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Chapter 4

Accreditation of Biomedical Calibration Measurements in Turkey

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Additional information is available at the end of the chapter

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1. Introduction

Biomedical calibration measurement is the measurement of the accuracy of the medical device or the medical system by using the standard measurement system whose accuracy is known, and is the determination and the record of the deviations. In shortly, by the biomedical calibration measurements, it is established whether the medical devices are appropriate to the international standards or not, and the problems are also determined if the device is not adequate to the international standards (Sezdi, 2012).

Biomedical calibration measurement is different from other industrial calibration studies. Measurements are generally performed where the medical device that will be tested, is used in hospital. Only some medical devices, for example pipettes, thermometers are tested in laboratory environment.

Accreditation is the appraising of a measurement service in according to the international technical criterias, is the acception of its qualification and the controlling of it regularly. For an enterprise, being accredited is a reputable status. It shows that the enterprise has a quality management system and performs the requirements of the implemented standards. The enterprices are periodically recontrolled by an accreditation agency to protect the status and to continue fulfilling of the requirements of the business standards. The controls create the most important quality assurance of the businesses that take service from these laboratories.

In many countries, from Brazilia to China, there are accreditation studies (Boldyrev et al., 2004; Boschung et al., 2001; Iglicki et al., 2006; Kartha et al., 2003; Alexander et al., 2008; Goff et al., 2009; McGrowder et al., 2010). In Turkey, the studies of accreditation is controlled by Turkish Accreditation Agency (TURKAK). If the list of the accredited laboratory is investi-

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gated from the web site of TURKAK, it is seen that there are approximately 14 accredited enterprises that give services in biomedical calibration measurements (TURKAK website). But these are not in a single accredited enterprise type. While some of them are accepted as testing laboratories, some of them are accepted as calibration laboratories, the others are accepted as inspection bodies.

The standard used in the accreditation of testing laboratories and calibration laboratories is TS EN ISO/IEC 17025:2005. ISO 17025 contains the quality management system of the testing and calibration laboratory. It examines all work flows, organization structure and technical suffiency. The standard used in the accreditation of inspection bodies is TS EN ISO/IEC 17020:2004 (ISO IEC 17025, 2005; ISO IEC 17020, 2004).

There is not yet a specific study about the medical accreditaton in TURKAK. If hospitals demand the medical accreditation during they take the medical calibration service, they must work with the accredited laboratory in according to their measured medical device or system. It can be a medical device, radiological system or only a parameter such as temperature, mass…etc. There is a confusion about which accreditation studies should preferred for which medical devices. Is the accreditation certificate about non-medical parameters sufficient technically for biomedical calibration? In other words, is testing of a defibrilator by the mass accreditation or testing of an anesthetic machine by the temperature accreditation, ethical?

There may be many parameters that must be considered during the biomedical calibration measurements of any medical device. For example, testing of a ventilator contains flow, pressure and volume parameters. If a sufficieny is wanted, sufficiency about three parameters must be wanted seperately. In addition to this, the personnel who will perform the measurement, must be professional. The biomedical calibration needs the specialization of the biomedical personnel. It brings many problems that the biomedical calibration is performed by the non-educated personnel about biomedical and that the industrial accreditation is accepted as sufficient. Particularly, inattentive studies, in operation rooms and intensive care rooms, causes many unexpected problems.

The important point that attracts the attention in this study is that the hospitals take the inadequate services if they don't investigate the accreditation content. If the content of the accreditation studies is known, the customer will be knowledgeable about which accreditation should be preferred for which medical device or medical system.

2. Accreditation

Accreditation is a quality infrastructure tool which supports the credibility and value of the work carried out by conformity assessment bodies. Accreditation provides formal recognition that an organisation is meeting internationally accepted standards of quality, performance, technical expertise, and competence.

A product or service accompanied by a conformity attestation delivered by an accredited conformity assessment body inspires trust as to the compliance with applicable speci-

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fied requirements. Thereby accreditation favours the elimination of technical barriers to trade. Accreditation provides a global acceptance of the services and establishs a confidence for the quality.

The trusting mechanism between accreditation bodies is constructed on the multi literal agreements at the international and regional accreditation body organisations, like IAF (International Accreditation Forum), ILAC (International Laboratory Accreditation Cooperation), EA (Europen Cooperation for Accreditation), etc.

