DESIGN OF THE BIOMEDICAL CALIBRATION LABORATORY QUALITY MANUAL FOR EN 17025: 2005

by

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I believe that my research can always be useful and serve for good purposes and for the whole humankind.

ABSTRACT

DESIGN OF THE BIOMEDICAL CALIBRATION LABORATORY QUALITY MANUAL FOR EN 17025: 2005

According to the New Approach Directives, the CE Marking is obligatory for medical products: the manufacturer affixes this marking in order to be allowed to sell his product in the European market. CE marked devices can only be tested and controlled by accredited laboratories. It is the aim of this project to design the laboratory quality manual in compliance with the EN 17025 standard, for the Biomedical Calibration Laboratory of Boğaziçi University.

By searching other related international standards, minimum documentation requirements are determined: besides a draft Laboratory Quality Manual, draft documents such as policies, procedures and instructions are prepared within the scope of this master thesis.

In the Appendices, a simple strategy plan on how to implement the EN 17025 standard in BME Biomedical Calibration Laboratory is also presented.

Keywords: Laboratory Quality Manual, Accreditation, CE Mark**,** Biomedical Equipment

ÖZET

BİYOMEDİKAL KALİBRASYON LABORATUVARI İÇİN EN 17025: 2005 STANDARDI İLE UYUMLU KALİTE EL KİTABI TASARIMI

CE markalı ürünlerin Avrupa Birliği içerisinde serbest dolaşabilmesi için "Yeni Yaklaşım Direktifleri" gereklerini sağlaması gerekmektedir. CE markalı ürünlerin ancak akredite laboratuvarlar tarafından test ve kontrolleri yapılabilmektedir. Bu tezde yapılan çalışma, Üniversitemiz Biyomedikal Mühendislik Enstitüsü Kalibrasyon Laboratuvarının EN 17025 standardı ile uyumlu hale getirilebilmesini sağlamaktır.

Bu master tezinin ana konusu, laboratuvar akreditasyonuna temel olması amacıyla, Biomedikal Kalibrasyon laboratuvarı el kitabının EN 17025 standardına uyumlu bir şekilde hazırlanmasıdır. İlgili diğer uluslararası standartlar incelenerek, minimum dokümantasyon gerekleri belirlenmiş ve bu tezin kapsamında kalite el kitabı, politikalar, prosedürler, talimatlar gibi gerekli dokümanlar taslak olarak hazırlanmıştır.

Tezde ayrıca, Biomedikal Kalibrasyon Laboratuvarı için EN 17025 standardına uygun basit bir akreditasyon uygulama planı bulunmaktadır.

Anahtar Sözcükler: Laboratuvar Kalite El Kitabı, Akreditasyon, CE Markası, Biyomedikal Cihaz

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*	Defines, sample provided
#	Defines, Empty form or file with layout provided

LIST OF ABBREVIATIONS

AAMI	Association for the Advancement of Medical Instrumentation.
AAPM	American Association of Physicists in Medicine.
ACR	American College of Radiology
ANZBMS	Australian and New Zealand Bone and Mineral Society.
BME	Biomedical Engineering
BRH	Bureau of Radiological Health, USA.
CE	Conformity to Europe
ECRI	Emergency Care Research Institute
EN	European Norm
HVL	Half-Value Layer
IEC	International Electro-technical Commission
ISO	International Organization for Standardization
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JD	Job Description
KV	Kilo-Volts or Kilo-Voltage
kVp	Kilovolt peak
mAs	Mili ampere-seconds
NCR	Nonconformity
PR	Procedure
POL	Policy
SI	International System of Units
SOP	Standard Operating Procedure
TURKAK	Turkish Accreditation Body

1. INTRODUCTION

CE marking of products which are included in New Approach Directives is a condition for their introducing into turnover on the territory of the European Union. Basically, all medical devices which our Institute concentrated on, shall be manufactured, controlled and distributed domestic and export markets by meeting the requirements of those new approach directives, mentioned below;

- 90/385/EEC Active implantable medical devices,
- 93/42/EEC Medical devices,
- 98/79/EC In vitro diagnostic medical devices,

Toys and electrical products which have been subjected so far to obligatory certification for safety mark may be covered by the following directives:

- 88/378/EEC Safety of toys,
- 89/336/EEC Electromagnetic compatibility,
- 73/23/EEC Low-voltage electrical equipment,
- 98/37/EC Machinery.

According to requirements of the above mentioned directives, before introducing of products into turnover, a manufacturer or his representative established on the territory of the European Union should:

- compile and keep technical file that identifies products and confirms their conformity to essential requirements of the directives;
- conduct conformity assessment of products with essential requirements specified in applicable directives;
- draw up a manufacturer's declaration of conformity with essential requirements;

- fix CE marking on products.

There is a gap between the Turkey's legislations and practical industrial applications because of the lack of experienced and independent Institute. The idea of establishing an accredited laboratory under the property of Biomedical Engineering Institute is generated for this purpose.

Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Accreditation bodies are established in many countries, often by government or with the encouragement of government, with the primary purpose of ensuring that certification/registration bodies in the country are subject to oversight by an authoritative body. Turkak is the only example of Accreditation Body established by Turkish government. Accreditation bodies visit certification/registration bodies regularly, and witness their staff conducting audits, to ensure that both the body and its staff remain competent to undertake operations. If Turkak accreditates BME, benefits of services offered by BME Institute shall be summarized as below;

- assurance of complying essential requirements,
- reduction of risk connected with medical products,
- acceleration of introducing medical products into the market,
- strengthening of competitive position within EU countries manufacturers.
- experience for academic purposes within testing and certification,
- professionalism and reliability,
- independence and neutrality,
- confidence of clients,
- competitive prices,

Therefore, minimum activities of the BME Institute after accreditation can be summarized as;

- performing tests and issuing applied documents for the purposes of CE-Marking according to regulations which include essential requirements for products (New Approach Directives);

- certification of calibration activities,

- advisory service in the scope of performing conformity assessment and completing necessary documentation.

Basically, BME Institute Biomedical Calibration laboratory should meet requirements of EN 17025: 2005 standard for accreditation. Details of the following sections are focused on this mission, to complete documentation requirements and manage quality system requirements.

2. SCOPE

The aim of this master thesis is to design laboratory quality manual for meeting documentation requirements of EN 17025 standard, which the standard defines General Requirements for the Competence of Calibration and Testing Laboratories. Design of quality manual and preparation of the documentation requirements will be a basis for the future plans of Biomedical Calibration Laboratory accreditation.

Scope of this master thesis is to establish document pyramid in accordance with quality manual. Common approach for Quality Manual Documentation Pyramid includes laboratory quality manual on the top; procedures, policies on the lower part, and instructions, job descriptions, forms, lists etc on the bottom of the pyramid. We assume documentation needs as design inputs which are detailed in the Section 3.

Outputs of the quality manual, including the original manual, procedures and application sheets are prepared in Boğaziçi University logo and format. Those documents are transferred and illustrated in the master thesis format in Appendix B and C.

Review of design inputs and outputs of the whole documentation system is given in Table 1.1. Also, reference of draft procedures is added in Table 1.1. for managing interrelationship between Appendix B (quality manual) and Appendix C (documented procedures handbook).

Verification of the quality manual design is maintained by the help of sample applications, such as method selection for performance testing of a surgical aspirator, and an X-ray Unit, in Appendix E, F, respectively. Also, a case study for handling nonconformities is given in Appendix G.

3. DESIGN AND DEVELOPMENT PLANNING FOR QUALITY MANUAL REQUIREMENTS

The BME (Biomedical Calibration Laboratory) will develop statutory and regulatory requirements and document a quality management system to better satisfy the needs of customer and to improve quality management system. For this purpose, a laboratory quality manual is prepared, and complied with the international standard EN 17025:2005. This manual has been prepared to define the quality system, establish responsibilities of the personnel affected by the system, and to provide general procedures for all activities comprising the quality system. In addition, this manual is utilized for the purpose of informing our customers about the quality system, and what specific controls are implemented to assure service quality.

EN 17025 is divided into two principal parts:

- Management requirements (Section 4 of the Standard)
- Technical requirements (Section 5 of the Standard)

A detailed documentation about the requirements for quality manual has been determined and listed in accordance with the standard terms and definitions. All documentation requirements are categorized as policies, procedures, instructions, files, jobs descriptions, files, charts, lists, agreements, plans, etc. and given in the below paragraphs. Numbering system of the EN 17025 standard used in the design of quality manual and procedures for easy adaptation, illustrated below;

- 4.0 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 Services and Supplies
- 4.7 Service to the Client
- 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 Audits
- 4.15 Management Reviews
- 5.0 Technical Requirements
- 5.1 Technical Requirements - General
- 5.2 Personnel
- 5.3 Accommodations and Environmental Conditions
- 5.4 Test and Calibration Methods and Method Validation
- 5.5 Equipment
- 5.6 Measurement Traceability
- 5.7 Sampling
- 5.8 Handling and Transportation of Test and/or Calibration Clauses
- 5.9 Assuring the Quality of Test and Calibration Results
- 5.10 Reporting the Results

Documentation needs, inputs of quality manual for policies are defined in the related section of the standard as “shall have a policy” and draft policies for each clause are detailed in the Quality Manual and Appendix C.

- Quality Policy (4.2.2),
- Confidentiality Policy (4.1.5.c),
- Gifts and Gratuities Policy (4.1.5.b),
- Internal Complaint Policy (4.1.5.b),

- External Complaint Policy (4.8),
- Laboratory Access Policy (5.3.3, 5.3.4),
- Good Housekeeping Policy (5.3.5),
- Use of Outside Support Services and Supplies Policy (4.5, 4.6),
- Acceptable Activities Policy (4.1.5.d),
- Nonconforming Calibration Work Policy (4.9.1, 5.5.7),
- Corrective Action Policy (4.10),

Documentation needs for Procedures are defined in the related section of the standard as “shall have a documented procedure” and draft procedures for each clause are detailed in Appendix C. Also, identification name of the procedures listed below should not follow the same procedure names defined in Appendix C.

- Quality Documentation Maintenance and Distribution Procedure (4.3.1, 4.3.2, 4.3.3),
- Traceability Procedure (5.5.2, 5.6.1, 5.6.3.1),
- Work Flow Procedure (4.4, 5.4.1, 5.8.2, 5.8.3, 5.8.4),
- Equipment Maintenance Procedure (5.4.7),
- Feedback and Corrective Action Procedure (4.9.1,4.10, 5.5.7),
- Complaint Procedure (4.8),
- Determining Calibration Intervals Procedure (5.6.1),
- Environment Recording Procedure (5.3.2),
- Suspect Equipment Procedure (5.5.7),
- Calibration Status Procedure (5.5.8),
- Equipment Acceptance Procedure (5.5.2),
- Certificate Preparation and Approval Procedure (5.4.7, 5.10., 4.2, 5.10.5),
- Data Backup Procedure (4.13, 5.4.7),
- Consumable Material Procedure (4.6.1,4.6.3),
- Electronic Transmission Procedure (4.13, 5.4.7, 5.10.7),
- Externally Generated Quality Documentation Maintenance and Distribution Procedure (4.3.1, 4.3.2, 4.3.3),
- Maintenance of Electronic Documents Procedure (4.3.3),
- Corrective and Preventive Action Procedure (4.11, 4.12),

- Record Control Procedure (4.13),
- Internal Audit Procedure (4.14),
- Transport and Storage Procedure for Reference Standards and Reference Materials (5.6.3.4)

Documentation needs for files are defined in the related section of the standard as "shall have adequate records" and draft file requirements are mentioned in Appendix C.

- Employee Personnel Files (General: 5.2.2, 5.2.5) ,
- Interlaboratory Comparison and Proficiency Test File (5.9),
- Audit Documentation File (4.14),
- Management Review File (4.15),
- Equipment File (5.5.1, 5.5.5, 5.5.6, 5.5.10).

Documentation needs for job descriptions are defined in the related section of the standard and draft job description is given in Quality Manual, Appendix B.

- Technical Manager Job Description (4.1.5.a, 4.1.5.f, 4.1.5.h, 4.2.4, 5.2.1, 5.2.4),
- Quality Manager Job Description (4.1.5.a, 4.1.5.f, 4.1.5.1,4.2.4, 5.2.1, 5.2.4),
- Technician Job Description (4.1.5.f, 5.2.1, 5.2.4).

Documentation needs for charts are defined in the related section of the standard and draft chart requirement is detailed in quality manual given in Appendix B.

- Organizational Chart (4.1.5.e, 4.1.5.f, 4.1.5.1)

Documentation needs for lists are defined in the related section of the standard as "shall have a list" or determined in related procedures given in Appendix C.

- Quality Document Master List (4.3.2),
- Major Equipment List (5.5.4),
- Reference Measurement Standards List (5.5.4),
- Outside Support Services and Supplies List (4.5, 4.6),

Documentation needs for plans are defined in the related section of the standard or detailed in related draft procedures given in Appendix C.

- Internal Audit Plan (4.14),
- Calibration Plan (5.4.),
- Annual Training Plan (5.2.2.).

Documentation needs for logs are defined in the related section of the standard or detailed in related draft procedures given in Appendix C.

- Corrective and Preventive Action Log (4.8, 4.11, 4.12),
- Complaints Review Log (4.8),
- Change Management Log (4.9).

Documentation needs can only be defined after application of instructions and procedures. Some sample form requirements are defined in the related section of the standard or detailed in related draft procedures given in Appendix C.

- Calibration Approval Form (5.8).
- Quality Documentation Update Form (4.2.1, 5.4.3),
- Internal Training Form (5.5.2),
- Nonconformity Record Form (4.9),
- Customer Complaint Record Form (4.8),
- Corrective or Preventive Action Review Form (4.12, 4.13).

Note 1: Forms mentioned above are given just to be an example, the real documentation requirements can only be defined after the implementation process. Sample forms in Appendix C are given as an illustration and

not reflected to Table A.1.

3.1. Detailed Descriptions of the EN 17025 Clauses

3.1.1. EN 17025: 2005 Clause 4.0 Management Requirements:

3.1.1.1. EN 17025: 2005 Clause 4.1 Organization and Management: BME Institute's Management holds legal responsibility for its operations and is organized to operate in accordance with the requirements of EN 17025, whether carrying out work in its permanent facilities or on location, at customer sites.

BME Institute is not part of an organization performing activities other than testing and/or calibration; therefore, there is no potential conflict of interest amongst its personnel. The organization of BME Institute is illustrated in Laboratory Quality Manual in Figure 1. Laboratory Personnel responsibilities are also described in Laboratory Quality Manual in Appendix B.

