights and measures for trading. (Spencer and Williams, 2002) The structure of NMIs varies widely across Europe, while some are very centralized as in Germany, others are quite decentralized as in France. Most NMI's are owned by the government but in some countries, private companies are employed as agencies.

Non-Science Measurement Groups: These groups include firms and laboratories that carry out calibration and testing services.

National Measurement System: NMIs, Legal Metrology Laboratories and the National Accreditation Agencies makeup the National Measurement System. The most common form of legal metrology is the regulation of weights and measures for trading.

Measurement Instrument Makers: These are the industrial producers of measurement equipment. Industrial use of measurement is one of the main areas of measurement instrument makers. Production of measurement instruments accounts about €49 billion per year (1% of total EU industrial output). Germany, the Netherlands and the UK are the major sources of EU measurement equipment. On the other hand, cost of measurement within the firms is estimated as €34 billion per year (1% of total costs).

The Intermediate Measurement Sector: The accredited and non-accredited calibration and testing laboratories and the measurement instrument makers are considered as the intermediate measurement sector. Accreditation systems offer a third-party quality assurance guarantee, and in terms of measurement industry, it ensures the degree of accuracy, traceability and service that customers can expect. On the other hand, non-accredited measurement activity, although less formal is carried out in the form of calibration and testing in the house without the requirement of certification at all.

Measurement Users: Measurement infratechnology is used by a wide variety of society including instrument makers, industry, public authorities and consumers. Measurement is used in many aspects of daily life, and although the social benefits are hard to quantify, they are quite apparent in health care, food safety and public health, vehicle emissions and safety and in petrol pumps.

A recent study (Spencer and Williams, 2002) demonstrates that the cost of measurement activity in the EU is large in economic terms: €83 billion (almost 1% of EU GDP) is spent each year in this sector by a diversity of organizations, (industry and official organizations) at both the national and super-national level. When social spending on health, environmental regulations, safety testing, anti-fraud tests and normal day-to-day activities are added, this figure rises considerably. When this cost figure is compared to the benefits of measurement, it can be concluded that the money is well spent. Direct impact of measurement activity suggests that this spending generates €230 billion of benefit.

Table 3.2 shows the impact of both domestic and foreign R&D on measurement on growth in EU countries. The impact of domestic measurement R&D on GDP is about 0.28% in EU-15, and that of foreign measurement R&D is much higher (0.49%). Thus, R&D expenditures on measurement technologies have increased EU-15 GDP by 0.77% in 1999/2000. (Williams, 2002)

Table 3.2. Economic Impact of Foreign and Domestic Measurement R&D in the EU (Impact 1999/2000) (Millions of Euro)

	GDP	Domestic Impact	%GDP	Foreign Impact	%GDP	Total Impact	%GDP
Austria	199,837	28	0.01	809	0.40	837	0.42
Belgium	233,590	109	0.05	1,112	0.48	1,221	0.52
Denmark	138,918	20	0.01	661	0.48	681	0.49
Finland	125,387	34	0.03	1,468	1.17	1,502	1.20
France	1,343,913	4,891	0.36	6,924	0.52	11,815	0.88
Germany	1,978,100	8,383	0.42	8,293	0.42	1,666	0.84
Greece	110,627	1	0.00	590	0.53	591	0.53
Ireland	87,079	1	0.00	426	0.49	427	0.49
Italy	1,099,100	1,259	0.11	5,189	0.47	6,448	0.59
Netherlands	373,907	285	0.08	1,624	0.43	1,909	0.51
Portugal	101,040	3	0.00	619	0.61	622	0.62
Spain	465,342	61	0.01	2,402	0.52	2,463	0.53
Sweden	231,928	137	0.06	1,420	0.61	1,557	0.67
United Kingdom	1,470,755	6,801	0.46	7,457	0.51	14,258	0.97
Total EU-15	7,959,523	22,012	0.28	38,994	0.49	61,006	0.77

Source: Williams, 2002

Another study for the economic assessment of the impact of measurement and testing infratechnology in Switzerland related with the European Measurement Project was prepared by Temple, Slembeck and Williams.

(Temple, Slembeck & Williams, 2002) Switzerland is one of the leading players in the area of measurement and testing. It has one of the highest rates of innovation and patenting in this area. The benefits of these activities have been calculated as 3.27% of GDP. The role and activities of the Swiss Office of Metrology and Accreditation (METAS) are assessed in this study. 77% of METAS's income comes from private sources. Whereas, in other centralized systems such as Portugal and Sweden, 90% and 82% of their income comes from private sources, respectively. In less centralized systems such as Denmark and the UK 57% and 47% of the income of the metrology institutes come from private sources, whereas, in Germany, majority of the income (90%) is covered by public sources. The sources of funding for metrology institutes at the EU level are as follows: 64% public, 26% commercial, 7% EU sources and 3% industrial partnerships. (Temple, Slembeck & Williams, 2002)

3.2 Metrology and Measurement Activities in the UK

UK National Measurement System (NMS) aims to "maintain and develop, at the national level, an infrastructure that ensures measurement in the UK is valid, fit for purpose, consistent and internationally recognized. This infrastructure exists primarily to promote the economic competitiveness of UK and support regulatory needs." (Williams et al., 2003). For this purpose, four national metrology institutions (NMIs) exist, namely, the National Physical Laboratory (NPL), the Laboratory of the Government Chemist (LGC), the National Engineering Laboratory (NEL), and the National Weights and Measures Laboratory. Two of these institutions, LGC and NEL, are fully ''privatized'' companies. The funding of the NMS is provided by an independent body, Measurement Advisory Committee (MAC), while the National Measurement System Policy Unit (NMSPU) determines the overall policy strategy. The national measurement activities is carried out through a wide range of programmes, in addition, the foundation programme and the national measurement partnership (NMP) support management strategy and technology transfer projects and the Legal Metrology programme supports measurement research for regulatory purposes, often related to health and safety or environmental protection (Williams et al., 2003).

The NMS is often viewed as the top layer of the measurement infrastructure in the UK. Industrial use of measurement technologies is diffuse and mostly carried out by a network of calibration, testing and inspection organizations, which form part of the technology infrastructure in the private sector. Voluntary third-party validation is often obtained from the United Kingdom Accreditation Service (UKAS), which is designated by the UK government as the sole accreditation body for conformity to international standards in measurement procedures (e.g. EN 45000 or ISO 9000). As of 2000, 342 calibration labs and 1161 testing and inspection bodies have taken UKAS accreditation (UKAS Annual Report 2000). Calibration laboratories sold around 600,000 UKAS authorized calibration certificates and around 10 times as many non-UKAS calibration certificates in 1999, mostly to SMEs. In addition calibration is carried out by non-UKAS organizations and by measurement departments within firms such as aerospace and automobile manufacturers. The number of these certificates and their associated costs are unavailable but are likely to be many times greater than those associated with accredited organizations.