Turkish Accreditation Agency (TURKAK) started to provide accrediation services in 2001 and became a cooperator of Europian Cooperation for Accreditation (EA) for all available accreditation schemes at 2008. Currently TURKAK is a full member of EA, IAF and ILAC. It serves as international accreditation agency.

Accreditation is beneficial to the accredited body itself, to Government and to users of accredited bodies.

Accredited bodies have benefits as below:

1. the laboratories are controlled by independent conformity assessment bodies and they meet international standards for competence,
2. an effective marketing tool is provided,
3. the measurements are demonstrated as traceble in according to the national or international standards,

Accredited service provides benefits for customers:

1. assurance that tests are performed by using calibrated equipment by personnel with the right level of expertise,
2. assurance that calibration or test devices are controlled and traced periodically in according to the international standards,
3. elimination of technical barriers to trade,
4. addition of credibility to the test results by accredited conformity assessment bodies,

Generally, accreditation applications are classified as 4 items.

- Accreditation of testing, calibration and medical laboratories,
- accreditation of product, service or inspection,
- accreditation of certification of management systems, and
- accreditation of personal certification bodies.

In laboratory and inspection accreditation, high respectability both at the national and international level as an indicator of technical competence is essential. Laboratory and inspection accreditation aim to give services accurate and reliable testing, analysis or calibration measurements. Laboratory accreditation ensures the official recognition of laboratory competence

and offers an easy method to customers in determining and choosing reliable testing, analysis and calibration services.

The process of laboratory accreditation is regulated and standardized according to the international standards. Reports and certificates issued by accredited laboratories are internationally accepted. While the standard for testing and calibration laboratories is ISO IEC 17025:2005, the standard for inspection bodies is ISO IEC 17020:2004.

Accreditation activities of certification bodies of management system provide quality of certification of management system. Accreditation services in this field is generally given for ISO 9001:2008 certification, ISO 14001:2004 certification, ISO 22000:2005 certification, ISO 27001:2005 certification and ISO 13485:2003 certification. For this type of accreditation, ISO/IEC 17021:2011 standard is used (ISO/IEC 17021, 2011).

Accreditation of personal certification bodies that certificate the personnel making conformity assessments to make their activities in accordance with specified national and international standards, is provided by using the standard of ISO/IEC 17024:2003 (ISO/IEC 17024, 2003).

Accreditation bodies use accreditation mark or logo over their certificates or reports that contain their measurement/test results. But, such logo or marks must be used only over the certificates or reports including accredited facilities. TURKAK also provides accreditation symbol to be used in the output documents to be issued for the accredited services. It contains information about the accreditation field, accreditation standard and unique number of the accredited body, the accreditation number. The logo used by TURKAK can be seen in figure 1.

Figure 1. The accreditation logo used by TURKAK (TURKAK website).

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2.1. Proficiency Testing & Interlaboratory Comparisons

For accreditation studies, the quality assurance of the test results is obtained by interlaboratory comparisons and proficiency testing (PT) (Bode, 2008; Kubota et al., 2008; Kopler et al., 2005). The interlaboratory comparisons and proficiency testing bring significant benefits to laboratories.

Proficiency Testing provides the infrastructure for a laboratory to monitor and improve the quality of its routine measurements (fig. 2). Proficiency Testing is the only quality measure which is specifically concerned with a laboratory's outputs. Proficiency Testing gives a possibility to identify any problems caused from other aspects of its quality system, such as staff training and method validation.

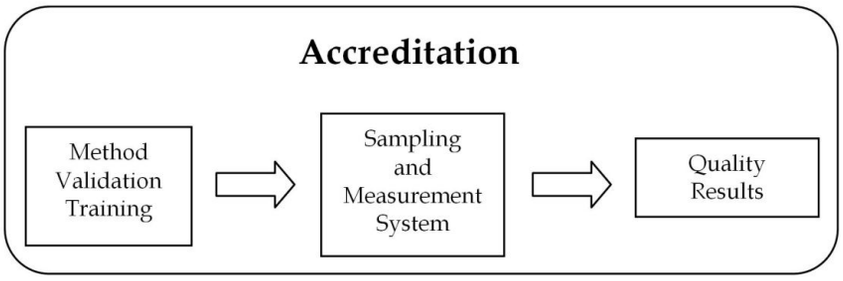

Figure 2. The factors in accreditation process.