3.1.1.2.EN 17025: 2005 Clause 4.2 Management Systems:

EN 17025: 2005 Clause 4.2.1 Policies and Procedures: The Quality Management System is established, implemented, and maintained by management. It is applicable to all fields of testing and activities in which the laboratory is involved and has undertaken. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated and available to, understood and implemented by the appropriate personnel.

EN 17025: 2005 Clause 4.2.2 Quality Policy Statement: The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement and reviewed during management review.

EN 17025: 2005 Clause 4.2.3 Commitment to the Management System: BME Institute Board is committed to the development and implementation of the management system and improvement of its effectiveness continuously.

EN 17025: 2005 Clause 4.2.4 Communication of Requirements: BME Institute Board communicates to the organization the importance of meeting customer requirements

as well as statutory and regulatory requirements.

EN 17025: 2005 Clause 4.2.5 Quality manual: This quality manual developed and used by Biomedical Calibration Laboratory for purpose including, but not limited to the following;

- communicating the quality policy procedures and requirements,
- describing and implementing an effective quality system,
- providing improved control of practices and facilitating assurance activities,
- providing the documented bases for auditing the quality system,
- providing the continuity of quality system and its requirements during changing circumstances,
- training personnel in the quality system requirements and methods of compliance,
- presenting the quality system for external purposes, such as demonstrating compliance with EN 17025,
- demonstrating compliance of the quality system with quality requirements in contractual situations.

EN 17025: 2005 Clause 4.2.6 Technical Management and the Quality Representative: The roles and responsibilities for Technical Management and the Quality Representative are outlined in section 4.1. , Laboratory Quality manual. Technical management ensures that section 5 of this manual is implemented and maintained. The Quality Representative ensures that section 4 of Laboratory Quality manual is implemented and maintained. Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 4.2.7 Maintenance: BME Institute Board ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented. Detailed descriptions for this clause are given in Laboratory Quality Manual given in Appendix B.

3.1.1.3. EN 17025: 2005 Clause 4.3. Management of documents: Quality System Documentation is the most effective way of implementation of quality management system. Biomedical Calibration Laboratory documentation system shall ensure the

approval of the documents by competent personnel, distribution of the documents and identification of the documents.

EN 17025: 2005 Clause 4.3.1. Document Control System: Document management system is described in detail in Procedure for Document Control System and given in Appendix C Handbook for Q.M.S. Procedures.

EN 17025: 2005 Clause 4.3.2. Document Approval and Issue: All documents issued as a part of quality system are reviewed by the Quality Representative and approved by the related manager. The details of the document control, review and approval responsibilities are given in Procedure for Document Control and given in Appendix C Handbook for Q.M.S. Procedures. Controlled copies are distributed, in case there is no way for the employee to reach the software system, In case of distribution of the new version of the document, old revisions should be taken and disposed by the employee, who is responsible for the distribution. Detailed descriptions for this clause are given in Appendix B.

EN 17025: 2005 Clause 4.3.3. Document Change: Changes on documents and reviews of the documents are performed by the same function. The person revising the document or reviewing the document shall have the experience and/or knowledge in the field of document application and has the authority to reach document revision history. Detailed descriptions are given in Appendix B.

EN 17025: 2005 Clause 4.3.4. Review of Requests, Tenders, and Contacts: All changes in the documents are written with underlined and a short description of the changes is given in the revision history part. It is forbidden to change the laboratory documents in the Laboratory Documentation system by hand. All revised documents' old revisions are archived in computer for 11 years. Detailed descriptions are given in Appendix B.

3.1.1.4.EN 17025: 2005 Clause 4.4 Review of Requests, Tenders and Contracts:, Requests from the clients has been reviewed and different tenders for each test method has been prepared in order to attain the purpose of providing promptness, efficient, qualified services to the clients. Before commencing the test, full approval of the related Study Leader and the client should be consent. Requests, tenders and contracts shall be clear for both clients and laboratory and evaluated for method applicability. Review of requests, tenders and contracts shall include the tests performed by the subcontractors. The primary

responsibility of the review shall belong to Biomedical Calibration Laboratory. Detailed descriptions are given in Appendix B.

3.1.1.5. EN 17025: 2005 Clause 4.5. Subcontracting of tests and Calibration: Biomedical Calibration Laboratory may use suppliers to perform tests that are within, or outside Biomedical Calibration Laboratory scope of test capabilities. Suppliers of test services shall be selected within the accredited Laboratories as per ISO 17025 or have an ISO 17025 management system that has been successfully audited by Biomedical Calibration Laboratory. All subcontractors' quality performance shall continuously be evaluated by Biomedical Calibration Laboratory. In case of having a subcontractor for a particular test, this information shall be communicated with the customer in the tender. Continuous evaluation of the subcontractors is the responsibility of related Study Leader and Quality Representative. Subcontracting of Test and Calibration are performed as per PR 02, Procedure for Procurement and given in Appendix C.

3.1.1.6 EN 17025: 2005 Clause 4.6. Purchasing Services and Supplies. Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due to the consideration of the quality, statutory obligations. A list of approved suppliers and sub-contractors is maintained in related published supplier list of the Authorities. Purchasing Services and Suppliers are performed as per PR 02, Procedure for Procurement given in Appendix C. Detailed descriptions are given in Appendix B.

3.1.1.7. EN 17025: 2005 Clause 4.7 Service to the Client: Biomedical Calibration Laboratory has the policy of client satisfaction. Clients' requests are fully determined; client service is conducted and evaluated efficiently. Communications and feedbacks are important. Confidentiality is ensured and operations are traced. Quality Representative is responsible for the application of the methods for gathering feedback from the clients and reporting the results to Laboratory Director. Detailed descriptions are given in Appendix B.

3.1.1.8. EN 17025: 2005 Clause 4.8. Complaints: Laboratory operations' focuses are based on customer. Complaints, received from the customer shall be recorded, evaluated and necessary corrective actions shall be taken. Results of the evaluation and the corrective

action shall be communicated to the customer. Complaints which are proceeding in conformity with PR 03 Procedure for Handling Customer Compliant given in Appendix C. Laboratory Director is responsible for communicating and reporting the customer complaint to Quality Representative. Detailed descriptions are given in Appendix B.

3.1.1.9. EN 17025: 2005 Clause 4.9. Control of Non-conforming Testing and/or Calibration Work: The test nonconformities performed by Biomedical Calibration Laboratory, shall be recorded and analyzed. Laboratory Director is responsible for communicating the nonconformity with the client. Control and calibration of nonconforming test is performed by PR 04 Procedure for Handling Nonconformities given in Appendix C. Detailed descriptions are given in Appendix B.

3.1.1.10. EN 17025: 2005 Clause 4.10. Improvement: Our Institute determines collects and analyses appropriate data to demonstrate the effect and suitability of the QMS and to evaluate where QMS can be improved continuously effective. Detailed descriptions are given in Appendix B.

3.1.1.11. EN 17025: 2005 Clause 4.11. Corrective Action Corrective Actions shall be initiated based on the following reasons. However, for any reason, not indicated below shall be the source of Corrective action;

- test non-conformance,
- quality management system deficiencies,
- customer complaint,
- nonconformities observed in statistical analysis,
- audits,
- management review meeting.

Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B. PR 05 Procedure for Corrective Action given in Appendix C.

3.1.1.12.EN 17025: 2005 Clause 4.12. Preventive Action: BME Laboratory determines potential nonconformities and their causes. Preventive Actions applied in Biomedical Calibration Laboratory shall be conducted as per PR 06 Procedure for Preventive Action

given in Appendix C. Changes applied for the preventive actions shall be proceed in conformity with PR 07 Procedure for Change Management Procedure given in Appendix C. Detailed descriptions are given in Appendix B.

3.1.1.13. EN 17025: 2005 Clause 4.13. Control of Records: The control of records in Biomedical Calibration Laboratory shall be performed in conformity with PR 08 Procedure for Control of Records given in Appendix C. Detailed descriptions are given in Appendix B.

3.1.1.14. EN 17025: 2005 Clause 4.14. Internal Audits. A comprehensive Audit Program should be compiled at least a year in advance however, should particular needs be identified, and the frequency of audit may be increased at the discretion of the Quality Representative. The internal audit plan covering each division at least once in each year shall be prepared with the minimum information and described in PR 09 Procedure for Internal Audits given in Appendix C. Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B

3.1.115. EN 17025: 2005 Clause 4.15. Management review: Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system. Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B.

3.1.2. EN 17025: 2005 Clause 5.0 Technical Requirements:

3.1.2.1. EN 17025: 2005 Clause 5.1 Technical Requirements – General: Our Institute recognizes that many factors determine the correctness and reliability of the tests and/or calibration performed by a laboratory. These factors include contributions from: human factors (5.2), accommodation and environmental conditions (5.3), test and calibration methods and method validation (5.4), equipment (5.5), measurement traceability (5.6), and handling of test and calibration Clauses (5.8). The extent to which of the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and

between (types of) calibrations. Our Institute takes into account these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment which is used.

3.1.2.2. EN 17025: 2005 Clause 5.2 Personnel: Our Institute's management ensures the competency of all who operate specific equipment, who perform tests and/or calibrations, who evaluate results and sign test reports and calibration certificates. All of Our laboratory personnel have an engineering background and are graduated from our Institute's Master program so they all have biomedical engineer diploma and they are all research assistants of our Institute. Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B.

3.1.2.3. EN 17025: 2005 Clause 5.3 Accommodations and Environmental Conditions: Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and accommodation shall be designed to facilitate correct performance of the tests and/or calibrations. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

3.1.2.4. EN 17025: 2005 Clause 5.4 Test and Calibration Methods and Method Validation: In general sampling, handling, transport, storage, and preparation of Clauses to be tested are performed in accordance with this manual.

EN 17025: 2005 Clause 5.4.1 General: The management of Laboratory equipment is performed as per PR 10, Procedure for Equipment Management. Laboratory has usage and operational instructions for of all relevant equipment, on the handling, preparation of Clauses for testing and calibration, where the absence of such instructions could jeopardize the results of tests and/or calibration, prepared as per Procedure for Document Control. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.2 Selection of Methods: used in our Laboratory including methods of sampling, are identified as suitable for client requirements. Before the initiation of these test methods, communication with the client shall be performed by Laboratory Director. The test shall be initiated after the approval of the client. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.3. Laboratory-Developed Methods: The introduction of

test and calibration methods developed by Laboratory for its own use are planned and applied by a qualified personnel equipped with adequate resources as per PR 12 Procedure for Test Method Development given in Appendix C. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.4. Non-Standard Methods: When it is necessary to use methods not covered by standard methods, these methods shall be communicated with the clients. The validation of these non-standard laboratory Methods shall be performed in conformity with PR 16, Procedure for Method Validation given in Appendix C. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.5 Validation of methods: All standard and non-standard test methods and procedures are validated to ensure that such methods and procedures are fit for their intended use and are relevant to the requirements of EN 17025 Clause 5.4.5. The validation of these laboratory Methods shall be performed in conformity with PR 16, Procedure for Method Validation. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.6 Uncertainty of Result: The uncertainty of calibration results is calculated and documented in accordance with the requirements of EN 17025 Clause 5.4.6. The Procedure for Uncertainty of Measurement is applied to all in house calibrations/tests. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

EN 17025: 2005 Clause 5.4.7. Control of Data Calculations; data transfers and systematic checks for the data generated in our Laboratory are performed as per Procedure for Control of Records. The analysis of data is performed as per Procedure for Maintaining the Quality of Test and Calibration Results. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

3.1.2.5. EN 17025: 2005 Clause 5.5 Equipment: Institute Board is responsible for maintaining necessary Financial Resources for, calibration, verification, training and maintenance etc. of that equipment. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

3.1.2.6. EN 17025: 2005 Clause 5.6 Measurement Traceability: In order to maintain the safety of measuring system performed in our Laboratory, all measurement equipment shall be calibrated as per predetermined schedule to maintain measurement traceability. The general criteria for Measurement Traceability are described in Procedure for Measurement Traceability given in Appendix C. Detailed descriptions for this clause are detailed in Laboratory Quality Manual given in Appendix B.

3.1.2.7. EN 17025: 2005 Clause 5.7 Sampling: The sampling in Biomedical Calibration Laboratory shall be performed with the scientific knowledge after the approval of the client. Sampling plans based on the feature of the test should be conforming to related standards, and statistical methods. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

3.1.2.8. EN 17025: 2005 Clause 5.8 Handling and Transportation of Test and/or Calibration Items: BME Laboratory shall apply all measures to handling of test and calibration articles described by the client, related standards to secure the result and the records of test performed. The procedures for avoiding deterioration and loss of the test or damage to the test or calibration Clause during storage, handling and preparation is described in related test instructions. Detailed descriptions for this clause are detailed in Appendix B.

3.1.2.9. EN 17025: 2005 Clause 5.9 Assuring the Quality of Test and Calibration Results: Laboratory takes all the safety measures, to assure the quality of test and calibration standards. Laboratory maintains a system for the continuity of these measures and monitor and analyze the system built. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

3.1.2.10. EN 17025: 2005 Clause 5.10 Reporting the Results: The results of each test, calibration, or series of tests or calibrations carried out by the laboratory are reported accurately, clearly, unambiguously and objectively in accordance with any specific instructions in the test or calibration methods. The results are normally reported in a test

report or a calibration certificate and include all the information requested by the client, all the information necessary for the interpretation of the test or calibration results, and all the information required by the method used. Detailed descriptions for this clause are stated in Laboratory Quality Manual given in Appendix B.

4. CONCLUSION

As quality manual including the related procedures and documentation is prepared for the EN 17025 standard compliance of the biomedical equipment measurement and calibration laboratory, in the Institute of Biomedical Engineering.

The management of documentation requirements was based on key steps of design control, which are; Planning, Design Inputs, Design Outputs, Design and Development Review, and Verification.

Templates are prepared for the inspection sheets of typical medical equipment and typical medical imaging systems. In order to prepare the inspection procedures for the medical devices, resources such as ECRI and AAMI will be employed. For imaging systems, however, AAPM and ACR reports and publications shall be used as reference.

The harmonized standards by the European Council can also be citied among the useful resources. The standards that have been implicitly used in a given procedure will be clearly stated on the cover page of the inspection forms.

All electrical safety measurements will be handled according to IEC 60601-1 and the results included in the inspection forms.

As additional information, Accreditation Implementation Plan is given in Appendix A.