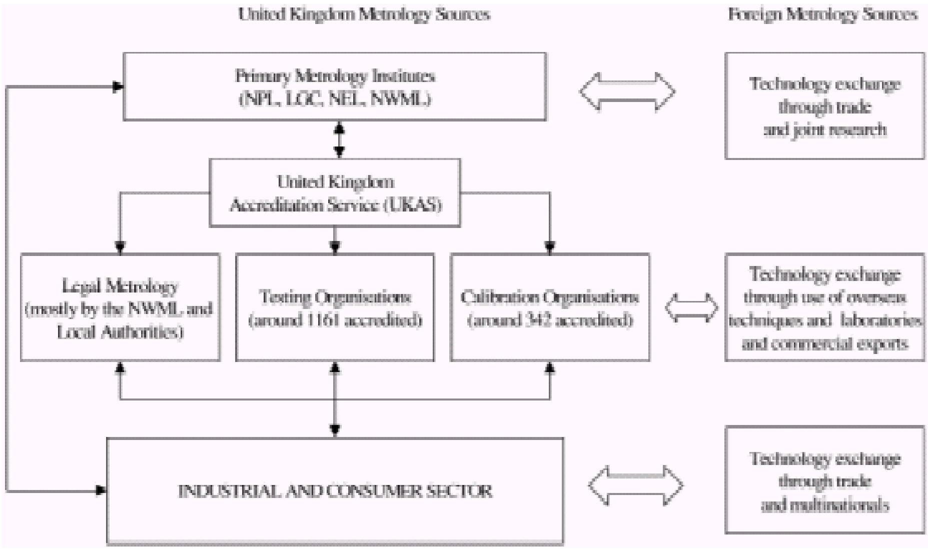

Figure 3.2. The United Kingdom National Measurement System (Source: Temple & Williams, 2002)

There are various studies on the impact of NMS activities. One of the studies that investigate the economic impact of metrology activities is "Measuring the economic benefits from R&D: improvements in the MMI model of the United Kingdom National Measurement System" (Williams et al., 2003). It explores the economic impact of public funding on metrology and measurement activities that support the development and use of new techniques and products, through an econometric model, the Mapping Measurement Impact Model (MMI). The model characterizes the impact of metrology on the society via the following (Williams et al., 2003):

A. Providing traceability to internationally recognized primary standards.
B. Generating exploitable new measurement technologies.
C. Using leading edge metrology to support advanced products.
D. Providing an expert service, usually consultancy, to diagnose and solve measurement related problems in industry.
E. Providing leadership and dissemination in frontier technologies.

F. Representing UK interests on international bodies.

The findings of the model imply a significant impact for the NMS programmes, and reflect their public good character. The results of this model put the impact of a selection of programmes at between €1.9 billion and 2.3 billion in 1999 with benefit to cost ratios (BCR) between 5 and 111 with an average of 16. The model has been developed by NPL and used to prioritize over 250 projects worth approximately £60 million for the UK government as part of 9 scientific research programmes. (NPL, 2005)

A review has been carried out in 1999 by a consortium led by PA Consulting Group to test the rationale for and economic benefits of the NMS, examine the NMS programmes and possible future programmes to establish cost/benefit ratios of all major NMS activities and to assess the value of having centers of excellence. (Bowns, 1999) The review has resulted that measurement in the UK as a whole delivers significant positive impact into the economy of 0.8% GDP.

In addition, the NMS generates significant non-economic benefits in the form of improvements to many aspects of ‘‘quality of life’’ for example in health and safety, environment, trade and consumer protection. ‘‘This is the first time that any structured and comprehensive attempt has been made to assess the non-economic benefits of NMS Programmes and the techniques at that stage are somewhat novel. (Bowns, 1999) The criteria to score each benefit has used two dimensions

a. The importance of this benefit to the ‘man in the street’, ranging in 3 steps from:
    - LOW (improves Quality of Life, low worry factor, small number of people affected) to

- HIGH (life and death issue, of great concern to individuals, affects many people)

b. The contribution that the NMS makes to improving Quality of Life in this area, ranging in 3 steps from
   - LOW (makes a minor contribution to delivering this benefit) to
   - HIGH (this benefit relies heavily on NMS input).

Figure 3.3 demonstrates the contribution of NMS to the issue of 'quality of life'

Importance to the man in the street

HIGH	5	7	9
	3	5	7
LOW	1	3	5
	LOW		HIGH

Importance of NMS

Figure 3.3. Contribution of NMS to Quality of Life (Source: Bowns, 1999)

After the scores for the benefits have been combined at the programme level, Ionizing Radiation has got the highest value of benefit and followed by Chemical Metrology Programme, that has a significant impact in the bio-medical applications.

3.3 NIST's Experience – USA

The National Institute of Standards and Technology (NIST), founded in 1901, is a non-regulatory federal agency within the US Commerce Department's Technology Administration. enhances the competitiveness of American Industry while maintaining its traditional function as lead national laboratory for providing measurement, calibrations, and quality assurance, techniques which underpin US commerce, technological progress, improved product reliability and manufacturing processes, and public safety and advance, through co-operative efforts among industries, universities, and government laboratories, promising research and development projects, which can be optimized by the private sector for commercial and industrial applications. (Link & Scott, 1997)

NIST's explicit mission is ''to promote US economic growth by working with industry to develop and apply technology, measurements, and standards.'' Accordingly, NIST's direct customer is the US industry. To carry out the mission and to serve US industry, NIST supports four programme areas, the NIST Laboratories, Baldridge National Quality Program, Manufacturing Extension Partnership and Advanced Technology Program.

A laboratory research programme is focused on meeting the infrastructural technology needs of the industry. These are primary research activities at NIST coming from eight laboratories: electronics and electrical engineering, chemical science and technology, materials science and engineering information technology, manufacturing engineering, physics, building and fire research, and technology services. In an effort to promote the economic growth and public welfare, NIST's laboratories provide technical leadership in measurement and standards infrastructure, and they assure the availability of needed measurement capabilities.