Proficiency Testing is treated as important performance criteria regarding the evaluation of the technical competence of the laboratories. Laboratories that will be accredited should participate to Proficiency Testing programme or/and interlaboratory comparison for the main and sub disciplines they demand for accreditation and should submit satisfactory results according to defined criterias.

Proficiency Testing providers demonstrate the quality of their Proficiency Testing programmes. There are two important international guides to which Proficiency Testing providers can demonstrate the quality of their Proficiency Testing programmes:

1. ISO/IEC 17043: Conformity assessment - General requirements for proficiency testing (ISO/IEC 17043, 2007)
2. ILAC G13: Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes (ILAC G13, 2007)

The basic of the ISO/IEC 17043 is the ISO/IEC Guide 43. For several years, this document has provided several guidance on the development and operation laboratory proficiency testing for a relatively new field of activity. It contained very basic guidance and little attention to the use of the outcomes by laboratory accreditation bodies (Tholen, 2007).

Guide 43 have provided guidance in 5 areas (ISO Guide 43, 1997). They are;

- to distinguish between use of interlaboratory comparisons for Proficiency Testing and for other purposes (introduction to Part 1)

- the development and operation of Proficiency Testing schemes (Part 1)
- the selection and the use of schemes by laboratory accreditation bodies (Part 2)
- guidance on statistical methods (Annex A) and
- guidelines for development of a quality manual for the operation of Proficiency Testing schemes (Annex B)

The statistical annex led to the development of ILAC Guide 13. ILAC G13 contains the technical guidelines from Guide 43-1 expressed as requirements and includes the quality management system requirements from ISO/IEC Guide 25. Since G13 has management system requirements that are consistent with ISO/IEC 17025, Proficiency Testing providers accredited to this document are considered to be in conformity with the requirements of ISO 9001:2000 (Tholen, 2007). The standard ISO/IEC 17043 describes the criteria concerning the quality to be respected when developing proficiency tests and the use that can be made of these tests by the accreditation bodies. ILAC-G13 is useful to organizers for competence (Fraville et al., 2010).

The Proficiency Testing programmes of many Proficiency Testing providers around the world are now accredited by their national accreditation bodies, normally against the above documents. However, not all countries are ready to accredit Proficiency Testing providers, and not all Proficiency Testing providers wish to be accredited.

Proficiency Testing programmes are operated by a variety of organizations within Europe and the rest of the world. Many Proficiency Testing programmes are international. There is a database of available Proficiency Testing programmes. In selecting the most appropriate Proficiency Testing it is important to consider a number of issues in order to judge its suitability for your purpose (ISO Guide 34, 2000; ISO Guide 43, 1997).

3. Accreditation Standards

The accreditation standards used in biomedical calibration measurements can be classified into 2 groups. TS EN ISO / IEC 17025 and TS EN ISO / IEC 17020. While the standard of 17025 is used for the accreditation of testing and calibration laboratories, the standard of 17020 is used for the accreditation of inspection bodies.

The laboratory accreditation standards should not be confused with ISO 9001 standard. ISO 9001 is widely used in the assessment of the quality systems of production and service organizations. Certification of organizations according to the ISO 9001 system expresses the compliance of that organization's quality system with this standard (ISO 9001). When certifying laboratories according to ISO 9001, this certification makes no statement on the technical competence of laboratories. From this point, the certificate's power to convince the market and prospects of laboratories is quiet insufficient.

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3.1. The standard of TS EN ISO / IEC 17025

ISO IEC 17025, entitled "General Requirements for the Competence of Testing and Calibration Laboratories", is an international standard describing the general requirements to meet for the recognition of that a laboratory is competent to perform specific tests (ISO IEC 17025; 2005). This international standard is used to develop the quality, management and technical systems of laboratories (Abdel-Fatah, 2010; Glavic-Cindro et al., 2006; Brantner et al., 2011; Zapata-Garcia et al., 2007; Jerone et al., 2008). Technical requirements are updated to include the addition of formal personnel training plans and detailed records, method development and validation procedures, measurement of method uncertainty, and a defined equipment calibration and maintenance program (Honsa et al., 2003). ISO 17025 certification can be applied to all organizations that give services of testing or calibration. These organizations are the first-party, second-party and third-party laboratories.

First–party Laboratories: Manufacturer Laboratories, Second-party Laboratories: Customer Laboratories, Third-party Laboratories: Independent Laboratories.