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EN 17025 Clauses	CONTENT	Documentation Needs /Inputs	Documentation Outputs	Procedure Index –App. C
4.1	Organization	Policy, JD, Chart	POL *, JD#	-
4.2	Management System	Policy, PR	POL *, PR#	-
4.3	Document Control	PR, List	POL * PR*	C.1.PR01
4.4	Review of Requests, Tenders and Contracts	PR, List	POL * , PR#	-
4.5	Subcontracting the Test and Calibration	Policy, List	POL *, PR*	C.2.PR02
4.6	Purchasing Services and Supplies	Policy, List	POL *, PR*	C.2.PR02
4.7	Service to the Clients	Policy	POL *	-
4.8	Complaints	Policy, PR, Log	POL *, PR*	C.3.PR03
4.9	Control Of Nonconforming Testing and/or Calibration	Policy, PR	POL *, PR*	C.4.PR04
4.10	Improvement	Policy, PR	POL * , PR*	C.7.PR07
4.11	Corrective Action	Policy, PR, Log	POL *, PR*	C.5.PR05
4.12	Preventive Action	Policy, PR, Log	POL *, PR*	C.6.PR06
4.13	Control of Records	Policy , PR	POL *, PR*	C.8.PR08
4.14	Internal Audits	PR, File, Plan	POL *, PR*	C.9.PR09
4.15	Management Reviews	Policy, File, Plan	POL *	-
5.1	Technical Requirements - General	Policy	POL *	-
5.3	Accommodation and Environmental Conditions	Policy, PR	POL *, PR#	-
5.4	Test and Calibration Methods and Method Validation	PR, Plan	PR*	C.12.PR12
5.5	Equipment	Policy, PR, List, File	POL *, PR*, List *	C.10.PR10
5.6	Measurement Traceability	PR	PR*	C.15.PR15
5.7	Sampling	Policy	POL *	-
5.8	Handling of Test and Calibration Items	PR	PR*	C.14.PR14
5.9	Assuring the Quality of Test and Calibration Results	File	PR*	C.11.PR11
5.10	Reporting the Results	PR	PR*	C.13.PR13

Table 1.1. Comparison Table for Documentation Requirements – Inputs / Outputs

Review of quality manual design inputs and outputs is given in Table 1.1. Outputs of the quality manual, including the original manual, procedures and forms are referred in appendices.

Note: Rest of the documentation system such as procedures (for technical needs), job descriptions, lists, files, plans, logs, forms etc can only be prepared during "Accreditation Implementation Project" with Project Team of Laboratory Management, with their support and interest. Samples of draft procedures and related forms are given in Appendix C. Laboratory Equipment List are given in Appendix D. Application samples of procedures are given in Appendix E, F and G.

APPENDIX A. DESIGN OF ACCREDIATION PROJECT FOR BIOMEDICAL CALIBRATION LABORATORY

Project Strategy Plan for Accreditation process will help to understand the next steps of this Master Thesis. Preparation of the basic documentation needs provides finding the resources easily, and timelines and milestones of the Accreditation process. Performing gap analysis of the requirements of the standard with our actual Laboratory conditions was exposed “to do list” for Implementation project. So a Project Strategy Plan is developed on how to implement EN 17025: 2005 standard to our Biomedical Calibration Laboratory. Work Breakdown Structure for Accreditation Project is given in the next Subsections.

Project plan prepared for biomedical calibration laboratory is given in Appendix A, Table A.1. Upon request, other BME Institute laboratories can be added in the project scope, such as Biomechanics or Medical Imaging Laboratory. Project phases - major project stages/activities has been planned by using the PDCA (Plan, Do, Check, and Add) cycle. Plan does not cover interfaces or integration with other systems in any or all phases cause of the lack of the similar departments’ documentation systems.

A.1. Accreditation Project Purpose

The laboratory has an existing documentation system but need to be upgraded. This master thesis documentation scope will help to revise the existing system. But there are some problems because of the structure of the BME Laboratory. Risk analysis of the Project will be given in the 4.1.4. Section, basic constraints can be summarized as;

- The laboratory is depending on Boğaziçi University and BME Institute. Research of the affects of the University Board will be performed carefully under the national legislations.
- Comparison with alternative approaches will not be possible, cause of no known similar projects

A.2. Accreditation Project scope

Services will be supplied by Biomedical Calibration Laboratory for the biomedical equipments are detailed below;

- calibration of the biomedical equipments,
- assistance in selection of harmonized standards and in verification of technical documentation meeting the requirements of EN ISO 13485: 2004 (medical products),
- assessment of technical file of a medical product or machine,
- advisor of conformity assessment of medical products of IIa, IIb and III classes, when an opinion of notified body is required,
- training on medical directives and quality management systems according to ISO 9001: 2001 and EN ISO 13485: 2004,
- medical product laboratory testing: in the scope of electrical requirements, mechanical requirements, and performance requirements,
- EC-type examination.

A.3. Resource Assessment for the Project

The resources assessment may require the development of additional supporting documentation, which referenced in the Project Plan given in Appendix A.

- institute Research Assistants can meet staffing requirements, as “Laboratory Personnel” or “Study Leaders”,
- external consulting/contracting requirements (contract documents may need to be developed) may be detailed in the second phase of the implementation process,
- need for Quality Representative” (can be external consulting/contracting position),
- separate physical facilities such as office space required for Project (for test reliability and security),
- hardware requirements such as new servers (machine specifications, quotes etc),

- infrastructure requirements for network (decision will taken later),
- if LIS required for the Project (decision will taken later) software – may include licenses to be purchased (if software will be developed, then additional plans and documentation will be developed).

A.4. Risk analysis of the Accreditation Project

Depending upon scope several “Risk Management Plans” can be achieved. However, the risks mentioned below will be identified with initiation phase of the Project.

- external constraints or impacts; such as University Board rejection,
- project delivery/completion risks; if the planned timeline extent more than 1 year, participation to the Project (by Institute’s staff) may be affected,
- business environment risks; a new and private laboratory can be accredited by TURKAK,
- managing cost; we can have problems with managing funds,
- need to plan marketing and communications strategy.

A.5. Success Factors of the Project

Research into what makes an EN 17025 implementation a success has revealed Critical Success Factors. They are, in order of importance:

- top management leadership and commitment,
- a simple, comprehensive implementation plan,
- training & support for everyone involved or affected by the implementation project,
- rapid and effective communication, feedback, and recognition on efforts made, results achieved, and work to be done,

- auditing, training, and remedial assistance to achieve consistent compliance to minimum requirements,
- continuous assessment, improvement, and re-registration of systems.

A.6. Project Management Approach

- Project reporting structure – who reports to whom, shall be defined, and team membership and role responsibilities shall be written down.
- If existing, various stakeholder roles and responsibilities shall be determined.
- Scheduled reporting and review – Project Team shall identify reporting requirements and frequency and add the issues on Project Plan in MS Project format.
- Estimated timelines for milestones are given in the Table A.1.
- Also, identification of specific milestones at which project review and re-evaluation should occur given in the Table A.1.

PHASE 1: PLANNING		
STEP 1: PROJECT INITITATION		
TASK NAME	**DURATION**	**Resources**
Project Leader assigned	4 days	Project Leader
Project Team assigned, Meeting held	4 days	Project Team, Project Leader
Project Plan Approval, A time scheduled plan	1 day	Top Management
Training for Project Team	2 days	External Trainer, Expert on ISO 17025
Top Management Commitment and Leadership	3 days	Top Management
STEP 2: GAP ANALYSIS for EN 17025		
Comparison of Legal and ISO 17025 Clauses with Laboratory Conditions	12 days	Quality Representative
Gap analysis-with the help of Institute Director, needs and resources are determined.	12 days	Institute Director; Project Team
Analysis of Documentation Requirements	40 days	Institute Director; Project Team
Preparation and distribution of Laboratory Quality Manual.	40 days	Quality Representative
Preparation and distribution of Documented Procedures	40 days	Laboratory Personnel; Quality Representative
Preparation and distribution of Test and Calibration Instructions.	40 days	Laboratory Personnel
Training & support for everyone involved or affected by the implementation project	40 days	Laboratory Director
Search about effective and strategic validation protocols for laboratory equipment and computer systems	30 days	Laboratory Director; Study Leaders
Preparation of Validation Protocols	30 days	Study Leaders
Preparation of Job Descriptions	30 days	Laboratory Director; Quality Representative
Preparation of work flow charts, if required	30 days	Laboratory Personnel
PHASE 2: APPLICATION		
Calibration planning for all in-house laboratory equipment	6 days	Study Leader

Table A1. Project Plan Summary for Implementation (Continued)

TASK NAME	DURATION	Resources
Determination of Internal Auditors, Internal Audit planning	7 days	Quality Representative[Laboratory Personnel
Determination of Subcontractors for external calibration services, if required	10 days	Laboratory Director; Study Leader
Planning Internal audits according to Q.M	6 days	Quality Representative
Recording nonconformities, determination of route causes, planning of corrective actions	7 days	Quality Representative; Laboratory Personnel
PHASE 3: CONTROL AND IMPLEMENTATION (MIN 3 MONTH PERIOD)		
Recording nonconformities, determination of route causes, planning of corrective actions	90 days	Quality Representative[50%];Laboratory Personnel[50%]
Calibration of all measurement equipments in the laboratory.	90 days	Study Leader
Performing tests in conformity with contracts, preparation of test certificates in accordance with quality manual.	90 days	Study Leader
Preparation of Approved Supplier List, Evaluation of the Suppliers, if required External Calibration Laboratory visits	15 days	Quality Representative
Following up corrective and preventive actions, if possible Closing up NCR reports prepared by Action Coordinators	90 days	Laboratory Director
Handling customer complaints and initiating corrective actions.	90 days	Quality Representative
Review of quality documentation for revision requests, Approval of revisions and distribution of the revised documents.	90 days	Quality Representative
Performing internal audits, preparation of the audit report, distribution and initiating required corrective actions.	15 days	Auditors; Quality Representative
PHASE 4-REVIEW AND IMPROVEMENT		
Data Analysis for Management Review Meeting; Test results and measurement uncertainties will be reported by Study Leaders.	14 days	Study Leader

Table A1. Project Plan Summary for Implementation (Continued)

TASK NAME	**DURATION**	**Resources**
Reporting of all items of ISO 17025 standard requirements and the results.	14 days	Quality Representative
Performing Management Review Meeting with the Laboratory Management	2 days	Laboratory Director; Quality Representative; Top Management
Preparation of Management Review Meeting Report, and Distribution, Actions will be planned.	2 days	Quality Representative
Continuous assessment, improvement, and re-registration of systems	15 days	Laboratory Director
Certification for accreditation	2 days	Laboratory Director

Table A1. Project Plan Summary for Implementation.

Graphical illustration of the Project Plan, planned on Microsoft Project software, based on Table A.1., given below:

ID	Task Name	Duration	Start	Finish	Pr	Resource Names
1	ISO 17025 LABORATORY ACCREDITATION PROJECT	197 days	Wed 28.03.07	Tue 09.10.07		
2	PHASE 1: PLANNING	26 days	Wed 28.03.07	Mon 30.04.07		
3	STEP 1: PROJECT INITIATION	14 days	Wed 28.03.07	Fri 13.04.07		
4	Project Leader assigned	4 days	Wed 28.03.07	Mon 02.04.07		Project Leader
5	Project Team assigned, Meeting held	4 days	Mon 02.04.07	Fri 06.04.07	4	Proje Team[50%]
6	Project Plan Aprovel, A time scheduled plan	1 day	Fri 06.04.07	Fri 06.04.07	5	Top Management
7	Training for Project Team (needs determined in WBS)	2 days	Mon 09.04.07	Tue 10.04.07	6	
8	Top Management Commitment and Leadership	3 days	Tue 10.04.07	Fri 13.04.07	7	Top Management
9	STEP 2: GAP ANALYSIS for ISO 17025	12 days	Fri 13.04.07	Mon 30.04.07	8	
10	Comparision of Legal and ISO 17025 Clauses with Laboratory Conditions	12 days	Fri 13.04.07	Mon 30.04.07		Kalite departman
11	Gap analysis-With the help of Institute Director, needs and resources are determined.	12 days	Fri 13.04.07	Mon 30.04.07		Institute Director[20%];Project Team
12	Analysis of Documentation Requirements	10 days	Fri 13.04.07	Thu 26.04.07	11	
13	Preparation and distribution of Laboratory Quality Manual.	10 days	Fri 13.04.07	Thu 26.04.07		Quality Representative
14	Preparation and distribution of Documented Procedure	10 days	Fri 13.04.07	Thu 26.04.07	13	Laboratory Personnel[50%];Quality Representative
15	Preparation and distribution of Test and Calibration Instructions.	10 days	Fri 13.04.07	Thu 26.04.07	14	Laboratory Personnel
16	Training & support for everyone involved or affected by the implementation project	10 days	Fri 13.04.07	Thu 26.04.07	15	Laboratory Director
17	Search about effective and strategic validation protocols for laboratory equipment and computer s	10 days	Fri 13.04.07	Thu 26.04.07	16	Laboratory Director;Study Leader
18	Preparation of Validation Protocols	10 days	Fri 13.04.07	Thu 26.04.07	17	Study Leader
19	Preparation of Job Descriptions	10 days	Fri 13.04.07	Thu 26.04.07	18	Laboratory Director;Quality Representative
20	Preparation of work flow charts, if required	10 days	Fri 13.04.07	Thu 26.04.07	19	Laboratory Personnel[20%]
21	PHASE 2: APPLICATION	10 days	Thu 26.04.07	Wed 09.05.07	20	
22	Step 1: Application and Planning	10 days	Thu 26.04.07	Wed 09.05.07		
23	Calibration planning for all in-house laboratory equipment	6 days	Thu 26.04.07	Thu 03.05.01		Study Leader[50%]
24	Determination of Internal Auditors, Internal Audit planning	7 days	Thu 26.04.07	Fri 04.05.01	23	Quality Representative[50%];Laboratory Personnel[5
25	Determination of Subcontractors for external calibration services, if required	10 days	Thu 26.04.07	Wed 09.05.07	24	Laboratory Director[20%];Study Leader[50%]
26	Planning internal audits according to Q.M	6 days	Tue 01.05.07	Wed 09.05.07	25	Quality Representative
27	Recording nonconformities, determination of route causes, planning of corrective actions	7 days	Tue 01.05.07	Wed 09.05.07	26	
28	PHASE 3: Control and Implementation - Min 3 month period	90 days	Wed 09.05.07	Wed 29.08.07	21	
29	Recording nonconformities, determination of route causes, planning of corrective actions	90 days	Wed 09.05.07	Wed 29.08.07		
30	Calibration of all measurement equipments in the laboratory.	90 days	Wed 09.05.07	Wed 29.08.07	29	Study Leader
31	Performing tests in conformity with contracts, preparation of test certificates in accordance with quality manual.	90 days	Wed 09.05.07	Wed 29.08.07	30	Study Leader
32	Preparation of Approved Supplier List, Evaluation of the Suplliers, if required External Calibration Laboratory visit	15 days	Thu 09.08.07	Wed 29.08.07	31	Quality Representative[264%]
33	Following up corrective and preventive actions, if possible Closing up NCR reports prepred by Action Coordinat	74 days	Tue 29.05.07	Wed 29.08.07	32	Laboratory Director[50%]
34	Handling customer complaints and initiating corrective actions.	74 days	Tue 29.05.07	Wed 29.08.07	33	Quality Representative[50%]
35	Review of quality documentation for revision requests, Approval of revisions and distribution of the revised docu	74 days	Tue 29.05.07	Wed 29.08.07	34	Quality Representative
36	Performing internal audits, preparation of the audit report, distribution and initiating required corrective actions.	14 days	Fri 10.08.07	Wed 29.08.07	35	Auditors;Quality Representative
37	PHASE 4-REVIEW AND IMPROVEMENT	47 days	Fri 10.08.07	Tue 09.10.07	58	
38	Data Analysis for Management Review Meeting; Test results and measurement uncertainties will be reported by Study Leaders.	14 days	Fri 10.08.07	Wed 29.08.07		Study Leader
39	Reporting of all items of ISO 17025 standard requirements and the results.	14 days	Wed 29.08.07	Fri 14.09.07	38	Quality Representative[250%]
40	Performing Management Review Meeting with the Laboratory Management	2 days	Fri 14.09.07	Tue 18.09.07	39	Laboratory Director[20%];Quality Representative[30%];Top Management
41	Preparation of Management Review Meeting Report, and Distribution, Actions will be planned.	2 days	Tue 18.09.07	Thu 20.09.07	40	Quality Representative
42	Continuous assessment, improvement, and re-registration of systems	15 days	Thu 20.09.07	Tue 09.10.07	41	Laboratory Director
43	CERTIFICATION	6 days	Tue 09.10.07	Tue 16.10.07	42	
44	Certification for meeting the accreditation requirements	6 days	Tue 09.10.07	Tue 16.10.07		

Figure A.1. MS Project Software Presentation for the steps described in Table A.1. – Print Screen Version – Continued.