The Program Office, established within NIST in 1968, performs programme and policy analyses, generates strategies, guidelines and formats for planning and performing long-range programme planning; and carries out economic analyses for NIST as a whole and provides analytical leadership for laboratory-focused impact assessments. In 1990, the Program Office initiated its first economic impact assessments as part of its overall mission and as part of an effort to establish the groundwork for future assessments.

Planning and evaluation have been the focus of the Congressional legislation, in particular, the 1993 Government Performance and Results Act (GPRA). (Tassey, 1999) The focus of GPRA is performance accountability; the purposes of the Act are to:

- improve the confidence of the American people in the capability of the Federal Government, by systematically holding Federal agencies accountable for achieving programme results;
- initiate programme performance reform with a series of pilot projects in setting programme goals, measuring programme performance against those goals, and reporting publicly on their progress;
- improve Federal programme effectiveness and public accountability by promoting a new focus on results, service quality and customer satisfaction, etc. (Link & Scott, 1997)

Under the Act, agencies are required to submit to the Office of Management and Budget a strategic plan for programme activities that contains a description of the programme evaluations used in establishing or revising general goals and objectives, with a schedule for future programme evaluations. (Link & Scott, 1997) Compliance with this Act is driving increased planning and impact assessment activity and is also stimulating greater attention to methodology. (Tassey, 1999) Although some of the basic tools for economic impact assessment have existed for some time, NIST has had to adapt this generic methodology along a number of dimensions: selection and application of impact (outcome) measures, integration of qualitative and quantitative analyses into a complete microeconomic assessment of a project's impacts, and interpretation of the results of these analyses in the context of ongoing R&D policy debates. (Link & Scott, 1997)

NIST uses some quantitative metrics such as Social Rate of Return (SRR), which is calculated as the discount rate that is needed to reduce the time series of net benefits under analysis to zero. SRR is estimated by the use of Internal Rate of Return (IRR) measure, which is the minimum acceptable rate of return. In addition, Benefit-to-Cost ratio (BCR) is used in order to estimate the impact of the programmes. Table 3.3 presents the data on SRR and BCR to various NIST projects conducted in 1991-1999. (Tassey, 1999)

Table 3.3. Summary of recent and ongoing economic impact studies for NIST measurement and standards laboratory projects

Industry: Project	Output	Outcomes	Measures
Photonics: optical instruments	Test method (calibration)	Increase productivity Lower transaction costs	SRR: 145% BCR: 13:1
Automation: machine tool software error compensation	Quality control algorithm	Increase R&D efficiency Increase productivity	SRR: 99% BCR: 118:1
Materials: thermocouples	Reference data (calibration)	Lower transaction costs Increase product quality	SRR: 32% BCR: 3:1
Pharmaceuticals: Radiopharmaceuticals	Reference materials	Increase product quality	SRR: 138% BCR: 97:1
Chemicals: alternative refrigerants	Reference data	Increase R&D efficiency Increase productivity	SRR: 433% BCR: 4:1
Materials: phase equilibria for advanced ceramics	Reference data	Increase R&D efficiency Increase productivity	SRR: 33% BCR: 10:1

Source: Tassey, 1999

There are significant differences in evaluation methodologies applied by the NIST. For example, a study of NIST's thermocouple calibration program (provides accuracy in temperature measurement) was largely relegated to one industry -a group of small firms that supply thermocouple wire and complete thermocouples. In this assessment study, NIST aimed at evaluating the economic impact on domestic industry. However, a wide range of industries in various supply chains such as automotive, chemical, consumer goods, HVAC, medical, metals, aerospace, petrochemical, plastics, and etc. are major consumers of thermocouples. Such industries are very difficult to include in impact studies because the component supported by NIST infrastructure is a small portion of the downstream products that these industries produce and sell. These user industries are frequently unwilling to allocate time to responding to a survey and, in fact, often cannot easily estimate the quantitative economic impact. (Tassey, 2003) In this scope, economic importance of thermocouples in the overall manufacturing economy has been put forward, and IRR has been calculated as 31.8% and this supports that NIST's thermocouple calibration research and related activities are worthwhile from a social perspective.

Another impact study has been carried out on US semiconductor industry (Technecon, 1998) This study estimates the amount of metrology-related costs in the semiconductor industry, including the industry's infrastructure, for 1990 and 1996 along with a projected range for 2001. ''Metrology-related costs'' in this study is the value of current period spending by the semiconductor industry to acquire metrology capability. Metrology-related cost of both the supply side and demand side has been estimated to get a final estimation for the metrology infrastructure's size in the US. The estimation for 1990 is between $625 million and $750 million, and the estimation for 1996 is between $2.3 billion and $2.5 billion, with expected growth to between $3.5 billion and $5.5 billion by the year 2001.

NIST has implemented an economic impact study on US industry for its program in laser power and energy measurement. (Marx, Scott & Fry, 2000) The report has been prepared to recognize the accurate calibrations of instruments measuring that output with traceability to primary standards. It is concluded that, in the absence of NIST's outputs, the respondents from this industry expressed that it would have had an extremely high cost for their companies. Benefit-to-Cost ratios for low, mid-point and high level of mentioned industry have been estimated as 8.1, 11.3, 14.9, respectively. As the laser have been used in medicine for a variety of diagnostic and therapeutic application, the impacts on medical applications have been assessed, since it provides increase in safety and effectiveness of a laser procedure, ensuing that complications do not occur for the patient, and etc. (Marx, Scott & Fry, 2000)

NIST regularly conducts programme evaluations. The purpose of these evaluations is to determine how well the portfolio of research projects within an industry- or technology-focused programmatic area aligns with the objectives of the programme or laboratory; to understand how effectively the programme is being managed; and to assess progress toward broader NIST objectives.

3.4 National Metrology Institute - TURKEY

UME is a government entity that is under the jurisdiction of TÜBİTAK and a large part of its financing is received from public resources. It is expected that this trend will change somewhat over the next several years and that UME will depend less on budget allocations for its sustainability. UME has conducted several assessment studies between 1997 and 2004. The first evaluation study was carried out with the finalization of the Technology Development Program (TDP), which supported the establishment of UME via World Bank loans. The second evaluation study was conuducted for the second World Bank Project called Industrial Technology Project (ITP) started in 1999 and will end by December 2005. In the following sections, these two evaluation studies are summarized.