This standard can be applied to all laboratories regardless of the scope of test or calibration activities and the number of personnel.

If testing and calibration laboratories comply with the requirements of this standard, a quality management system to meet the principles of ISO 9001 will be also applied. There is a cross-match among TS EN ISO 17025 standard and ISO 9001. TS EN ISO 17025 standard covers technical competence requirements, not covered by ISO 9001.

3.1.1. The content of the standard of TS EN ISO / IEC 17025

TS EN ISO 17025 standard is assessed in two main categories. The standard of TS EN ISO IEC 17025 contains both the management and technical requirements. In standard, 4th item describes the management system and 5th item describes the technical activities. The content of 17025 standard is as follows:

0 Introduction

1 Scope

2 Cited in standards and / or documents

3 Terms and definitions

4 Management requirements

4.1 Organization

4.2 Management system

4.3 Document control

4.4 Review of requests, tenders and contracts

4.5 Subcontracting of tests and calibrations

4.6 Purchasing of service and materials

4.7 Customer service 4.8 Complaints

4.8 Complaints

4.9 Control of nonconforming testing and / or calibration work

4.10 Improvement

4.11 Corrective action

4.12 Preventive action

4.13 Control of records

4.14 Internal controls

4.15 Management reviews

5 Technical requirements

5.1 General

5.2 Personnel

5.3 Accommodation and environmental conditions

5.4 Test and calibration methods and method validation

5.5 Devices

5.6 Measurement traceability

5.7 Sampling

5.8 Calibration procedures

5.9 Assuring the quality of test and calibration results

5.10 Reporting of the results

The laboratory must be an institution that can be held legally responsible. Laboratory management system must consist of facilities in fixed laboratory and temporary or mobile facilities that are linked to the laboratory.

3.2. The standard of TS EN ISO / IEC 17020

ISO 17020, entitled "General Criteria for the Operation of Various Types of Bodies Performing Inspection", is an internationally recognized standard for the competence of inspection bodies. Inspection parameters may include such aspects as the quantity, quality, safety, suitability, facilities or systems (ISO IEC 17020; 2004).

There are 3 types of inspection organizations. They are:

Type A: Inspection body must be independent. Both the inspection organization and its personnel must not be related to the inspected materials. They must not be the material's designers, manufacturers, suppliers, installers, purchasers, owners or operators.

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Type B: Inspection services should be given to the organization that consists of the inspection body. Type B bodies can not service to other organizations.

Type C: This type of bodies give services to both the organization that consists of the inspection body and other organizations.

TS EN ISO 17020 standard can be applied regardless of the scope of inspection activities in the company. TS EN ISO 17020 certification can be given all kinds of inspection bodies that are willing to give service in accordance with this standard.

3.2.1. The content of the standard of TS EN ISO / IEC 17020

In the standard of TS EN ISO IEC 17020, the technical requirements are the main aspect. TS EN ISO 17020 standard consists of 16 items. They are:

0 Introduction

1 Scope

2 Definitions

3 Administrative Rules

4 Independence, impartiality and integrity

5 Privacy

6 Organization and management

7 Quality System

8 Personnel

9 Equipment

10 Inspection methods and procedures

11 Samples and materials to be inspected

12 Records

13 Inspection reports and inspection certificates

14 The use of subcontractors

15 Complaints and appeals

16 Co-operation

4. Accreditation Types

As it was mentioned earlier, there are 3 accreditation types for biomedical calibration measurements. They are:

- Calibration laboratories

- Testing laboratories
- Inspection bodies

4.1. Calibration Laboratories

A calibration laboratory is a laboratory that performs test, calibration and repair of measuring instruments. The calibration of equipment is achieved by means of a direct comparison against measurement standards or certified reference materials. These standards are also regularly calibrated themselves, in comparison with another standard of lower uncertainty.