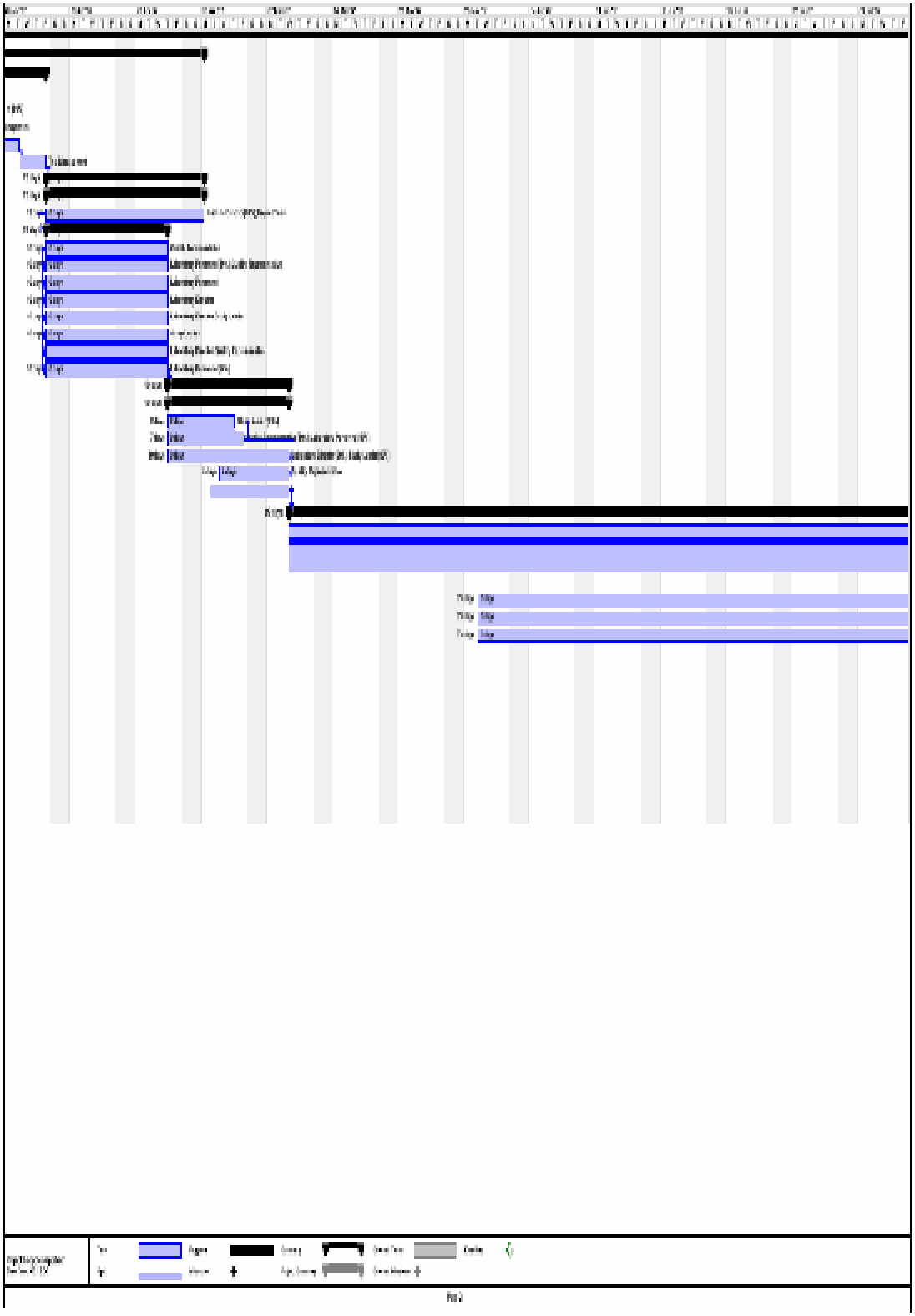


Figure A.1. MS Project Software Presentation for the steps described in Table A.1. – Print Screen Version – Continued

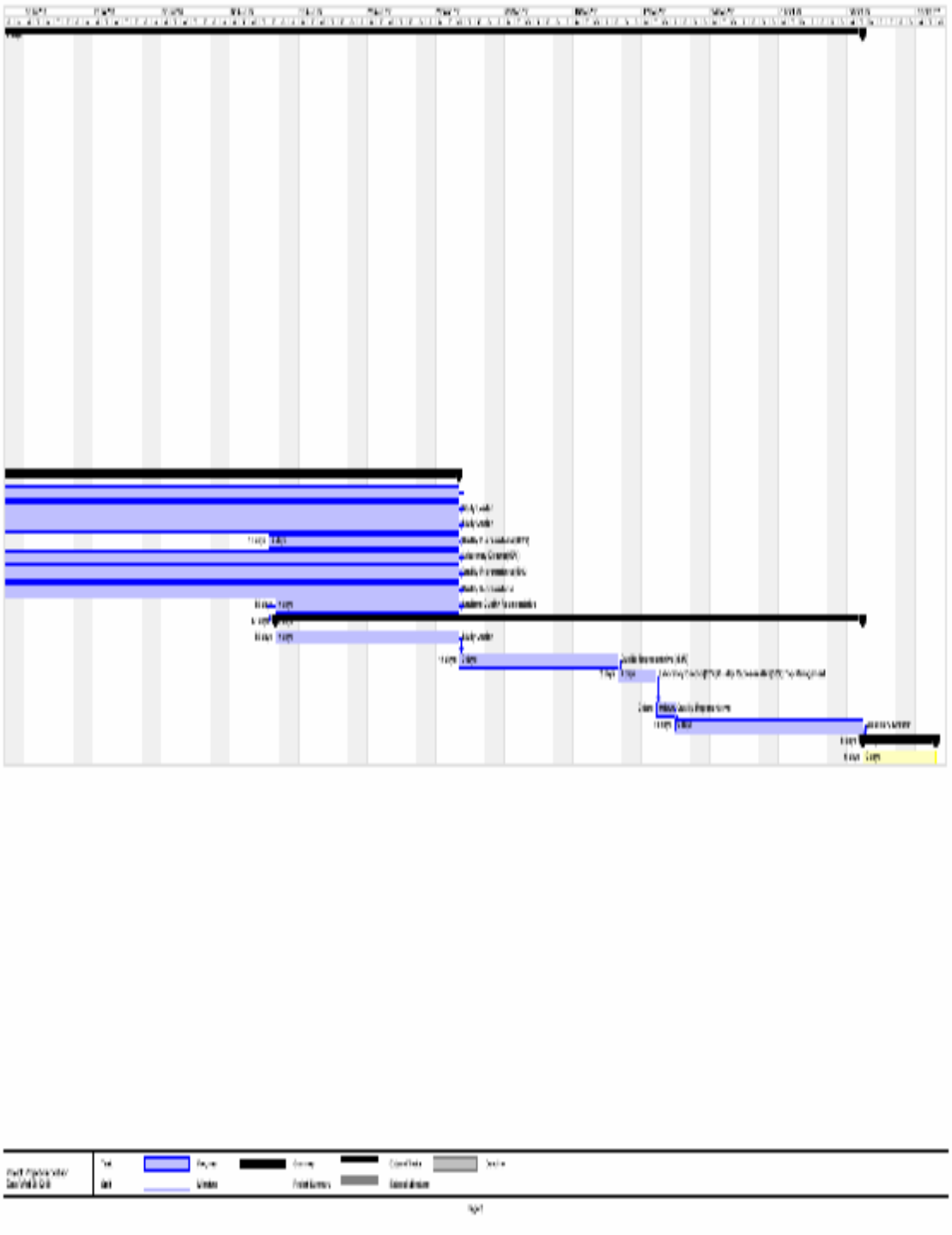


Figure A.1. MS Project Software Presentation for the steps described in Table A.1. – Print Screen Version

APPENDIX B. QUALITY MANUAL for BIOMEDICAL CALIBRATION LABORATORY

B.1 General Information

Laboratory Test Scope and equipment used is given in the Appendix D. Applicable Standards and Regulations are listed below that form basis in the preparation of this manual.

- ISO 9001: 2000
- ISO 19011: 2003
- ISO 10013: 1995
- EN 17025: 2005

Institute of Biomedical Engineering of Boğaziçi University was established in 1982 as an interdisciplinary graduate school in the field of Biomedical Engineering. The Institute of Biomedical Engineering is unique in Turkey and offers interdisciplinary instructional programs and research, leading to MS and Ph.D. degrees in three major areas, namely in Bioelectronics, in Biocybernetics and Biomechanics, and in Prosthetics and Artificial Organs. The field of Biomedical Engineering has emerged as an important profession in developed as well as developing countries and is concerned with the application of engineering technology and science methodology to the analysis of biological, physiological and health care problems.

During the past several decades the medical profession has grown to depend increasingly on machines and sophisticated electronic instrumentation supported by elaborate clinical data processing procedures for the delivery of quality health care. As a response to these requirements biomedical engineers are responsible for producing high technology medical equipment and biological instrumentation, for devising new and efficient methods for physiological measurements, medical data processing and analysis, for developing prosthetic materials and artificial organs, and for introducing the suitable technological developments to the health care system.

From September 1982 to October 1992, the Institute had been receiving UNDP and UNESCO assistances in the framework of a development project, the consulting services, training programs and fellowships. The aim of the project was to support the activities of the Institute and strengthen its capacities in order to respond to the critical health care problems in Turkey, with the long-term objective of becoming a Regional Canter for neighbouring countries with similar problems

Our Institute's Laboratory shares its knowledge with Medical Health Care Centres, Hospitals since 2000. By releasing of EU directives and regulations in Turkey our Management is considered our Laboratory applying all regulations according to ISO 17025.

B.2. Abbreviations and Terminology

Abbreviations

Q.M.R	: Quality Management Representative
T.M	: BME Institute Board (Top Management)
Q.M.S.	: Quality Management System
DCR	: Document Change Request

Terminology

- **quality management system:** management system to direct and control an organization with regard to quality.
- **quality policy:** overall intentions and direction an organization related to quality, as formally expressed by the BME institute board.
- **audit:** systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine to extent to which audit criteria are fulfilled.
- **audit program (audit calendars):** set of one or more audits planned for a specific time frame and directed towards a specific purpose.
- **non-conformity (NCR):** non-fulfilment of a requirement**.**

- **non-conformity report (NCR):** A standard form is used for a non-conformance found during an audit. NCRs are prepared / issued by the Quality Department. Each NCR is written for only ONE non-conformance.
- **auditor:** person with the competence to conduct an audit.
- **audit evidence:** records, statements of fact or other information which are relevant to the audit criteria and verifiable.
- **audit findings:** result of the evaluation of the collected audit evidences against audit criteria.
- **product** is defined as "result of a **process.**
- **process** is defined as "set of interrelated or interacting activities which transforms inputs into outputs".
- **requirement:** need or expectation that is stated, generally implied or obligatory
- **customer satisfaction:** customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled
- **correction**: action to eliminate a detected nonconformity
- **corrective action:** action to eliminate the cause of a detected nonconformity or other undesirable situation
- **measurable quantity:** attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively.
- **general sense quantities:** length, time, mass, temperature, electrical resistance, amount-of-substance concentration.
- **particular quantities**: length of a given rod, electrical resistance of a given specimen of wire, amount-of-substance concentration of ethanol in a given sample of wine.
- **value of a quantity:** magnitude of a particular quantity generally expressed as a unit of measurement multiplied by a number.
- **true value of a quantity**: value consistent with the definition of a given particular quantity. true values are by nature indeterminate.
- **conventional true value of a quantity:** value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose.

- **measurement:** set of operations having the object of determining a value of a quantity
- **principle of measurement:** scientific basis of a measurement
- **method of measurement:** logical sequence of operations, described generally, used in the performance of measurements
- **measurand:** particular quantity subject to measurement
- **influence quantity:** quantity that is not the measurand but that affects the result of the measurement
- **result of a measurement:** value attributed to a measurand, obtained by measurement
- **relative error:** error of measurement divided by a true value of the measurand
- **random error:** result of a measurement minus the mean that would result from an infinitive number of measurements of the same measures carried out under repeatability conditions.
- **systematic error:** mean that would result from an infinitive number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand.
- **correction:** value added algebraically to the uncorrected result of a measurement to compensate for systematic error.
- **correction factor:** value added algebraically to the uncorrected result of a measurement to compensate for systematic error. since the systematic error cannot be known perfectly, the compensation cannot be complete.
- **uncorrected result:** result of a measurement before correction for systematic error.
- **corrected result:** result of a measurement after correction for systematic error.
- **accuracy of a measurement:** closeness of the agreement between the result of a measurement and a true value of the measurement accuracy is a qualitative concept.
- **repeatability of results of measurements:** closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.
- **reproducibility of results of measurement:** closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement.