3.4.1 A Study of the Second Phase of UME investment programme for consideration by the IBRD

In order to deepen its institutional capacity and invest in new schemes, by the use of World Bank - IBRD Loans, UME has conducted an assessment study in 1997. The report published in May 1997 mainly provides an overall overview of the importance of investing in national standards, an assessment of UME's current facilities and services and an evaluation of UME's role in the Turkish economy. (NPL, 1997)

A major outcome from this study is the development of a model of the Turkish economy, using a typical EU country as a benchmark, and adjusting this to allow for Turkish market requirements determined from information obtained from visits, interviews, documentary evidence and knowledge of the capabilities of other national metrology institutes. The outcome of the economic evaluation has been very favorable. The model indicates that the net present value of the additional value-added generated by the measurement infrastructure, which will be created by the first two phases of investment in UME, is about US$2.8 billion. The minimum average cost-benefit ratio for the historic and proposed investments in UME was estimated as 44. This is a highly favorable ratio and fully supports the view expressed in the UME strategy document that "metrology is an investment which has a high value and is extremely lucrative in industrializing countries". (NPL, 1997)

The findings of this report were further supported by a supplementary study by NPL. (NPL, 1998) It includes cost-benefit analysis for the past and future investments of UME and covers major services provided by UME (measurement and calibration services, test methods, and basic standards setting), and the benefits of these services to basic categories of users (industrial users, and second-tier laboratories). For a lifetime of 15 years, it is estimated that $2.5 billion will have been generated as the added value (benefit) due to the investments yielding benefit cost ratio of 44.9.

UME, established in 1992, completed the first and second phases of its development plans. At the end of the first phase, which was implemented as part of the Technology Development Project, UME has become capable of satisfying 40% of the national needs in metrology. The second phase of development began with the start of the ITP.

3.4.2 Monitoring and Evaluation of the ITP

ITP comprises four main components –Technology Development Foundation of Turkey (TTGV), Turkish Patent Institute (TPE), Marmara Research Center (MAM) and UME. This second World Bank funded project has supported the expansion of UME's facilities by allocating US$33 million to serve a greater portion of the country's metrology needs.

The overall strategy for the future development of UME's measurement services involves upgrading

(a) the existing measurement services by improving the efficiency of performing measurements; and
(b) embarking upon measurement services in new areas such as chemical and medical metrology.

By increasing the coverage of metrology services provided in the country, the aim of the institute is to reduce the proportion of routine calibrations performed and increase the types and level of sophistication of calibrations. Routine calibrations would be performed by secondary level laboratories, which UME assists through calibration, accreditation and provision of training. While UME does not refuse routine calibration work from its industrial clients, its pricing policy would be such that its services are more expensive than that of secondary laboratories within Turkey.

ITP's monitoring and evaluation studies are planned to be conducted regularly and they involve firm level surveys that are carried out by the State Institute of Statistics (SIS). The first survey was conducted in the beginning of the project to benchmark performance of firms, and the second one was repeated in 2002 as a mid-term review for monitoring and feedback purposes. The final survey will be implemented, towards the end of the project to enable evaluation.

Two reports by Prof. Erol Taymaz present the main findings of the monitoring and evaluation studies on the ITP. They are based on four databases collected by the SIS: (i) The Annual Survey of Manufacturing Industries, (ii) The R&D Survey, (iii) The Innovation Survey, and (iv) The Industrial Technology Services Survey (specifically designed for the monitoring and evaluation study and it covers technology services provided to the client firms) (Taymaz, 2003)

Some findings on the analysis for UME services are summarized in Table 3.4.

Table 3.4. Assessment of UME Services

<table>
<tr><td>Typology of UME clients
o UME clients have higher R&D intensity.
o UME client firms usually operate in R&D intensive industries.
o UME clients seem to employ more skilled-employees than an average firm does.</td><td>Information about ITP services
o The main source of information on UME services is “other firms”
o Distribution of catalogues is also an important tool for UME.
o The services of UME have an immediate impact on the firms that require a short-term vision.</td></tr>
<tr><td colspan="2">Service demanded
o The services supplied by the UME are competitive services that they can be supplied from other institutions in Turkey and abroad, however, foreign metrology institutions are not very competitive in the Turkish market
o The data indicates that there is a substantial increase in the demand for metrology services. The proportion of firms who use metrology services had increased from 29% to 35% in 3 years
o Sources and types of metrology services demanded by firms reveal that UME’s share in the “metrology services market” is not higher than 20%, but there is a slight increase in the market share of UME from 1998 to 1999.
o UME’s market share is more than 20% in the power, acoustic/vibration/ultrasonic, optic radiation, density/volume/viscosity/liquid or gas flow, EMI/EMC, RF and microwave, chemical metrology, medical metrology and ionized radiation.
o The cost of UME services seems to be the most important factor that hinders the use of these services (54%), however technological level and coverage of UME services are rated generally “very good” by most of the firms.</td></tr>
</table>

Source: Taymaz, 2003

The analysis of Taymaz (2003), supports the overall conclusion that the ITP programs have a positive impact on the performance of participant firms, and, possibly of some of non-participants through spillover effects: spillovers from research results, imitation of “best practices”, and, diffusion of information about the ITP programs.

The impact of ITP programs on productivity and employment has been analyzed in the companion report that has focused on the economic impact analysis, which was published in June 2004. (Lall & Taymaz, 2004) Major findings of this study can be summarized as follows:

- UME has been quite successful in enhancing the types and quality of calibrations it could provide. (The number of calibrations increased almost 25% from 2001 to 2003.
- As a result of R&D activities, the range of uncertainty of 10% of calibrations has been reduced every year.
- The average duration of providing these services reduced from 7 days to 6 days in 2003.
- The types of training provided have increased from 44 to 67.
- Calibration services account for about 90% of UME's industrial income that reached to 1.4 million USD in 2003.
- UME now covers some 25% of its current expenses (personnel and others) from its industrial income.
- UME clients are 5-7% more productive than are non-clients.
- The analysis suggests that output of all firms increased by 6% in 1997 and 2000 as a result of ITP.
- The impact in medium/high-tech industries is higher than low-tech industries (8.4% vs. 4.8% in 2000)

This interim survey has suggested that ITP has been successful in almost of its objectives. UME has upgraded its equipment and capabilities, and it played a critical role in establishing the national measurement system in Turkey, maintaining national primary standards, and in providing traceability for various types of measures. UME has also provided high quality calibration services demanded by the industry.

With the establishment of TÜRKAK, UME began to withdraw from low-end calibrations. These calibrations started to be handled by the accredited laboratories.