Measurement Parameter	Example Measurement Range	Measurement Condition	Example Measurement Uncertainty	Method Standard
Pressure	0 - 70 bar	Air	0,2 %	Euramet CG-17 / v.01
	70 - 700 bar	Hydraulic	0,2 %	
Temperature distribution of controlled volume	-40 +200 °C	In controlled volume (oven, incubator, freezer….)	0,68 °C	Euramet CG-13 / v.01
Scales (non automatic)	0 – 600 gr	E2 class mass	$2\ 10^{-6}$	Euramet CG-18 / v.03
	0 – 10 kg	F1 class mass	$1\ 10^{-5}$	
	0 – 150 kg	M1 class mass	$1\ 10^{-4}$	
	0 – 1000 kg	M1-M2 mass	$2\ 10^{-4}$	
Temperature of glass thermometer	0 – 60 °C	Water bath	0,72 °C	Measurement in laboratory by using comparison method
	60 – 150 °C	Dry block oil bath	0,74 °C	
Volume Piston pipettes	50 – 100 µl	in laboratory	0,100 µl	TS ISO 4787 TS EN ISO 8655-2 TS EN ISO 8655-6
	200 µl		0,158 µl	
	500 µl		0,315 µl	
	1 ml		0,452 µl	
	2 ml		1,209 µl	
	5 ml		2,851 µl	
	10 ml		5,991 µl	
Temperature meters with display	0 – 250 °C	Ice bath and dry block oven	0,56 °C	Measurement in laboratory by using comparison method
	250 – 600 °C		0,82 °C	
Moisture	20% - 70% RH	Humidity cabinet	1,4% RH	Measurement in laboratory by using comparison method
	70% - 90% RH		2,2% RH	

Table 1. The content of accreditation studies of calibration laboratories.

Calibration laboratories give services to all industry, textile, paint, food or health care etc. The company's working area is not important. The parameter to be measured is essential. For example, the mass for the weighing of food, rotational speed of the paint mixing device, hardness of the material used in manufacturing, the temperature of refrigerators used for drug store. The parameters are measured and a calibration certificate is prepared.

The biomedical measurements in calibration laboratories are also performed generally as parameter measurements. The parameters can be classified as electrical parameters, pressure-vacuum parameters, temperature-humidity parameters, mass-volume parameters. An example study for accreditation of calibration laboratories can be seen in Table 1.

The accreditation of calibration measurements is carried out via parameter measurements. Unlike other types of accreditation studies, parameter measurement is accredited for calibration laboratory. As of today, ISO IEC 17025 is taken as the basis for laboratory accreditation purposes. This standard is recognized worldwide. The requirements of this standard are provided for the general requirements on a laboratory's quality management system and technical competence. Laboratories accredited according to ISO IEC 17025 are re-evaluated periodically by the accreditation body and decision is made for the maintenance of accreditation based on results obtained.

Laboratories intending to maintain accreditation are required to participate inter-laboratory comparison and proficiency testing programs on their scope of accreditation and achieve successful results.

4.2. Testing Laboratories

The biomedical measurements in testing laboratories are performed on the basis of the medical device. The test procedures are prepared to test all parameters in the medical device. Defibrillators, ventilators...etc. are tested completely to measure all parameters in it. If there are many parameters in a device such as ECG parameters (electrical), blood pressure parameters (pressure), body temperature parameters (temperature), they are measured in according to the measurement procedures in the place of where medical device works and a certificate is prepared.

In Turkey, the standard of 17025 is applied to testing laboratories for the medical devices. The content of the accreditation studies of testing laboratories can be seen in Table 2 and Table 3.

Device Under Test	Testing Name	Testing Method - Standard
Electrical Safety Tests for all Electrical Biomedical Devices	Earth resistance	TS EN 60601-1 (item 8.7)
	Chassis leakage current	TS EN 60601-1 (item 8.7)
	Patient leakage current	TS EN 60601-1 (item 8.7)
	Patient auxiliary leakage current	TS EN 60601-1 (item 8.7)