- **uncertainty of measurement:** parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
- **standard uncertainty:** uncertainty of the result of a measurement expressed as a standard deviation.
- **type A evaluation of uncertainty:** method of evaluation of uncertainty by the statistical analysis of series of observation.
- **type b evaluation of uncertainty:** method of evaluation of uncertainty by means other than the statistical analysis of series of observation.
- **combined standard uncertainty:** standard uncertainty of the result of a measurement when result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariance of these other quantities weighted according to how the measurement result varies with changes in these quantities.
- **expanded uncertainty:** quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.
- **coverage factor:** numerical factor used as a multiplier of the combined standard uncertainty in order to obtained an expanded uncertainty. a coverage factor is typically in the range of 2 to3.
- **probability:** a real number in the scale 0 to 1 attached to a random event.
- **random variable:** a variable that can take any of the values of a specified set of values and with which is associated a probability distribution.
- **correlation:** the relationship between two or several random variables within a distribution of two or more random variables.
- **standard deviation:** (of a random variable or of a probability distribution) the positive square roots of the variance.
- **characteristic**: a property which helps to identify of differentiate between items of a given population. the characteristic may be either quantitative or qualitative.
- **arithmetic mean, average:** the sum of values divided by the number of values.
- **variance:** a measure of dispersion, which is the sum of the squared deviations of observations from their average divided by one less than the number of

observations.

- **statistic:** a function of the sample random variables.
- **estimation:** the operation of assigning, from the observations in a sample, numerical values to the parameters of a distribution chosen as the statistical model of the population from which this sample is taken.
- **confidence coefficient/ confidence level:** the value of the probability associated with a confidence interval or a statistical coverage interval.
- **statistical coverage interval:** an interval for which it can be started with a given level of confidence that it contains at least a specified proportion of the population.
- **degrees of freedom:** the number of terms in a sun minus the number of constraints on the terms of the sum.
- **verification**: this is performed in order to control the stability of the deviation until the second calibration.
- **calibration:** under determined conditions, calibration is comparing measurement equipment with a calibrator, which has a documented relationship with national and / or international standards and therefore detecting measurement capacity with a known uncertainty.

Note: This section shall be used for the Quality Manual's abbreviations and terminology, when approved. Abbreviations and terminology is given above only represents examples.

B.3 Organization Chart

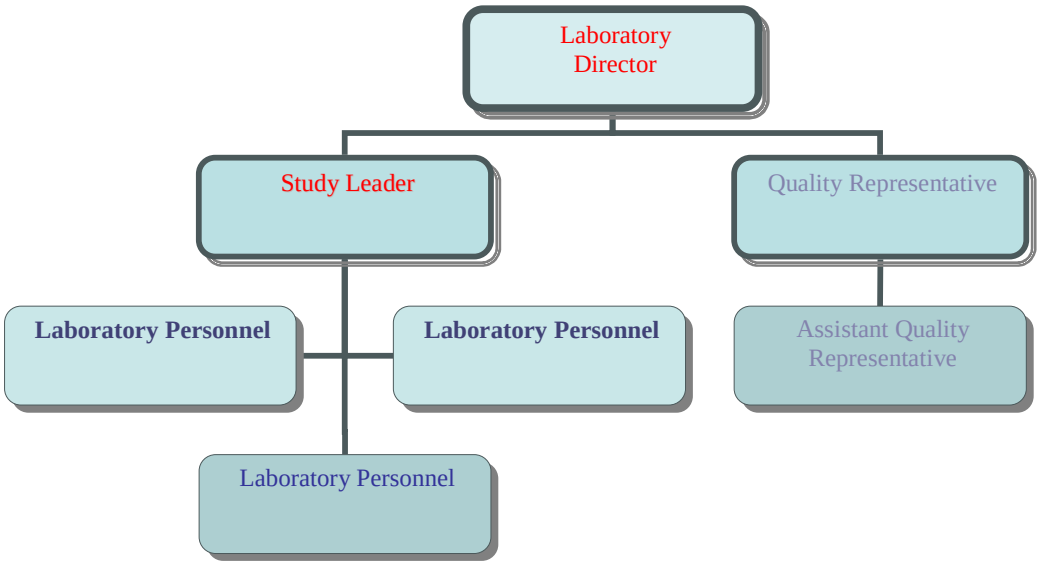


Figure B.1.Draft Organizational Chart for a Calibration Laboratory.

Note: Draft organization chart originated as a part of this project, for meeting the standard needs. These roles have responsibilities in the Section C, procedures part.

B.4 Management Requirements

B.4.1. Organization and Management

Quality Management System is established, implemented, and maintained by BME Institute's Board. BME Institute is not part of an organization performing activities other than testing and/or calibration; therefore, there is no potential conflict of interest amongst its personnel. The organization of BME Institute is illustrated in Figure 1.1. Laboratory Personnel responsibilities are described below:

Laboratory Director Responsibilities: He / She shall

- Ensure that qualified personnel, appropriate facilities, equipment, and materials are available.
- Ensure that a record of the qualifications, training, and experience and job description for each professional and technician individual is maintained.
- Ensure that personnel clearly understand the functions they are to perform and where necessary provide training for these functions.
- Ensure that for each timely individual study, a sufficient number of personnel are available for its timely and proper conduct.
- Ensure that health and safety precautions are applied according to national and/or international regulations.
- Ensure that appropriate Standard Operating Procedure is established and followed.
- Ensure that there is a Quality Management Program with designated personnel.
- Where appropriate, agree to the study plan in conjunction with the client.
- Ensure that amendments to the study plan are agreed upon and documented.
- Ensure that copies of all study plans and historical file of all Standard Operating Procedures is maintained.
- Ensure that for each study designate an individual with the appropriate qualifications, training and experience as the Study Leader before the study is initiated. If it is necessary to replace a Study Director during a study, this should be documented.

Study Leader Responsibilities: He / She shall

- Ensure that the procedures specified in the study plan are followed, and that authorization for any modification is obtained and documented together with the reasons
- Ensure that all data generated are fully documented and recorded.

- Ensure that the final report to indicate the acceptance of responsibility for the validity of the data and to confirm compliance with these Principles of Good Laboratory Practice is signed and dated.
- Ensure that after termination of the study, the study plan, the final report, raw data and supporting material are transferred to achieve.

Quality Representative Responsibilities: He/she shall

- Ensure that the Standard Operating Procedures are followed by periodic inspections of the test facility and/or arranging audits for the study in progress. Records of such procedures should be retained.
- Ensure that the coordination with internal departments and external organizations is in respect of the subjects included in the main functions.
- Ensure that an independent Quality System which includes a Quality Assurance Program for all operational departments is established.
- Ensure that compliance with and adequacy of procedures required to ensure safe operational practices is monitored.
- Ensure that any findings or poor standards are brought to the attention of person concerned via his manager, with a time scale for remedial action.
- Ensure that corrective and/or preventive actions for all non-conformities which are found during scheduled and unscheduled (random) audits are taken by reporting to the Laboratory Director and following those up.

Laboratory Personnel Responsibilities:

- Exercise health precautions to minimize risk to them and to ensure the integrity of the study.
- Correct problems after they occur.
- All employees engaged in making decisions affecting the quality of laboratory output shall undergo training programs designed to be commensurate with their positions, duties and responsibilities.

- The laboratory personnel shall use published analytical and test methods wherever available.
- All laboratory studies shall conform to all the provisions given in EN 17025.
- The laboratory personnel shall retain copies of all test and analytical reports in a manner and for a specified period for regulatory or accrediting bodies.

B.4.2 Management System

B.4.2.1 Policies and Procedures: The Quality Management System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

The purpose of our Quality Management System is to ensure that all services and products satisfy the customer's requirements and have been designed, manufactured, and delivered under controlled conditions. The effectiveness of the Quality Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality management system
- by regular management reviews of the suitability and effectiveness of the quality management system
- by analysis of potential and actual problems as shown by customer complaints and supplier and subcontractor assessments

Documentation includes:

- quality policy and quality objectives,
- this Laboratory Quality Manual,
- documented procedures required by all applicable standards and regulations,
- documents needed to ensure the effective planning, operation and management of its processes,

- records required by all applicable standards per EN 17025.

The Quality Management System applies to all activities of our Laboratory, and has been developed in accordance with EN ISO 17025. The Quality System is fully documented and structured in 3 levels:

Level 1: Quality Manual

Level 2: Operating Procedures,

Level 3: Test protocols, validation reports, calibration reports, test reports, records, forms, etc

B.4.2.2 Quality Policy Statement: The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement and reviewed during management review. The Quality Policy Statement is issued under the authority of the Laboratory Director on the effective date.

Sample Quality Policy Statement:

a) Management commitment to good professional practice and quality of services provided to the customer: Tests and calibrations are always carried out in accordance with stated standardized methods and customers' requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected. Excellence in the workplace is promoted by providing all employees with the knowledge, training, and tools necessary to allow for the completion of accurate and timely work.

b) Standards of service include:

- Customer Satisfaction
- Accurate
- Timely

c) Purpose of management system related to quality: to manage our business by meeting the needs of our customers.

d) Personnel: familiarize them with quality documentation and implement the policies and procedures in their work.

e) Management is committed to complying with ISO 17025 and ISO 9001 international standards and to continually improve the effectiveness of the

management system: the objective of this Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system. Additional objectives include:

- to establish the level of the laboratory's performance
- to make test method changes to improve performance
- to participate in proficiency testing or quality evaluation programs with peer laboratories
- to ensure that all personnel are trained to a level of familiarity with the quality management system appropriate to the individual's degree of responsibility
- to improve and validate laboratory methodologies by participation in method validation collaborative tests
- to establish and report on quality savings

B.4.2.3 Commitment to the Management System: Institute Board is committed to the development and implementation of the management system and continually improving its effectiveness.

B.4.2.4 Communication of Requirements: BME Institute Board communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

In general, the underlying message in all oral and written management communications involves meeting the aforementioned requirements. Meeting customer requirements ensures that ongoing business relationships secure the contracts that keep everyone employed. Meeting statutory and regulatory requirements ensures that laboratory operations will not be disrupted and the organization can continue to meet customer needs.

B.4.2.5. Quality manual: This quality manual developed and used by Biomedical Calibration Laboratory for purpose including, but not limited to the following

- communicating the quality policy procedures and requirements,
- describing and implementing an effective quality system,

- providing improved control of practices and facilitating assurance activities,
- providing the documented bases for auditing the quality system,
- providing the continuity of quality system and its requirements during changing circumstances,
- training personnel in the quality system requirements and methods of compliance,
- presenting the quality system for external purposes, such as demonstrating compliance with EN 17025,
- demonstrating compliance of the quality system with quality requirements in contractual situations.

Preparation of Quality Manual: Quality Representative is responsible for compilation of the Laboratory Quality Manual and ensuring its compliance with the requirements of Biomedical Calibration Laboratory and EN 17025.

Distribution of the Quality Manual: Each distributed copy of the Laboratory Manual shall be assigned a Copy Number that shall be displayed on the front cover in ink. The original copy shall retain in the hard disk. The uncontrolled distribution can be performed, in case uncontrolled stamp is on the copy.

B.4.2.6 Technical Management and the Quality Representative: The roles and responsibilities for technical management and the Quality Representative are outlined in section B.4.1.

Technical management ensures that section B.5 of this manual is implemented and maintained. The Quality Representative ensures that section B.4 of this manual is implemented and maintained.

B. 4.2.7 Maintenance: BME Institute Board ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

B. 4.3. Management of documents:

Quality system Documentation is the most effective way of implementation of quality system, established. Biomedical Calibration Laboratory documentation system shall ensure the approval of the documents by competent personnel, distribution of the documents and identification of the documents.

Document management system is described in detail in PR 01 Procedure for Document Control System. All documents issued as a part of quality system are reviewed by the Quality Representative and approved by the related manager. The details of the document control, review and approval responsibilities are given in Procedure for Document Control. In case there is no way for the employee to reach the software system, controlled copies are distributed. In case of distribution of the new version of the document, old revisions are taken and disposed by the employee, responsible for the distribution. Only the copies with the controlled stamp and the documents in the Computer program are the current version. All documents are reviewed in two years intervals for the currency and operation. Document revision periods for the documents are identified in the document itself. All Quality System documents of Biomedical Calibration Laboratory include

- document name,
- document number,
- document revision number,
- document effective date,
- page number,
- total page,
- issuing authority.

Changes to documents and review of the documents are performed by the same function. The person revising the document or reviewing the document shall have the experience and/or knowledge in the field of document application and has the authority to reach document revision history.

All changes in the documents are written with underline and a short description of the changes is given in the revision history part. It is forbidden to change the laboratory documents in the Laboratory Documentation system by hand. All revised documents' old

revisions are archived in computer for 11 years.

B 4.4 Review of requests, tenders and contacts:

To attain the purpose of providing services to the clients with promptness, efficiency and quality, requests from the clients has been reviewed and different tenders for each test method has been prepared. Before commencing the test, full approval of the related Study Leader and the client should be consent. Requests, tenders and contracts shall be clear for both clients and laboratory and evaluated for method applicability. Biomedical Calibration Laboratory prepares different tenders of services to its clients, attending to their specific requirements. In addition to these tenders, the laboratory applies a procedure for the review of requests from clients, before performing the tests and analysis to the specified items. In any case the laboratory assures that the clients' requirements and the test methods to be used are adequate, defined, communicated and understood by the responsible person who will perform the test.

Related Study Leader involved and Laboratory Director shall review the client request and evaluate the actual capability of the laboratory and the necessary resources to accomplish it according to the Procedure for the review of requests from the client. If there are differences between the request and the tender, these shall be solved with the client before the analytical work commences. For the tests contracted for the long term and tests performed within Biomedical Calibration, requests and tenders shall not be evaluated for each test. Unless any change is mentioned, the tests shall be performed as agreed by the contract signed between the client and the Laboratory.

Review of requests, tenders and contracts shall include the tests performed by the subcontractors. The primary responsibility of the review shall belong to Biomedical Calibration Laboratory. In case of any deviation from the contact, this deviation shall be informed to the client. If there is any need for a change in the contract, review of contract procedure shall be reconsidered and change shall be communicated with all related parties.