CHAPTER 4

AN ASSESSMENT OF THE IMPACT OF CALIBRATION OF MEDICAL DEVICES

The main aim of this thesis is to analyze and explain the use of metrology services and the socio-economic impact of medical metrology on consumers in Turkey. The initial thoughts for this study have arisen from the recent monitoring and evaluation activities that have been carried out for assessing the impact of metrology services on the Turkish industry. The driving force is that the measurements have close relationships with humans in terms of its influence on not only the safety of products being used, but also on the health care services. Table 4.1 shows what is being analyzed within the scope of this study.

Table 4.1. Impact Assessment Activities In Turkey

Customers \ Functions		1 Keeping Metrology Standards (1mt, 1kg)	2 Development of Methodology (R&D)	3 Development of Equipment	4 Measurement and Calibration Services	5 Certification
A	Industrial Users (Firms)	Not Assessed			*	*
B	Second-Tier Laboratories				*	*
C	Others (consumers, public sector, military serv.)				?	Not measured.

As discussed earlier in Section 3.4 of this thesis, the impact assessment activities for the industrial users and the second-tier laboratories, which are the main users of metrology services, have been conducted as a part of assessment studies on UME, the primary laboratory in Turkey. In Table 4.1, the impact studies, carried out in recent years, are positioned in the cells A4, A5, B4 and B5. In this study, the impact on cell C4 is targeted for assessment.

Metrology has an impact on consumers in many ways. To give example from daily lives, the calibration of pumps in the fuel stations are of primary importance. The calibration periods for these pumps are all defined, but when the pumps are not periodically calibrated, the flow rate of the fuel through the pump may increase or decrease somewhat 0,1%. When the fuel consumption of 3,8 millions cubic meters in 2004 in Turkey (PETDER, 2005) is taken into consideration, a large amount of flow of cost can be realized from the purchaser to the seller, or reverse, from the seller to the purchaser. On the other hand, the taximeters that are being used in the cabs can be a good example. Some more examples can also be given as the following:

- Exhaust Emmision Measurement Device – environmental emphasis (increase in sulphur or other detrimental gases to the air)
- Speed Radar - Incorrect measurement may cause consumers to pay fines
- Alcoholmeters - Incorrect measurement may cause consumers to get punished
- Air Pumpers to the automobile tyres - Incorrect measurement may cause car accidents.

Some of the examples given from the daily life above, may have little impact when the results are considered at the macroeconomic level. There is always a flow of cost from one segment of population to another, as a result of the laxity of calibration activities. However, this may beconsidered as a simple transfer of resources from a part of the population to others with a negligible net impact.

Medical devices are expensive to manufacture. Failure or inappropriate operation can have terrible implications. Engineers have been working with the medical profession to develop artificial organs, replacement joints, life-enhancing systems, diagnostic and imaging technologies – remarkable machines, materials, and devices that save lives and significantly improve the quality of life for millions. Each year, worldwide, physicians implant 200,000 pacemakers, 100,000 heart valves, 1 million orthopedic devices, and 5 million intraocular lenses. (NAE, 2000) The impact of engineering in the medical arena and the resulting benefits to the average person are incalculable.

In this scope, it is obvious to mention that the health care services are of paramount importance for society, especially when the irreversible effects of the uncalibrated medical devices are taken into account. Medical devices create a significant impact on the costs of health care services, such as additional medicine treatments, longer hospital stays, and etc. In order to reduce these costs, the device should operate efficient and properly, and it needs to be under maintenance for calibration in periods varying with the usage frequencies.

We chose three medical devices that are frequently used after the surgeries as cases for our study. Their impact on patients and the effects of calibration on the overall Turkish economy are explained in terms of cost-benefit analysis. These medical devices chosen are as follows:

- Patient Bedside Monitors
- Ventilators
- Pacemakers

These medical devices have been selected for impact analysis, since they are required for use especially after the open-heart surgeries. The model is based on the statistics of applied open-heart surgeries in Turkey.

In the following sections, first, the role of the mentioned medical devices is explained. Then, the data used for the model are briefly summarized, followed by the cost-benefit analysis for each of the selected device. Finally, the results are discussed in terms of their importance for the society.

4.1 Medical Devices: The Sample

In the following sub-sections, the descriptions and operation principles of the selected medical devices are briefly explained.

4.1.1 Patient Bedside Monitors with ECG

Monitoring systems in Intensive Care Units (ICUs) are of paramount importance that include integrated monitoring devices, central monitoring consoles, more reliable sensors, advanced signal processing techniques, and methods to standardize data exchange between biomedical devices. However, all these advanced systems in the modern critical care environment in the hospitals are badly affected with uncalibrated devices.

Those who mostly need physiologic monitoring are the patients in ICUs. Care of the critically ill patient requires accurate decisions so that life-protecting and lifesaving therapy can be appropriately applied. The patient bedside monitors are designed for maximum flexibility and optimum monitoring at any site in the hospital. These monitors at least include the analysis and display of one or more electrocardiographic leads, at least two fluid pressures, and direct or indirect measures of arterial oxygen levels. These values must be displayed both in graphic and digital formats by offering visual waveforms, numeric version of rate and highest, least and mean numeric values.

The parameters to be monitored in their order of importance are respiration, heart rate (ECG), temperature, non-invasive blood pressure, pulse oximetry, blood oxygen saturation, and arrhythmia analysis. Interconnects between sensors should be kept to a minimum for system reliability, ease of use and subject comfort.

4.1.2 Ventilators

Mechanical ventilation may be defined as a life support system designed to replace or support normal ventilatory lung function. Ventilator dependence is caused by an imbalance between ventilatory capacity and demand. A ventilator-assisted individual requires mechanical aid for breathing to achieve medical stability or to maintain life.

Ventilator is the heart-lung machine that mechanically pumps and maintains a patient's blood circulation and pulmonary function during heart and lung transplant surgery by shunting blood away from the heart, oxygenating it, and returning it to the body. It has been documented that ventilators can prolong the lives of patients, but there are very few studies assessing effects of their use on individual functioning, or the quality of survival. Although significant progress has been made in the treatment of patients with acute lung failure in the critical care setting. Advances in the mechanical ventilator (through microprocessor technology); biosurface technology;

liquid ventilation; and, in some cases, returning to so-called ‘antiquated’ practices of patient care (e.g., prone positioning) seem to have had an impact nonetheless. (Shapiro, Anderson, Bartlett, 2000)

4.1.3 Pacemakers

Heart disease continues to be the leading cause of death, worldwide. Mechanical or electromechanical devices such as pacemakers regulate heartbeats and correct rhythm dysfunction, usually implanted after a cardiac surgery. The effects of pacemakers on health economy measures are considerable that these are frequently used and expensive devices and their implantation may need long hospital stays. The lifetime of the batteries of pulse generators is accepted to be 5 years, if there has been no demonstrable electronic malfunction. The sensitivity of cardiac pacemakers and the severity of the effects are very dependent on design and model.