Device Under Test	Testing Name	Testing Method - Standard
	Applied part leakage current	TS EN 60601-1 (item 8.7)
	RMS chassis voltage	TS EN 60601-1 (item 8.9)
	DC chassis voltage	TS EN 60601-1 (item 8.9)
	Mains voltage	TS EN 60601-1 (item 8)
	Device current	TS EN 60601-1 (item 8)
Performance-Safety Tests for Defibrillators	ECG pulse test	TS EN 60601-2-27 (item 50.102.15)
	ECG amplitude test	TS EN 60601-2-27 (item 50.102.15)
	ECG frequency test	TS EN 60601-2-27 (item 50.102.8)
	ECG arythmia test	TS EN 60601-2-27 (item 56.8)
	Energy test	TS EN 60601-2-4 (item 50)
	Charge time test	TS EN 60601-2-4 (item 101)
	Synchronized discharge test	TS EN 60601-2-4 (item 104)
Performance-Safety Tests for Electrosurgical Units	Power distribution test	TS EN 60601-2-2 (item 50.1)
	HF leak test	TS EN 60601-2-2 (item 19.3.101)
	REM alarm test	TS EN 60601-2-2 (item 52)
Performance-Safety Tests for Pulse Oximeter (sPO2)	sPO2 performans test	TS EN ISO 9919 (item 50.101)
	ECG pulse test	TS EN 60601-2-27 (item 50.102.15)
	sPO2 alarm test	TS EN ISO 9919 (item 104)
Performance-Safety Tests for Electrocardiography (ECG)	ECG pulse test	TS EN 60601-2-27 (item 50.102.15)
	ECG amplitude test	TS EN 60601-2-27 (item 50.102.15)
	ECG frequency test	TS EN 60601-2-27 (item 50.102.8)
	ECG arythmia test	TS EN 60601-2-27 (item 56.8)
	ECG ST test	TS EN 60601-2-27 (item 50.102.15)
	ECG printer test	TS EN 60601-2-27 (item 50.102.16)
Performance-Safety Tests for Noninvasive Blood Pressure Monitor (NIBP)	NIBP performans test	TS EN 60601-2-30 (item 50.2)
	NIBP cuff pressure test	TS EN 60601-2-30 (item 22.4.1)
	NIBP cuff leakage test	TS EN 60601-2-30 (item 50.2)
	NIBP alarm test	TS EN 60601-2-30 (item 51.103)
Performance-Safety Tests for Aspirators	Vacuum test	TS EN ISO 10079-1
	Accuracy test	TS EN ISO 10079-1
	Flow test	TS EN ISO 10079-1

Table 2. The content of accreditation studies of testing laboratories.

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Device Under Test	Testing Name	Testing Method - Standard
Performance-Safety Tests for Infusion Pumps	Air control test	TS EN 60601-1-24 (item 51-104)
	Flow accuracy test	TS EN 60601-1-24 (item 50-103)
	Congestion performance test	TS EN 60601-1-24 (item 2-122)
	Alarm test	TS EN 60601-1-24 (item 51-106)
Performance-Safety Tests for Aspirators	Vacuum test	TS EN ISO 10079-1
	Accuracy test	TS EN ISO 10079-1
	Flow test	TS EN ISO 10079-1
Performance-Safety Tests for Shymphonometers	System leak test	TS EN 1060
	Manometer test	TS EN 1060
	Accuracy test	TS EN 1060
Performance-Safety Tests for Patient Monitor	ECG pulse test	TS EN 60601-2-27 (item 50.102.15)
	ECG amplitude test	TS EN 60601-2-27 (item 50.102.15)
	ECG frequency test	TS EN 60601-2-27 (item 50.102.8)
	ECG arythmia test	TS EN 60601-2-27 (item 56.8)
	ECG ST test	TS EN 60601-2-27 (item 50.102.15)
	ECG printer test	TS EN 60601-2-27 (item 50.102.16)
	Pacemaker test	TS EN 60601-2-27 (item 50.102.12)
	ECG alarm test	TS EN 60601-2-27 (item 51.102)
	Breath performance test	TS EN 60601-2-27 (item 50.102.8)
	Breath alarm test	TS EN 60601-2-27 (item 51.102)
	NIBP performans test	TS EN 60601-2-30 (item 50.2)
	NIBP cuff pressure test	TS EN 60601-2-30 (item 22.4.1)
	NIBP cuff leakage test	TS EN 60601-2-30 (item 50.2)
	NIBP alarm test	TS EN 60601-2-30 (item 51.103)
	IBP static pressure test	TS EN 60601-2-34 (item 51.102)
	IBP dynamic pressure	TS EN 60601-2-34 (item 51.102)
	IBP alarm test	TS EN 60601-2-34 (item 51.203.1)
	sPO2 performans test	TS EN ISO 9919 (item 50.101)
	sPO2 alarm test	TS EN ISO 9919 (item 104)

Table 3. The content of accreditation studies of testing laboratories (continued).