B 4.5. Subcontracting of tests and calibration:

Biomedical Calibration Laboratory may use suppliers to perform tests that are within, or outside Biomedical Calibration Laboratory scope of test capabilities. Suppliers of test services shall be selected within the accredited Laboratories as per ISO 17025 or have an ISO 17025 management system that has been successfully audited by Biomedical Calibration Laboratory All subcontractors quality performance shall continuously

evaluated by Biomedical Calibration Laboratory. In case having a subcontractor for a particular test, this information shall be communicated with the customer in the tender.

Biomedical Calibration Laboratory has all the responsibility for the tests performed by a subcontractor except in case where the client or a regulatory authority specifies which subcontractor is to be used. All technical communication related with the tests, subcontracting should be performed by the Study Leaders. All other aspects of communication are the responsibility of Laboratory Director. Continuous evaluation of the subcontractors is the responsibility of related Study Leader and Quality Representative. Subcontracting of Test and Calibration studies are performed as per PR 02, Procedure for Procurement.

Biomedical Calibration Laboratory is supported by Biomedical Calibration Laboratory support team. For the calibrations that cannot be performed by Calibration unit, subcontractors shall be used. All subcontractors for test and calibration services shall be evaluated and the results of this evaluation shall be kept by Laboratory Quality Assurance Unit. All subcontractors approved by Biomedical Calibration Laboratory are listed in List for Approved Suppliers.

B 4.6. Purchasing Services and Supplies:

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due consideration to the quality, statutory obligations. A list of approved suppliers and sub-contractors is maintained in related published supplier list of the Authorities.

Purchasing Services and Suppliers are performed as per PR 02, Procedure for Procurement. All suppliers of Biomedical Calibration Laboratory shall be evaluated and Approved Suppliers are given in he annex of this instruction. The consumable material/equipment came in laboratory shall be waited in the quarantine area until accept decision is taken. After the control, accepted consumable material/equipment shall be taken use. All laboratory equipment receiving by the Laboratory shall be pre-checked by the related Study Leader. This pre-check covers the normal operating conditions of the equipment. Purchasing records (contracts, technical drawings) and control records and documents shall be filed by the Laboratory according to date and/or report number and kept for 6 years.

B 4.7 Service to the Client:

Biomedical Calibration Laboratory has the policy of client satisfaction. Clients' requests are fully determined; client service is conducted and evaluated efficiently. Communications and feedbacks are important. Confidentiality is ensured and operations are traced. Quality Representative is responsible for the application of the methods for gathering feedback from the clients and reporting the results to Laboratory Director.

If requested, Clients should obey the Laboratory safety rules while participating. Related Study Leader shall describe the safety rules to the client's representative not to risk the people performing the test, test result and client representative. Clients shall audit Laboratory Quality System and/or the test requested. This audit shall be conducted a date agreed by the client and the Laboratory Director.

Biomedical Calibration Laboratory shall perform the tests for number of samples agreed in the contract. Samples not tested shall be sent back to the client or disposed as agreed in the contract. Samples tested and appropriate for further tests shall be send back to the clients, if requested. Laboratory Director shall communicate any delay or deviation in the test with the client. Information related with the client can only be communicated to the third party after the approval of the client. Special test methods, developed for a specific client shall not be used for other clients unless the approval is taken. Feedback from the client report prepared by the Quality Representative is an important tool for continuous improvement. This information shall be communicated routinely with the Laboratory Director and evaluated in Management Review Meeting.

B 4.8. Complaints:

Biomedical Calibration Laboratory operations are based on customer focus. Complaints, received from the customer shall be recorded, evaluated and necessary corrective actions shall be taken. Results of the evaluation and the corrective action shall be communicated to the customer.

Complaints are proceeding in conformity with PR 03 Procedure for Handling Customer Compliant. Laboratory Director is responsible for communicating the customer complaint to Quality Representative. Laboratory Director shall send the customer complaints, received to Quality Representative. Quality Representative is responsible for

recording the complaint and sending the nonconformity report to Related Study Leader. For the communication with the clients, all studies performed shall be reported to Laboratory Director and related data shall be filed.

B. 4.9. Control of Non-conforming Testing and/or Calibration Work:

The test nonconformities performed by Biomedical Calibration Laboratory, shall be recorded and analyzed. Laboratory Director is responsible for communicating the nonconformity with the client. Control of nonconforming test and calibration is performed by PR 04 Procedure for Handling Nonconformities. Nonconformity shall be recorded and delivered to Related Study Leader. Laboratory Study Leaders shall decide about the nonconformity or potential nonconformity. If the nonconformity is observed for the ongoing test, and if the nonconformity can be solved in the system and does not effect the test result, the nonconformity shall be solved and there is no need for the client notification. If the nonconformity is for the ongoing test and affects the result or the time of the test, related client shall be informed about the nonconformity.

The test reports shall be collected from the client if the nonconformity observed after the completion of the test report. Tests shall be repeated under conditions that nonconformity does not exist.

B 4.10. Improvement:

Laboratory continually improve the effectiveness of the QMS through the use of quality policy, quality objectives, internal audit reports, corrective and preventive actions and Management Review meetings. Our Institute determines, collects and analyses appropriate data to demonstrate the effective and suitability of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.

B 4.11. Corrective Action:

The definition of "corrective action" is “action to eliminate the cause of a detected nonconformity.” Corrective action cannot be taken without first making a determination of the cause of nonconformity.

Corrective Actions shall be initiated based on the following reasons. However, for any reason, not indicated below shall be the source of Corrective action

- test non-conformance,
- quality management system deficiencies,
- customer complaint,
- nonconformities observed in statistical analysis,
- audits,
- management review meeting.

Our laboratory use many methods and tools available to an organization for determining the cause of a nonconformity, from simple brainstorming to more complex, systematic problem solving techniques (e.g. root cause analysis, fish-bone diagrams, “five whys", etc). Nonconformities observed are processed as per Procedure for Nonconformity Control. At the end of nonconformity handling, if its is decided to proceed with Corrective Action, the 8-D steps shall be applied for the nonconformity and described in PR 05 Procedure for Corrective Action. Additionally, we ensure that the corrective action taken does not itself create further problems relating to product quality or to implementation of the QMS.

B 4.12. Preventive Action:

The definition of preventive action is “action to eliminate the cause of a potential nonconformity or other undesirable potential situation”. BME Institute determines potential nonconformities and their causes. Besides, BME Institute determines what action is required, and how it is implemented, records of the results of the actions taken and review of the preventive actions taken.

Typical data analysis includes:

- alarms to provide early warning of approaching "out-of-control" operating conditions.
- monitoring of customer perception, by either formal or informal feedback systems.
- evaluation of nonconformities that have occurred in similar circumstances, but for other products, processes, or other parts of the organization, or even in other organizations.

Preventive Actions applied in Biomedical Calibration Laboratory shall be conducted as per

PR 06 Procedure for Preventive Action. Changes applied for the preventive actions shall be proceeding in conformity with PR 07 Procedure for Change Management Procedure.

B 4.13. Control of Records:

The minimum quality element, which record control system, applied is given below.

- analytical and testing reports,
- laboratory notebooks,
- validation reports,
- vendor and internal audit reports,
- calibration and preventive maintenance records,
- purchasing records,
- technical document change requests,
- corrective/preventive action records,
- management review records.

The control of records in Biomedical Calibration Laboratory shall be performed in conformity with PR 08 Procedure for Control of Records. The quality records, which are originated and maintained as hard copies, shall be retained for a period of 11 years in laboratory files. After a period of 11 years, they will be reviewed for disposition by the Quality Representative. Those not discarded shall be transferred to PDF format, computer files and retained for an additional determined time by the Quality Representative. Records on the software shall be kept for six years. After a period of six years, they will be reviewed for disposition by the Quality Representative. For these documents, new retrieval period shall be determined by the Quality Representative. Technical Records include all the raw data and final reports. The examples for the technical records are given below. There may be other records evaluated as technical records, not listed below:

- forms,
- contracts,
- work sheets and books,
- work books,
- control graphs,
- internal and outside test reports,

- calibration certificates,
- customer notes,
- information about feedback,
- validation test reports.

Technical records shall be kept for six years unless specified by the client. The records shall kept minimum for six years, although client requires less than six years. The mistakes occur in records shall be corrected by the personnel performing the mistake by crossing out the mistake and writing the correct information, putting the sign and date.

B 4.14. Internal Audits:

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Policy. A comprehensive Audit Program is compiled at least a year in advance however, should particular needs be identified, and the frequency of audit may be increased at the discretion of the Quality Representative.

Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited within that Company. Non-conformance observed is brought to the attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification. The internal audit schedule, covering each division at least once in each year shall be prepared with the minimum information and described in PR 09 Procedure for Internal Audits. Unplanned audits can be performed based on Corrective action or change control implementation. In unplanned audits all the documentation and rules for the planned audit shall be used.

Nonconformities determined during the audits shall be handled as per Procedure for Nonconformity Control. Corrective Action shall be initiated for all the nonconformities that will affect the test results. If the nonconformity determined effect the result of the test conducted or the test still in process, the deviation shall be informed to the client. All corrective actions initiated after the audit shall be proceed as per Procedure for Corrective and Preventive action. All records for the audit, corrective actions and follow-up audit shall be prepared and stored as per Procedure for Control of Records.

B 4.15. Management review:

Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

- to establish that the quality management system is achieving the expected results and meeting the requirements, continuing to conform to the standard, continuing to satisfy the customer needs and expectations, and functioning in accordance with the established operating procedures.
- to expose irregularities or defects in the system, identify weaknesses and evaluate possible improvements.
- to review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the company.
- to review any complaints received, identify the cause and recommend corrective action if required.
- to review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.
- to review the reports of nonconforming items and trend information to identify possible improvements.

Our Meeting agenda contains the following reports and we;

- examine audit results
- examine product conformity data.
- examine opportunities to improve.
- examine feedback from customers.
- examine process performance information.
- examine corrective and preventive actions.
- examine changes that might affect your system.
- examine previous quality management reviews

At the end of the Management Review meeting our meeting report shall include these requirements determined below:

- generate actions to improve your quality system.
- generate actions to improve your products.
- generate actions to address resource needs.

B 5 Technical Requirements

B 5.1 Technical Requirements – General:

Our Institute recognizes that many factors determine the correctness and reliability of the tests and/or calibration performed by a laboratory. These factors include contributions from: human factors (5.2), accommodation and environmental conditions (5.3), test and calibration methods and method validation (5.4), equipment (5.5), measurement traceability (5.6), and handling of test and calibration items (5.8).

The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. Our Institute takes into account these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

B 5.2 Personnel:

Our Institute’s management ensures the competency of all who operate specific equipment, who perform tests and/or calibrations, evaluate results and sign test reports and calibration certificates. All of Our laboratory personnel have an engineering background and graduated from our Institute’s Master program so they all have biomedical engineer diploma and research assistants of our Institute. When using staff that is undergoing training, adequate and appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required.

B 5.3 Accommodations and Environmental Conditions

Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and accommodation shall design to facilitate correct performance of the tests and/or calibrations. Design and consistency of Laboratory accommodation and environmental conditions, which will facilitate the performance of the tests and/or calibration is the responsibility of Laboratory Director. All Laboratory personnel are responsible for performing their jobs without adversely effecting Laboratory accommodation and environmental conditions. Monitorization of environmental conditions is performed by periodically. In case of out of limit values, Procedure for Nonconformity Control shall be applied and testing in the area, where out of limit environmental conditions observed shall be stopped. For the test and/or calibration performed outside the Laboratory facility, environmental conditions descried in the related test instruction shall be recorded in the related test report. Tests shall only be performed in the areas, having suitable environmental conditions described in the test instruction.

B 5.4 Test and Calibration Methods and Method Validation

B 5.4.1. General: In general sampling, handling, transport, storage, and preparation of items to be tested are performed in accordance with this manual. Detail sampling procedures are given in related test instructions.

The uncertainties for the tests performed are calculated as per Procedure for Measurement Uncertainty. The management of Laboratory equipment is performed as per PR 10, Procedure for Equipment Management. Laboratory has instructions for use and operation of all relevant equipment, and on the handling and preparation of items for testing and calibration, where the absence of such instructions could jeopardize the results of tests and/or calibration, prepared as per Procedure for Document Control. All instructions, standards, manuals and reference data relevant to the work of laboratory are kept up to date and readily available to the personnel as per Procedure for Record Control.

Deviations from the test and calibration methods shall be evaluated and communicated with the client as per Procedure for Handling Nonconformities. Deviations form the test and / or calibration methods can only be accepted, if the deviation has been documented, technically justified, authorized and accepted by the client.

B 5.4.2. Selection of Methods: Test and calibration methods, including methods of sampling, used in our Laboratory are identified as suitable for client requirements. Before the initiation of these test methods, communication with the client shall be performed by Laboratory Director. The test shall be initiated after the approval of the client.

Test methods used in our Laboratory is generated on the basis of National and International standards. Additional description of standard test method application is given in the test instructions, prepared as per Procedure for Document Control

B 5.4.3. Laboratory-Developed Methods: The introduction of test and calibration methods developed by Laboratory for its own use are planned and applied by qualified personnel equipped with adequate resources as per PR 12 Procedure for Test Method Validation. Plans for the method development are updated as development proceeds as per Procedure for Test Method Validation and communicated to the personnel involved.

B 5.4.4. Non-Standard Methods: When it is necessary to use methods not covered by standard methods, these methods shall be communicated with the clients. The validation of these non-standard laboratory Methods shall be performed in conformity with PR 12, Procedure for Method Validation.

Laboratory has test instructions, prepared in conformity with Procedure for Document Control for both standard and laboratory developed test methods. The minimum information given in these instructions are given below:

- appropriate identification,
- scope,
- description of the type of item to be tested or calibrated,
- parameters or quantities and ranges to be determined,
- apparatus and equipment, including technical performance requirements,
- reference standards and reference materials required,
- environmental conditions required,

Description of procedure including

- Affixing of identification marks, handling, transporting, storing, preparation of items,
- Checks to be made before the work is started,

- Checks that the equipment is working properly and, when required calibration and adjustment of the equipment before each use,
- The method of recording the observations and results,
- Any safety measures to be observed,
- Criteria and/or requirements for approval/rejection,
- Data to be recorded and method of analysis and presentation,
- The uncertainty or the procedure for estimating uncertainty.