Pacing is called the stimulation of the heart using electrical pulses. Knowing how much electricity to release and at what time intervals is the most important issue for the patient safety. Pacemaker technology runs with lead wires and electrode technology. Insulated wires are threaded through a patient’s veins to the heart. Pacemakers generate electrical pulses that reach the heart through the leads. There is a threshold point at which the stimulus is sufficient to produce a heartbeat. Sending more energy than necessary to the heart has no benefit in terms of the resulting heartbeat, since the heart either contracts or it doesn't. Sending a pulse stronger than threshold uses more battery energy than needed. A series of pulses may be characterized or described by three criteria:

- *Rate*: the number of pulses or beats per minute
- *Amplitude*: The voltage of the pulse.
- *Duration*: Time in milliseconds.

A strong pulse of short duration may cause the heart to beat, but so may a weak pulse of greater duration. Pacemakers charge a capacitor from a battery, then, periodically discharge the capacitor into the heart, and, recharge the capacitor. The average human heart rate is about 72 beats per minute as measured over an entire day. The normal range for the heartbeat per minute is accepted to be between 60 to 80 beats. The basic dual chamber pacemaker paces both the upper and lower chambers of the heart (the "Atrium" and "Ventricle"). The pacing rate is 60 beats per second. The delay between the atrium and ventricle is 0.150 seconds. The synchronization of the atrium to the ventricle provides optimum pumping of blood through the heart; the atrium is where the natural pacemaker of the heart is located. (www.pacemakerproject.com)

In some countries, for example in the US, the governments do not permit the re-use of pacemakers, for the consideration of potential complications on the patients. But, this issue is being re-evaluated as an effort to reduce the cost of medical care. For example, if 20% of pacemakers implanted in the United States were to be reused, there could be a saving of about $100,000, each year. (Parsonnet & Bernstein, 1985)

4.2 The Data

In the following sub-section, the data used in the cost-benefit analysis are presented. These data are obtained from the State Institute of Statistics (SIS) and the Ministry of Health. (MoH)

Table 4.2 presents the import data on patient bedside monitors, ventilators and pacemakers. Because the export values for the selected devices are so small compared with the import values, their exports will be ignored. Also, it is assumed that there is no data available on domestic production. This assumption has also been supported by the interviews with some persons in the bio-medical sector.

Table 4.2 Imports of the Medical Devices, Turkey, 1995-2004

Year of Import	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Bedside Monitors with ECG										
Quantity (Kg)	34.521	27.610	40.842	35.862	44.418	60.808	47.830	20.908	20.321	27.449
Number	793	690	1.021	897	1.110	1.520	1.196	523	508	686
Amount (US$)	3.698.735	3.906.769	6.116.872	5.127.576	6.230.866	5.515.695	5.370.086	2.624.197	2.953.056	5.079.718
Pacemakers										
Quantity (Kg)	-	1.056	1.362	1.058	1.435	11.258	3.908	1.810	1.171	1.721
Number	2.407	3.351	6.574	10.287	4.380	6.494	5.518	5.807	3.695	11.183
Amount (US$)	4.011.064	4.284.349	5.358.824	6.858.306	8.314.226	10.861.925	13.858.579	13.615.796	8.251.001	8.926.053
Ventilators										
Quantity (Kg)	34.747	19.188	28.445	40.523	38.502	54.957	37.831	50.367	69.482	66.613
Number	-	-	-	-	-	-	-	-	-	-
Amount (US$)	2.998.832	2.489.577	3.285.194	3.377.519	3.155.526	5.814.695	2.508.028	3.351.936	5.348.400	6.172.290
Total Amount (US$)	10.708.631	10.680.695	14.760.890	15.363.401	17.700.618	22.192.315	21.736.693	19.591.929	16.552.457	20.178.061
Total Import on Medical Devices (US$)	283.313.617	370.980.495	412.345.800	484.109.469	452.561.015	481.693.265	405.857.215	419.501.406	510.262.741	756.544.524
Import % of three selected devices to the overall medical devices	3,78%	2,88%	3,58%	3,17%	3,91%	4,61%	5,36%	4,67%	3,24%	2,67%

Source: SIS, 2005

The data on selected medical devices between the years 1995-2004 shows that total amount of import of these devices to Turkey is around $15-20 million.

For our analysis, we need the data on the annual number of open-heart surgeries and the duration of hospital stays after surgery in order to calculate the frequency and cost of using medical devices under investigation. According to the MOH, there are 1,172 hospitals in Turkey in 2003 (Table 4.3). There were 40,963 open-heart surgeries performed in these hospitals in the same year (Table 4.4). The average number of days s patient stays in a hospital after the open-heart surgery is 5.58 days (Table 4.5).

Table 4.3. Number of Hospitals In Turkey

Hospitals According to Their Institutional Type	Number of Hospitals	Share of hospitals in total
Ministry of Health	668	57,0
SSK	121	10,3
University	50	4,3
Ministry of Defense	42	3,6
Other Public	19	1,6
Private	272	23,2
Total	**1,172**	**100**

Source: MOH, 2003

Table 4.4. Open-Heart Surgeries In Turkey

Hospitals According to Their Institutional Type	Number of Open-Heart Surgeries	Share in Total Open-Heart Surgeries
Ministry of Health	7,206	18%
SSK	800	2%
University	9,695	24%
Other Private	23,262	56%
Total	**40,963**	**100%**

Source: MOH, 2003

Table 4.5. Average Number of Hospital Stays In Turkey Between 1998-2003

Years	Number of Days
1998	5,6
1999	5.6
2000	5.4
2001	5.5
2002	5.7
2003	5.7
Average	**5.58**

Source: MOH, 2003

Total number of bedside monitors in hospitals under the jurisdiction of MOH is given as 876, according to figures provided by MOH. (MOH, 2003) Since no accurate data are available on other hospitals, the number of bedside monitors in these hospitals is assumed to be linearly proportional to the percentage of their share in the total number of hospitals in Turkey. Total number of bedside monitors (ECG) in the hospitals in Turkey in year 2003 is estimated to be 1,537 (Table 4.6)

Table 4.6. Number of Bedside Monitors

Hospitals According to Their Institutional Type	Number of Hospitals	# of Bedside Monitors
Ministry of Health	668	876
SSK	121	159
University	50	66
Ministry of Defense	42	55
Other Public	19	25
Private	272	357
Total	**1,172**	**1,537**

Source: MOH, 2003

4.3 Benefits and Costs of the Calibration of Selected Medical Devices

4.3.1 Assumptions

The assumptions of the model, which is used for determining the benefits and costs of calibration of three selected devices, are as follows:

1. One of the most important assumptions for this model is the duration of additional stay in the hospital when an uncalibrated device badly affects a patient. The duration of excessive stays in the hospital as a result of the improper functioning of the device is estimated as 1 day in ICU and 1 day in intermediate care. The average hospital stays after the open-heart surgery in 2003 is 5.7 as mentioned in Table 4.4. The assumption here implies the 2 days excessive stay for a patient. This creates an additional cost to the patient. Preventing this cost

with the periodic calibration of the devices is the benefit of the society.