4.3. Inspection Bodies

Inspection bodies which applied for accreditation must accomplish the requirements of standard ISO IEC 17020:2004. Inspection means investigation of the product design, product, service, process or the factory and their professional judgment based on the determination of the conformity of the general rules. Inspection bodies are conformity assessment companies. After the inspection, they transmit report to the customer, no certification. In Turkey, 17020 standard is applied for the radiography systems and clean room classification. The content of the accreditation studies of inspection bodies can be seen in Table 4.

Medical Device	Inspection Type	Standard
CONVENTIONAL RADIOGRAPHY	kVp	IPEM Report No 32, European Commission Radiation Protection No 91
	Exposure time	IPEM Report No 32, European Commission Radiation Protection No 91
	Exposure repeatability and linearity	IPEM Report No 32, AAPM Report No 74, European Commission Radiation Protection No 91
	Tube output and stability	IPEM Report No 32, European Commission Radiation Protection No 91
	Filtration and half value layer	IPEM Report No 32, AAPM Report No 74, FDA 21 CFR 1020.30, European Commission Radiation Protection No 91
	Collimation	IPEM Report No 32, European Commission Radiation Protection No 91
	X-ray beam alignment	European Commission Radiation Protection No 91
	Focal spot size	IPEM Report No 32, European Commission Radiation Protection No 91
	Automatic exposure control	IPEM Report No 32, European Commission Radiation Protection No 91
	Grid adjustment	European Commission Radiation Protection No 91 AAPM Report No 74
	Leakage radiation	European Commission Radiation Protection No 91 FDA 21 CFR 1020.30
INTRA-ORAL and	kVp	European Commission Radiation Protection No 91 IPEM Report No 91

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Medical Device	Inspection Type	Standard
PANORAMIC CONVENTIONAL DENTAL RADIOGRAPHY	Exposure time	European Commission Radiation Protection No 91 IPEM Report No 91
	Tube output	European Commission Radiation Protection No 91
	Patient entrance dose	IPEM Report N:91, European Commission Radiation Protection N 162
	Filtration and half value layer	European Commission Radiation Protection No 91 FDA 21 CFR 1020.30
	X-ray beam size	European Commission Radiation Protection No 91 IPEM Report No 91
	Patient focus distance	European Commission Radiation Protection No 91
	Image repeatability	IPEM Report No 91
CONVENTIONAL MAMMOGRAPHY	Focus film distance	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis
	Tissue thickness sensor	IPEM Report 89
	Compression force	European Commission Radiation Protection No 91,
	kVp accuracy and repeatability	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, European Commission Radiation Protection No 91, ACR Mammography QC Manual
	Tube output, tube output speed and repeatability	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, European Commission Radiation Protection No 91 IPSM Report N59, ACR Mammography QC Manual, IPEM Report No 89
	Tube output-mAs	IPEM Report No 91, IPEM Report No 89
	Filtration and half value layer	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, IPEM Report 89, ACR Mammography QC Manual
	Mean glandular tissue dose	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, ACR Mammography QC Manual

Medical Device	Inspection Type	Standard
	Image contrast and high contrast resolution	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, European Commission Radiation Protection No 91 and 162, ACR Mammography QC Mn
	Collimation, Grid factor and determination of grid errors	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, IPEM Report 89, European Commission Radiation Protection 91, ACR Mammo QC Manual
	Image homogeneity and assessment of artifacts	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, IPEM Report 89, ACR Mammography QC Manual
	Leakage radiation	European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis
DIGITAL (FLAT PANEL) and CONVENTIONAL IMAGE AMPLIFIED FLOROSCOPY (DSA ANJIO, CARDIAC, C ARM MOBIL)	kVp	IPEM Report No 32, IPEM Report No 91, European Commission Radiation Protection No 91, AAPM Report No 74
	Filtration and half value layer	IPEM Report No 32, IPEM Report No 91, IPEM Report No 32, European Commission Radiation Protection No 91, AAPM Report No 74
	Tube Output	IPEM Report No 32, AAPM Report N:70
	Maximum exposure speed	European Commission Radiation Protection No 91 and 162, IPEM Report No 32, AAPM Report No 70 - 74
	Patient entrance dose	Draft European Commission Radiation Protection No 162, AAPM Report No 70, AAPM Report No 74
	Image amplified entrance dose	European Commission Radiation Protection No 91 and 162, AAPM Report No 70 and 74
	Brightness control	IPEM Report N:32, AAPM Report No 70
	Gray scale	IPEM Report No 32
	Image artifacts	IPEM Report No 32
	Compliance of areas (exposured-displayed)	European Commission Radiation Protection No 91, IPEM Report No 32