B 5.4.5 Validation of methods: All standard and non-standard test methods and procedures are validated to ensure that such methods and procedures are fit for their intended use and are relevant to the requirements of EN 17025 Clause 5.4.5. The validation of these laboratory Methods shall be performed in conformity with PR 12, Procedure for Method Validation. The results of such validation are recorded together with the procedure utilized and any other relevant information. The record states whether the method or procedure is fit for the intended use. The changes on the validated non-standard methods shall be controlled as per Procedure for Change Control. If required the method shall be revalidated. The selection of validation procedures can also be justified on a cost-benefit basis as long as the fitness-for-purpose is maintained. Different validation methods can be characterized as “scientific” or “comparative”

B 5.4.6 Uncertainty of Results: The uncertainty of calibration results are calculated and documented in accordance with the requirements of EN 17025 Clause 5.4.6. The PR 11, Procedure for Uncertainty of Measurement is applied to all in house calibrations/tests. PR 11 procedure is applied for estimating uncertainty of measurement, except when the test methods preclude such rigorous calculations. In certain cases it is not possible to undertake metrological and statistical valid estimations of uncertainty of measurement. In these cases the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope, and makes use of previous experience and validation data. The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- Requirements of the test method,
- requirements of the client,
- the existence of narrow limits on which decisions on conformance to a specification are based.

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the test method and reporting instructions (see section 5.10).

B 5.4.7. Control of Data: Calculations, data transfers and systematic checks for the data generated in our Laboratory are performed as per Procedure for Control of Records. The analysis of data is performed by Study Leader.

B 5.5 Equipment:

Top Management is responsible for maintaining necessary Financial Resources for the sufficient equipment and calibration, verification, training and maintenance etc. of that equipment. Laboratory Director shall inform the Top Management for the status of the equipment and necessary resources.

Our Laboratory is furnished with all items of sampling, measurement and test equipment, capable of accuracy required and complies with specifications relevant to test and calibration and required for the correct performance of the tests and calibrations. The equipment in our Laboratory is listed in Annex 1 Equipment List for Biomedical Calibration Laboratory. In order to guarantee the appropriate operation of Laboratory Equipment in conformity with the specifications, all Laboratory Equipment shall be controlled or calibrated before put in operation. In case the equipment goes outside the direct control of our Laboratory, equipment shall be controlled or calibrated again for appropriateness to the specifications. Only approved equipment shall be reused in the Laboratory.

Equipment that has been subjected to overloading or mishandling gives suspect results or has been shown to be defective or outside specified limits shall be labelled as

“Out of Use”. Those devices shall not be used until the problem is solved or the device is proving to be performing correct measurement.

B 5.6 Measurement Traceability:

In order to maintain the safety of measuring system performed in our Laboratory, all measurement equipment shall be calibrated as per predetermined schedule to maintain measurement traceability.

Calibration of all equipment used for tests and/or calibration, (including equipment for subsidiary measurements having significant effect on the accuracy or the validity of the result of the test) shall be performed as per PR14, Procedure for Laboratory Equipment Calibration before use. All equipments are calibrated as indicated in Procedure for Procurement and routinely on a Schedule basis.

In Procedure for Equipment Management, a method for the selection, usage, calibration, control and maintenance of the test and calibration equipment is described. The general criteria for Measurement Traceability are described in PR 15, Procedure for Measurement Traceability.

The measurement traceability of the measurement equipment calibrated in our Laboratory or by a third party laboratory is given in Procedure for Measurement traceability. The traceability of measurement is maintained by the traceability of its own measurement standards and measuring instruments to the SI by means of unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI unit of measurement. The link to SI units is achieved by reference to national measurement standard described in Procedure for Measurement Traceability.

The calibration certificates given by our Laboratory contains the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. For the proof of the traceability of calibration results, accredited as per ISO 17025, the certificate bearing an accreditation body logo is sufficient.

Certificates for the calibrations performed in our Laboratory are detailed in 5.10. In these certificates, there is identification of metrological specification or the number of metrological specification.

The calibration frequency of reference, primary, transfer and working standards and materials, are described in Procedure for Laboratory Equipment Calibration. The reference standards and materials are labelled as reference and kept in special storage places in the Laboratory. Reference standards are used for calibration purpose only and not for any other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are calibrated before and after any adjustments. In our Laboratory all reference materials are maintained with the certificate. These materials are traceable with the SI units. The list of reference materials, their traceability properties and control frequencies are described in the list.

B 5.7 Sampling

The sampling in Biomedical Engineering Institute's Laboratory shall be performed inconformity with the scientific knowledge after the approval of the client. Sampling plans based on the feature of the test is conforming to related standards, and statistical methods.

Based on the agreements, if our Laboratory is required to take the samples, sampling is performed in conformity with related harmonized standards requirements. Sampling plans are described in the related test instruction. The scientific resource, which the sampling is based on, is given in the related test instruction. While sampling, attention is given to the factors to be controlled to ensure the validity of the test and calibration results. The test forms prepared as per 5.10 Test Reports Clause of this manual covers sampling procedure, the identification of the sampler, if relevant environmental conditions, sampling locations, and statistics the sampling procedures are based upon.

B 5.8 Handling and Transportation of Test and/or Calibration Items

Institute's Laboratory shall apply all measures for handling of test and calibration articles described by the client, related standards to secure the result and the record of test performed and applications or complimentary tests after the test. Agreements signed respectively with client and our Institute's Management covers the transportation, receipt, handling, protection, storage, retention and/or disposal test and calibration items, including all provisions necessary to protect the interest of our Laboratory and the client. For identification, all samples covered the sample number; number shall be present on the

sample. In order to prevent confusion in the samples, all physical measures like labelling and sample storage area are used. The procedures for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation is described in related test instructions.

Our Institute's Laboratory shall only accept samples that appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Because of our Laboratory has no facility to store and maintain the security of the test samples or portion of the test samples, no accept to secure the items or portions of the items in the contracts or agreements signed with the client

B 5.9 Assuring the Quality of Test and Calibration Results

Laboratory takes all the safety measures for assuring the quality of test and calibration standards maintain a system for the continuity of these measures and monitor and analyze the system built.

All data related with the tests shall be recorded to analyze with the statistical methods, appropriate for the type and volume of the work undertaken described in this procedure also. The monitoring includes, but not limited to the following:

- regular use of certified reference materials and/or international quality control using secondary reference standard.
- participation of interlaboratory comparison or proficiency testing programs.
- replicate tests or calibrations using the same or different methods.
- retesting or recalibration of retained items.
- correlation of results of different characteristics of items.

B 5.10 Reporting the Results

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test or calibration methods. The results are normally reported in a test report or a calibration certificate and include all the information

requested by the client and necessary for the interpretation of the test or calibration results, and all information required by the method used.

Each test certificate shall include minimum the following information;

- test report title,
- unique identification of the test certificate, (serial no)
- the name and address of the client,
- the name and address of the laboratory and the location where the tests were carried out in different from the address of the laboratory,
- on each page and identification in order to ensure that the page is recognized as a part of the certificate and a clear identification of the end of the certificate,
- identification of the method used,
- a description of, the condition of, and unambiguous of the item tested,
- the date of receipt of the test item where this is a critical to the validity and application of the results and the date of performance of the test,
- reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results,
- the test or results with, where appropriate, the units of measurement,
- the name, function and signature of person authorizing the test certificate.
- where relevant, a statement to the effect that the results relate only to the items tested or calibrated,
- page number and total number of pages.
- it is recommended that laboratories include a statement specifying that the certificate shall not be reproduced except in full, without written approval of the laboratory.

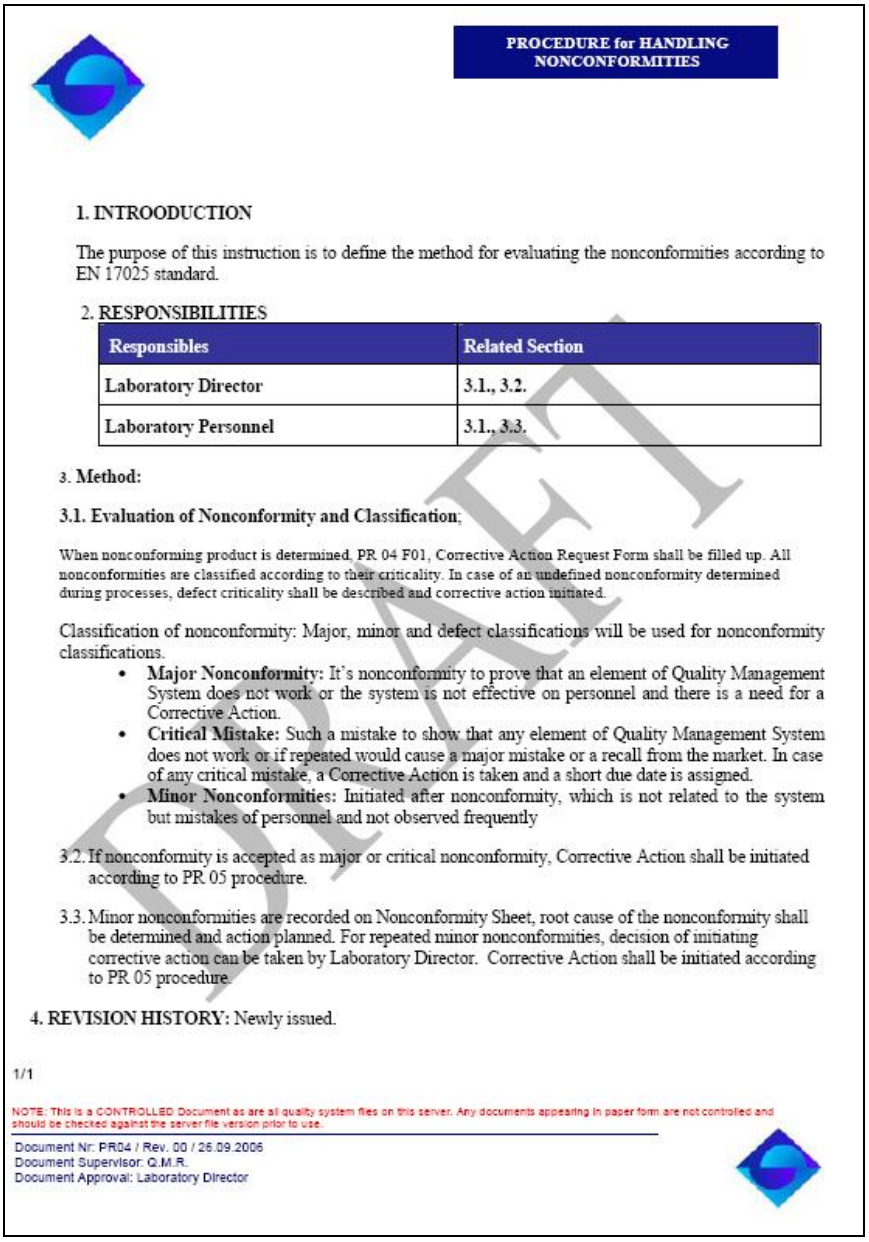
Generally conformity/nonconformity is not interpreted in the test certificate. Upon client request certificates shall include the following for the interpretation of test results.

- the date of sampling,
- unambiguous identification of the substance, material or product sampled,
- the location of sampling, including any diagrams, sketches or photographs,

- a reference to the sampling plan and procedures used.
- details of any environmental conditions during sampling that may affect interpretation of the test results.
- any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications.
- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when a client requires, or when the uncertainty affects compliance to a specification limit.
- where appropriate and needed, opinions and interpretations,
- additional information that may be required by specific methods or clients.
- when opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. opinions and interpretations shall be clearly marked as such in a test report.
- opinions and interpretations included in a test certificate may comprise, but not be limited to, the following,
- an opinion on the statement of compliance /non-compliance of the results with requirements.
- fulfilment of contractual requirements,
- recommendations on how to use the results,
- guidance to be used for improvements.

APPENDIX C. DOCUMENTED PROCEDURES HANDBOOK

Note: Procedure format of all required procedures of our Laboratory is described in PR 05 Document Control Procedure. Normally, our laboratory procedures should have logo, revision date, revision number, Title, Document Responsibilities, etc. Here, I only can add the text part or application part of all procedures for using Master Thesis official format. However, I added a PDF document for illustrating Procedure "ready to approval" form in section above.



PROCEDURE for HANDLING NONCONFORMITIES

1. INTROODUCTION

The purpose of this instruction is to define the method for evaluating the nonconformities according to EN 17025 standard.

2. RESPONSIBILITIES

Responsibles	Related Section
Laboratory Director	3.1., 3.2.
Laboratory Personnel	3.1., 3.3.

3. Method:

3.1. Evaluation of Nonconformity and Classification;

When nonconforming product is determined, PR 04 F01, Corrective Action Request Form shall be filled up. All nonconformities are classified according to their criticality. In case of an undefined nonconformity determined during processes, defect criticality shall be described and corrective action initiated.

Classification of nonconformity: Major, minor and defect classifications will be used for nonconformity classifications.

- **Major Nonconformity:** It's nonconformity to prove that an element of Quality Management System does not work or the system is not effective on personnel and there is a need for a Corrective Action.
- **Critical Mistake:** Such a mistake to show that any element of Quality Management System does not work or if repeated would cause a major mistake or a recall from the market. In case of any critical mistake, a Corrective Action is taken and a short due date is assigned.
- **Minor Nonconformities:** Initiated after nonconformity, which is not related to the system but mistakes of personnel and not observed frequently

3.2. If nonconformity is accepted as major or critical nonconformity, Corrective Action shall be initiated according to PR 05 procedure.

3.3. Minor nonconformities are recorded on Nonconformity Sheet, root cause of the nonconformity shall be determined and action planned. For repeated minor nonconformities, decision of initiating corrective action can be taken by Laboratory Director. Corrective Action shall be initiated according to PR 05 procedure.

4. REVISION HISTORY: Newly issued.

1/1

NOTE: This is a CONTROLLED Document as are all quality system files on this server. Any documents appearing in paper form are not controlled and should be checked against the server file version prior to use.

Document Nr: PR04 / Rev. 00 / 26.09.2006
Document Supervisor: Q.M.R.
Document Approval: Laboratory Director

Figure C.1. Sample Procedure for showing original procedure layout – Draft procedure for Handling Nonconformities

C.1. PR 01 Draft Procedure for Document Control

Scope: The purpose of this procedure is to describe methods for identification, preparation, control, approval, implementation, revision, storage, review, and disposition of all documents included in BME Quality Assurance System.

Responsibilities For New Document Issuing and Changes: Each personnel responsible for preparing correct and complete documents and reflecting correct and complete changes into document.

Laboratory Director ensures that changes are made under change control system and all cross references and other related documents are revised.

Document Review Period: All documents shall be reviewed at two year-intervals for revision need by individuals who prepare, control, and approve documents. If revision is not needed document shall be still effective and no re-distribution is made.

Document Revision: BME personnel have the right/responsibility to request for a revision or cancelling of a document that may conflict with the QMS or that may have an adverse effect on the QMS.