2. Rates for costs of one-night stay of a patient in intensive care (ICU) and intermediate care units are given as follows:
    - ICU Cost (Average Cost Per Patient Day): 1.5 Billion TL, which is equal to US$1,072*
    - Intermediate Care Cost: 750 Million TL, that is equal to US$536
    - Total cost for one day: US$1,608

3. It is assumed that the periodic calibration activities cover 90% of all devices being used by the patients after the surgeries. It is assumed that 10% of the devices were left without calibration. (Lower-bound assumption) On the other hand, the probability of negative effect from an uncalibrated device has been estimated as 50%.

4. It is assumed that 50% of the patients using uncalibrated devices faces longer hospital stays. This assumption can also be used as a basis for the lower-bound estimation. Actually, the cost can be much more higher than estimated. But this percentage may be taken as 100% for pacemaker users, since the uncalibrated pacemakers directly affect the patients' health in a bad way.

5. Cost of calibration for each device is provided by the interviews with the representatives of a private biomedical calibration company (MED-KAL) and TSE. The calibration prices for each device for year 2003 are given in Table 4.7.

* The exchange rate is 1 US$ = 1,399,998 TL

Table 4.7 The Calibration Rates for MED-KAL and TSE in 2003

Type of Device	The Frequency of Calibration	Rate of MED-KAL	Rate of TSE
Bedside Monitor (full-option)	3-6-12 months	US$ 125	US$ 155
Ventilator	3-6-12 months	US$ 150	US$ 325
Pacemaker	3-6-12 months	US$ 70	US$ 75

6. Total usage frequency of each device is assumed equal to the number patients who had open-heart surgeries, because the necessary variable to be used is the usage frequency of the mentioned medical device by the patients in a given period of time. It is very hard to estimate the number of unused or inactive devices in the country. 2003 statistics have been used for this purpose.

7. Total number of pacemakers is assumed on the basis of information provided by our interviewers (doctors and authorities in the cardiology units in Bayındır Hospital (private) and Hacettepe University Hospital). It is assumed that the pacemakers are implanted to 5% of patients who had open-heart surgeries)

8. The approximate lifetimes of the selected medical devices according to the usage guides and interviews are given as follows:
    - Bedside Monitors with ECG: 10 years
    - Ventilator: 10 Years
    - Pacemakers: 5 years

9. The equation for the Benefit-to-Cost ratio used in this model is as follows:

B/C = (Benefits – Disbenefits – O/M Costs) / Initial Investment

Where,

- Disbenefits are the indirect costs generated by the benefits, assumed to be zero.
- O/M Cost is the net operation and maintenance costs. Since calibration does not have any effect on O/M costs, the net change is zero.
- Initial investment is the cost of calibrations for mentioned uncalibrated devices in the country.

4.3.2 Cost-Benefit Analysis

(i) Patient Bedside Monitors

- Total number of open-heart surgeries (40,963) in 2003 is equal to the total usage of the bedside monitors. This value excludes the number of surgeries done in the hospitals of Ministry of Defense. Total number of bedside monitors has been estimated as 1,537. Therefore, this value drops to 1,482, with the linear proportion, when the surgeries in Ministry of Defense are not taken into account.

- With the given data above, the usage frequency of one bedside monitor is calculated as 27.64, annually. This means 27.64 patients use one unique bedside monitor in a given year.

- Out of 1,482 bedside monitors, 10% of them (148.2 monitors) are left uncalibrated according to the Assumption 3.

- The number of patients affected from the uncalibrated device is the multiplication of the usage frequency with the number of uncalibrated device. Therefore, 148.2 * 27.64 = 4,096.25 patients may be affected from these devices. According to the Assumption 3, the probability of negative effect from an uncalibrated device has been estimated as 50%; so, the number of affected patients becomes 2,098.62.

- The cost of an affected patient: 1 day in ICU, one day in intermediate care unit. Then the total cost becomes 1,608 (the total cost of staying two more days in hospital) * 2,098 (number of affected patients) = US$ 3,374,581. This is the value of the benefit of calibration.

- The cost of calibration of these 10% uncalibrated bedside monitors is calculated as:
  155$ (cost of calibration for one device) * 148,2 (10% of all devices) * 4 (calibration frequency in a year – lower-bound estimation)
  The cost of calibration is calculated as US$ 91,884.

- The Benefit-to-Cost Ratio for calibrating bedside monitors with a lowest-bound estimation becomes:
  B/C = US$ 3,374,581 / US$ 74,100 = 36,73

(ii) Ventilators

The same methodology can also be applied to the ventilators. The values of the variables for the ventilators differ in terms of the total number of these devices and their calibration costs. First, the number of ventilators in the country has been estimated by a top-down approach, since only the total number of ventilators in the country can be estimated. According to the interviews with the private biomedical calibration companies and some hospitals in Ankara, the average number of ventilators in a hospital is estimated as 10. As the total number of hospitals in Turkey is 1,172, total number of ventilators is estimated as 11,720. On the other hand, other changing variable for ventilators is the cost of its calibration. It is taken as US$ 325 for the lower-bound estimations.

- Total # of open-heart surgeries (40,963) in 2003 is equal to the total usage of the ventilators. Total number of ventilators has been estimated as 11,720.

- With this data, the usage frequency of a ventilator is calculated as 3.5, annually. This means 3.5 patients use one unique bedside monitor in one year.

- Out of 11,720 ventilators, 10% of them are left uncalibrated according to the Assumption 3 of Section 4.3.1. This value is equal to 1172 ventilators.

- The number of patients affected from the uncalibrated device is the multiplication of the usage frequency with the number of uncalibrated device. Therefore, 1172 * 3.5 = 4,102 patients may be affected from these devices. According to the Assumption 3, the probability of affection from the uncalibrated device has been estimated as 50%; so finally, the number of affected patients becomes 2,101.