Medical Device	Inspection Type	Standard
	High contrast and low contrast resolution	European Commission Radiation Protection No 91, IPEM Report No 32
	Contrast detail	IPEM Report No 32
FLOROSCOPY RADIOGRAPY (STOMACH TABLE)	kVp	IPEM Report No 91
	Exposure time	IPEM Report No 91 and 32, European Commission Radiation Protection No 91
	Exposure repeatability and linearity	IPEM Report No 91 and 32, European Commission Radiation Protection No 91, AAPM Report No 74
	Tube output and stability	IPEM Report No 91 and 32, European Commission Radiation Protection No 91
	Collimation	IPEM Report No 91 and 32, European Commission Radiation Protection No 91
	Gray scale	IPEM Report No 32
	High contrast and low contrast resolution	European Commission Radiation Protection No 91, Draft European Commission Radiation Protection No 162, IPEM Report No 32
	Contrast detail	IPEM Report No 32
COMPUTED TOMOGRAPHY	kVp	IPEM Report No 32,
	Half value layer test	IPEM Report No 32,
	Position of external and internal scanning lights	IPEM Report No 32, IPEM Report No 91
	Coronal and Sagittal Alignment	IPEM Report No 32, IPEM Report No 91
	The slope of gantry	AAPM Report No 39
	Table axial motion accuracy	IPEM Report No 32, IPEM Report No 91, IEC 61223-2-6
	Table helical motion accuracy	IPEM Report No 32, IPEM Report No 91, IEC 61223-2-6
	Table distance sensor	IPEM Report No 32, IPEM Report No 91
	Computed tomography dose index (CTDI)	IPEM Report No 32, EC EUR 16262
	Tube output (CTDI Air) and linearity	IPEM Report No 32
	Slice thickness	IPEM Report No 32, IEC 61223-2-6

Medical Device	Inspection Type	Standard
	CT number linearity	IPEM Report No 32, IPEM Report No 91
	Highcontrastresolution	IPEM Report N:32 and 91, IEC 61223-2-6
	Low contrast resolution	IPEM Report No 32
	Noise measurement	NCRPM Report No 99, IPEM Report No 32 and 91
	CT number uniformity	IPEM Report N:32 and 91, IEC 61223-2-6
ULTRASOUND DEVICE	Image homogeneity	AAPM Report of Task Group No 1
	Image depth	AAPM Report of Task Group No 1
	Distance accuracy	AAPM Report of Task Group No 1
	Axial resolution	AAPM Report of Task Group No 1
	Lateral resolution	AAPM Report of Task Group No 1
	Dead zone	AAPM Report of Task Group No 1
	Cyst diameter	AAPM Report of Task Group No 1
NEGATOSKOP and VIEWING ROOM	Negatoskop brigthness and levels of bright of viewing room	IPEM Report 89, IPEM Report No 32, European Commission European Guidelines for Quality in Breast Cancer Screening and Diagnosis, ACR Mammography QC Manual

Table 4. The content of accreditation studies of inspection bodies.

5. Discussion

In Turkey, accreditation studies about biomedical calibration are performed in 3 different types. Calibration laboratories, testing laboratories and inspection bodies. Normally, although the scope of their applications seems like they are nested, they are separated from each other with little detail. Inspections of radiography devices and clean rooms are performed by inspection bodies. Other medical devices except for pipettes, thermometers, humidity meters that must be measured in laboratory conditions, are tested by testing laboratories and they are accredited in according to the standard of ISO IEC 17025. In calibration laboratories, it is essential to ensure appropriate environmental conditions for measurements. Because of this, measurements that require special measuring environment are performed in calibration laboratories.

If the differences and details of accreditation studies about biomedical calibration measurements are known by the health organizations, to make the right choice in the selection of calibration laboratory, testing laboratory or inspection body is inevitable.

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6. Conclusion

Quality service can be only taken from the accredited laboratories. As a matter of fact, the national and international procedures of accreditation say, "There is not an obligation. The accreditation depends on the base of voluntary." (TURKAK website).

Even if accreditation is not obligated, the expectation in medical calibration measurements is that the personnel must be professional, the calibration procedures and the test devices, calibrators must be appropriate to the international standards.

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