- The cost of the affected patients: 1 day in ICU, one day in intermediate care unit. The total cost has been estimated as US$

1,608. Then the total cost becomes 1,608 * number of affected patients = US$ 3,378,408. This is the value of the benefit of calibration.

- The cost of calibration of these 10% uncalibrated ventilators is calculated as:
  325$ (cost of calibration for one device) * 1,172 (10% of all devices) * 4 (calibration frequency in a year – lower-bound estimation)
  The cost of calibration is calculated as US$ 1,523,600.

- The Benefit-to-Cost Ratio for calibrating ventilators with a lowest-bound estimation becomes:
  B/C = US$ 3,378,408 / US$ 1,523,600 = 2,22

(iii) Pacemakers

A similar methodology could be applied to the pacemakers. There could be some other assumptions with respect to the usage properties of pacemakers. The effects of uncalibrated pacemakers can normally be seen after the ICU period. Therefore the cost of one-day ICU stay can be neglected for the impact analysis of pacemaker calibration. One other different assumption (Assumption 7) is used for the application of the model for the pacemakers, other than the bedside monitors and ventilators. According to that approach, pacemakers are used in the 5% of open-heart surgeries. On the other hand, other changing variable for a pacemaker is the cost of its calibration. It is taken as US$ 75 for the lower-bound estimations.

- Total # of open-heart surgeries (40,963) in 2003 is equal to the 5% of the total usage of the pacemakers. Then the total number of pacemakers has been estimated approximately as 2,050.

- Out of 2,050 pacemakers, 10% of them are left uncalibrated according to the Assumption 3 of Section 4.3.1. This value is equal to 205 pacemakers.

- The number of patients affected from the uncalibrated pacemaker is the multiplication of the usage with the number of uncalibrated device. Therefore, there are similarly, 205 patients may be affected from these devices. According to the Assumption 3, the probability of affection from the uncalibrated pacemaker has been estimated as 100%; so finally, the number of affected patients becomes 205.

- The cost of the affected patients: One day in intermediate care unit. The total cost has been estimated as US$ 536. Then the total cost becomes US$536 * number of affected patients = US$ 109,880. This is the value of the benefit of calibration.

- The cost of calibration of these 10% uncalibrated ventilators is calculated as:
  75$ (cost of calibration for one device) * 205 (10% of all devices) * 4 (calibration frequency in a year – lower-bound estimation)
  The cost of calibration is calculated as US$ 61,500.

- The Benefit-to-Cost Ratio for pacemaker calibration becomes:
  B/C = US$ 109,880 / US$ 61,500 = 1,79

4.4 Results and Discussions

The results taken from the Section 4.3 are summarized in Table 4.8.

Table 4.8: Ratios of Cost-Benefit Analysis for Patient Bedside Monitors, Ventilators and Pacemakers

Type of Device	Benefit-to-Cost Ratio
Patient Bedside Monitors	36.72
Ventilators	2.22
Pacemakers	1.79

As seen in the Table 4.8, all of the B/C ratios are found to be greater than 1. As the B/C ratio is greater than 1, a calibration programme that guarantees regular calibration of medical devices would be cost-effective.

The B/C ratio for bedside monitors is considerably high. The B/C ratio is calculated on the basis of lower-bound estimates. Therefore the actual impact of calibrating bedside monitors could be extremely high.

The B/C ratios for the other two devices are still greater than 1, although the lowest bound estimations have been taken into account in the analysis. The impact of calibration would be much more beneficial, if the estimations were done more pessimistically.

It is necessary to mention the scope of the selected medical devices for this thesis in the medical device market across Turkey. These three devices constitute nearly 4% of all medical device imports and they are necessarily used not only after the open-heart surgeries, but in other cases as well. Bedside monitors and ventilators have a broad range of use in the medical surgeries.

In addition, 4% share of import for these devices is relatively a high percentage, when the thousands of types of medical devices are considered in this field. The reason is that the open-heart surgeries have nearly 12% share in all types of critical surgeries. Therefore, the total impact of calibration of all medical devices in Turkey could be quite substantial. In this regard, a legal framework and necessary regulations should be constituted on calibration of medical devices in designated periods.

CHAPTER 5

CONCLUSION

The role of measurement and testing in society is very important. The fact that measurements are performed in every segment of industry and social life with a broad range of application fields, varying from clinical tests in medical laboratories to weighing scales in supermarkets, explains one of the reasons why metrology should be given more importance. Another reason for the increasing importance of metrology is the turbulence related with the globalization -the attempts to improve competitiveness in the international markets. However, the social benefits of the use of accurate measurement within society are rather qualitative than quantitative and the outcomes usually require complex metrics.

In this study, the effect of calibration in medical sector is investigated since the metrology services in this sector have a direct impact on patients. In this sector, there are a variety of medical testing devices, from which the decisions on human lives are taken based on measurement results. The application of periodical calibration procedures on medical testing devices during their operation life-times, not only leads to higher quality and reliability of service to the patients but also increases the benefit-to-cost ratios for the applied tests on patients, minimizing the risks such as patient deaths, incidence or extension of illnesses, etc.

The main aim of this thesis is to demonstrate the socio-economic impact of medical metrology on consumers in Turkey. For this purpose, a framework for economic impact assessment of the calibration activity for 3 specific medical devices, namely as patient bedside monitors, ventilators and pacemakers has been developed and a model for cost-benefit analysis has been constructed to evaluate the impact of calibration activity. Results of the analysis performed for each medical device indicate that, calibration activity seems very favorable Benefit-to-Cost ratios even based on the lower-bound estimations. The Benefit-to-Cost ratios of the calibration activity on patient bedside monitors, ventilators and pacemakers were calculated as 36.74, 2.22 and 1.79, respectively. These results imply that there should be a periodical calibration activity programme through out the country, and the government should develop and monitor this programme.

Other than the economic objectives, the findings in this thesis also imply that calibration of medical devices save lives and decrease the mortality rates. The economic impact of death is not easily quantifiable. Beginning from the procurement of mentioned devices to a hospital, that hospital is liable to any defect, disorganization and patient safety that may come out in the operation of these testing devices. The application of periodical calibration procedures on medical testing devices during their operation life-times, leads to not only the higher quality and reliability of service to the patients but also increase in the benefit-to-cost ratio for the applied tests on patients, and also the minimization of risks such as patient deaths and incidence or extension of illnesses.

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