Document revision/cancelling requests shall be processed by Study Leader or Laboratory personnel with filling Document Revision / Cancelling Form. This form shall include the reason for revision. Request is delivered to Quality Representative. Laboratory Director approves or rejects request by controlling or ensuring the request. Cross-references shall be established between related documents and are indicated as appendix and related documents. Controlling and approving cross-references is the responsibility of the individual whom preparing the document. Revision history shall be monitored by revision requests. Procedures and instruction shall be in Times New Roman Format and the font shall be 11. Quality manual text character font will be Arial 11 font. Revised parts in documents shall be underlined. When a new revision is made, underlined parts shall be changed into default format and new changes shall be indicated by underlining.

Duplicating and Recording Forms; Quality Representative gives the print-out of the new revision original with limiting note section of the procedure. If anyone takes a print-out, as an uncontrolled copy, the red “Note” section will be on the copies.

Numbering of Procedures and instructions; ensure that documents remain legible and easily identifiable, in frame of a basic coding system, documents are grouped and for each group, a code number is assigned.

Document Issuing: All documents in scope of BME Quality Management System shall be kept in a master list showing old and new coding system, revision state and distribution list. New documents shall be distributed after the personnel who have prepared the document give training. Documents shall never be distributed without training. Such training shall be documented by Document Distribution List. Study Leaders receiving controlled documents shall be responsible for working in conformity with these SOP'S and following up the actions. Originals of duplicated documents shall be preserved in Quality Management. Study Leader follows up implementation of the new procedure. The Study Leader is responsible for the implementation and follow-up of the issued documents. S/he gives training to his/her personnel or requests from Laboratory Director with regard to the new procedure.

Document Achieving: Documents shall be achieved in conformity with Procedure for Quality Records.

C.2. PR 02 Draft Procedure for Procurement

Scope: The purpose of this quality system procedure is to describe the method for procurement process according to ISO 17025.

Purchasing of Equipment: Supplier agreement shall be prepared including University and Institute requirements. Deviation of equipments that will be used for measurement purpose should be smaller than allowed deviation value. If not the equipment is sent back. The consumable material/equipment came in laboratory shall be waited in the quarantine area until accept decision is taken. After the control, accepted consumable material/equipment shall be taken use. All suppliers of Biomedical Calibration Laboratory shall be evaluated and Approved Suppliers are taken into list.

All laboratory equipment receiving by the Laboratory shall be pre-checked by the related Study Leader. This pre-check covers the normal operating conditions of the equipment.

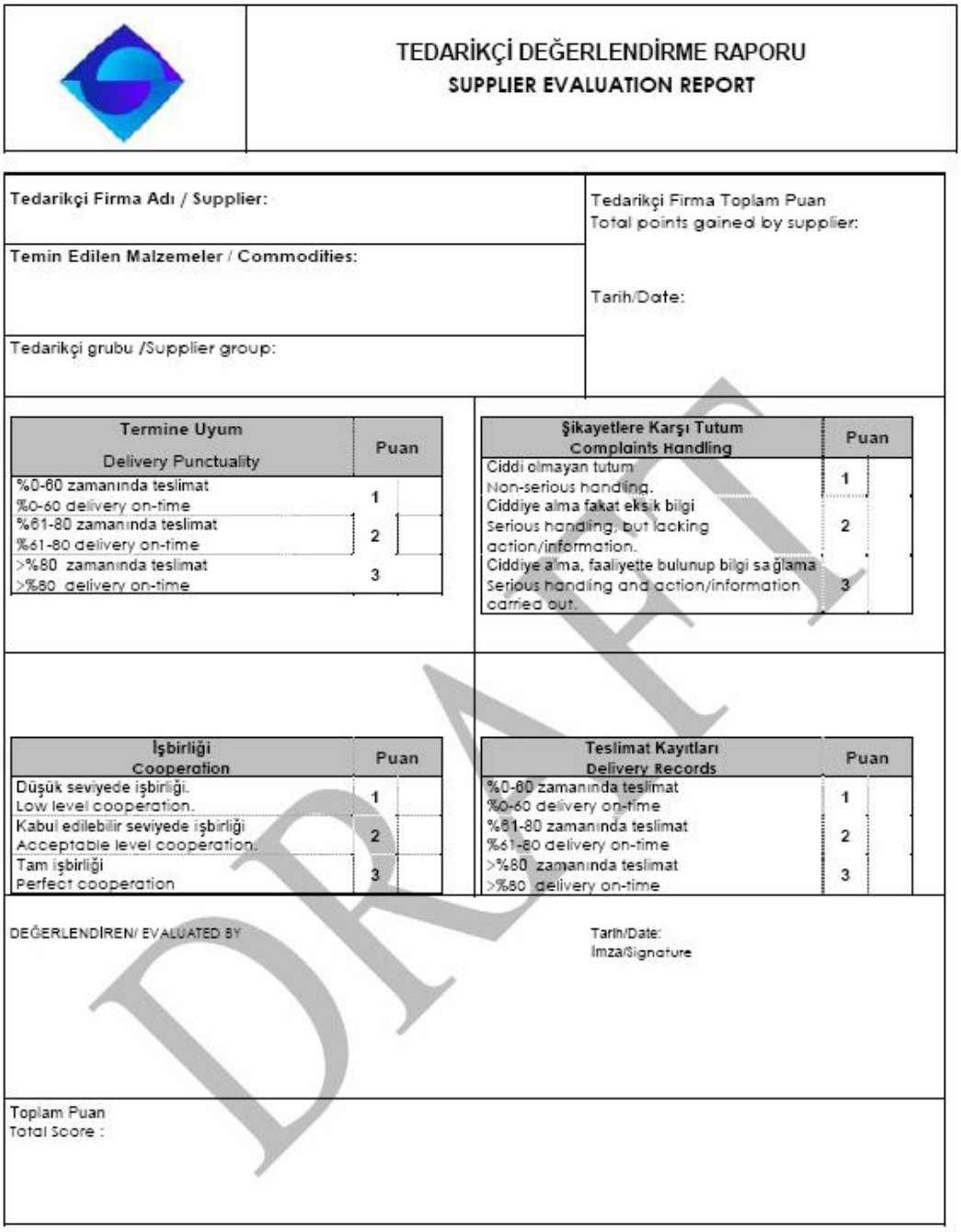
Purchasing records (contracts, technical drawings) and control records and

documents shall be filed by the Laboratory according to date and/or report number and kept for 6 years.

Product purchasing specification having a definite coding system shall be attached to the supplier agreement. Each product specification shall include;

- product name,
- specification no,
- supplier ref no,
- product physical features,

Evaluation of the Subcontractors, Suppliers**:** All suppliers of Biomedical Calibration Laboratory shall be evaluated and Approved Suppliers are taken into list. Evaluation of the supplies can be performed by checklists or site visits or supplier audits.



TEDARİKÇİ DEĞERLENDİRME RAPORU
SUPPLIER EVALUATION REPORT

Tedarikçi Firma Adı / Supplier:

Tedarikçi Firma Toplam Puan
Total points gained by supplier:

Temin Edilen Malzemeler / Commodities:

Tarih/Date:

Tedarikçi grubu /Supplier group:

Termine Uyum Delivery Punctuality	Puan	
%0-60 zamanında teslimat %0-60 delivery on-time	1	
%61-80 zamanında teslimat %61-80 delivery on-time	2	
>%80 zamanında teslimat >%80 delivery on-time	3	

Şikayetlere Karşı Tutum Complaints Handling	Puan	
Ciddi olmayan tutum Non-serious handling.	1	
Ciddiye alma fakat eksik bilgi Serious handling, but lacking action/information.	2	
Ciddiye alma, faaliyette bulunup bilgi sağlama Serious handling and action/information carried out.	3	

İşbirliği Cooperation	Puan	
Düşük seviyede işbirliği. Low level cooperation.	1	
Kabul edilebilir seviyede işbirliği Acceptable level cooperation.	2	
Tam işbirliği Perfect cooperation	3	

Teslimat Kayıtları Delivery Records	Puan	
%0-60 zamanında teslimat %0-60 delivery on-time	1	
%61-80 zamanında teslimat %61-80 delivery on-time	2	
>%80 zamanında teslimat >%80 delivery on-time	3	

DEĞERLENDİREN/ EVALUATED BY

Tarih/Date:
İmza/Signature

Toplam Puan
Total Score :

PR02.F01.00

Figure C2. Sample form for Supplier Evaluation Report

C.3. PR 03 Draft Procedure for Handling Customer Complaints

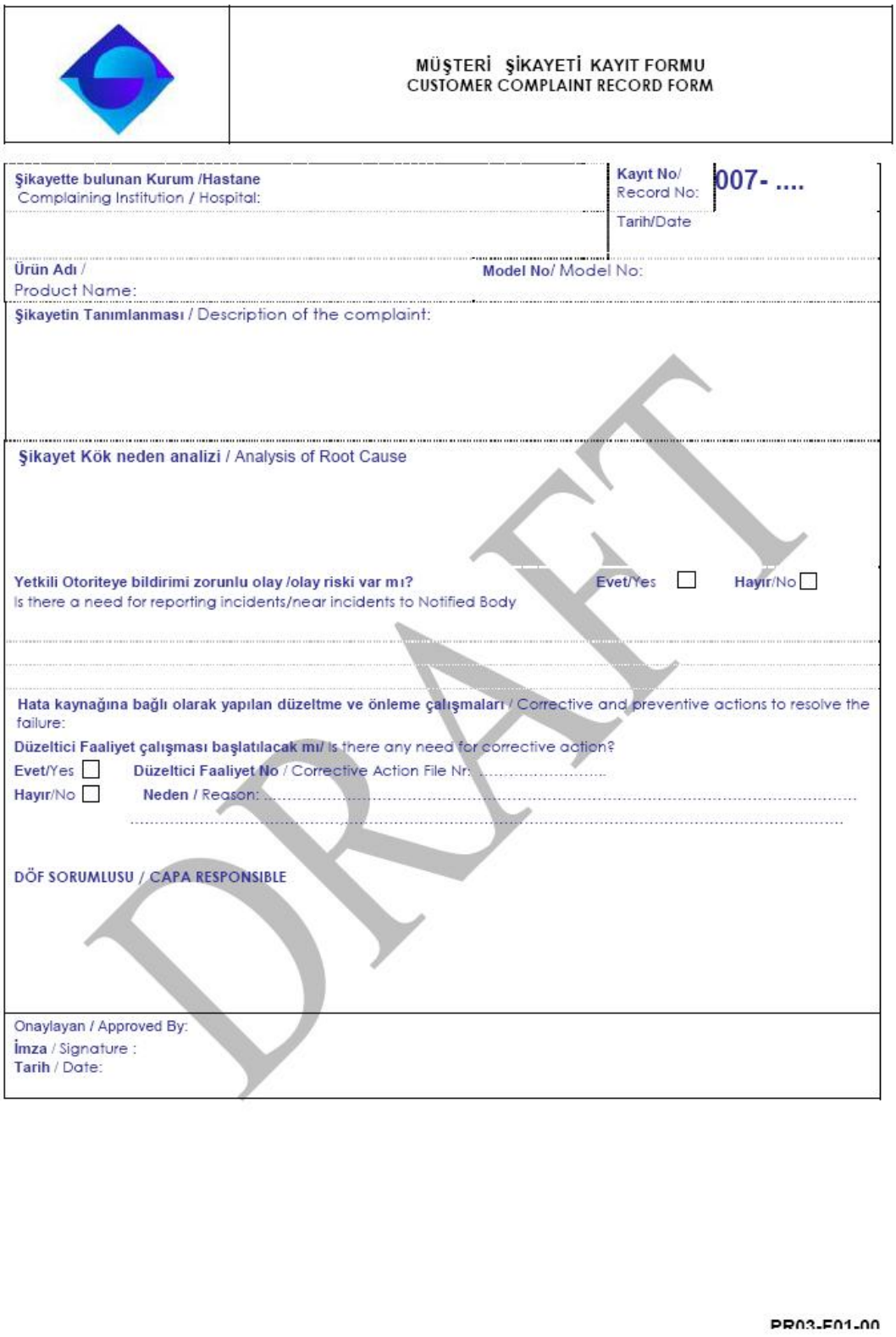
Scope of the procedure: This procedure defines methods to establish an organized route of handling customer complaints and to maintain an orderly and complete complaint file to meet requirements of the regulations in effect.

Evaluation of customer complaints: Coordinator inspects and investigates or assigns a responsible to investigate the complaint. H/she records the related investigations, the reason and the source of the complaint and his/her comment on related form. Laboratory Director follows up the investigations.

Coordinator or responsible assigned by the coordinator are required to perform the investigations on time. The date is registered on form and follow-up action taken, as necessary, to assure completion. All completed investigations will be returned to the Coordinator for closing the file, preparing the required final incident report and to coordinate any outside action that may be necessary, such as an explanation to the customer, or decide to recall the product.

Closure of the Complaints: Coordinator delivers the form to Laboratory Director when h/she ends investigations and fills the form. Laboratory Director inspects and determines the criticality of defect and records on customer complaint investigation form with his/her comment. In case the related studies are not adequate, Laboratory Director may demand for further studies.

Laboratory Director signs and then informs the sponsor by faxing or e-mailing. Laboratory Director follows up the complaints on a quarterly basis in QA performance report. H/she may initiate the corrective and preventive action as a base on statistical analysis. All customer complaints for each product group shall be recorded on form annually, and kept in the technical files of each product.



MÜŞTERİ ŞİKAYETİ KAYIT FORMU
CUSTOMER COMPLAINT RECORD FORM

Şikayette bulunan Kurum /Hastane
Complaining Institution / Hospital:

Kayıt No/
Record No: 007- ....

Tarih/Date

Ürün Adı /
Product Name:

Model No/ Model No:

Şikayetin Tanımlanması / Description of the complaint:

Şikayet Kök neden analizi / Analysis of Root Cause

Yetkili Otoriteye bildirimi zorunlu olay /olay riski var mı?
Is there a need for reporting incidents/near incidents to Notified Body

Evet/Yes ☐ Hayır/No ☐

Hata kaynağına bağlı olarak yapılan düzeltme ve önleme çalışmaları / Corrective and preventive actions to resolve the failure:

Düzeltici Faaliyet çalışması başlatılacak mı/ Is there any need for corrective action?

Evet/Yes ☐ **Düzeltici Faaliyet No** / Corrective Action File Nr: .....

Hayır/No ☐ **Neden** / Reason: .....

.....

DÖF SORUMLUSU / CAPA RESPONSIBLE

Onaylayan / Approved By:
İmza / Signature :
Tarih / Date:

DRAFT

PR03-F01-00

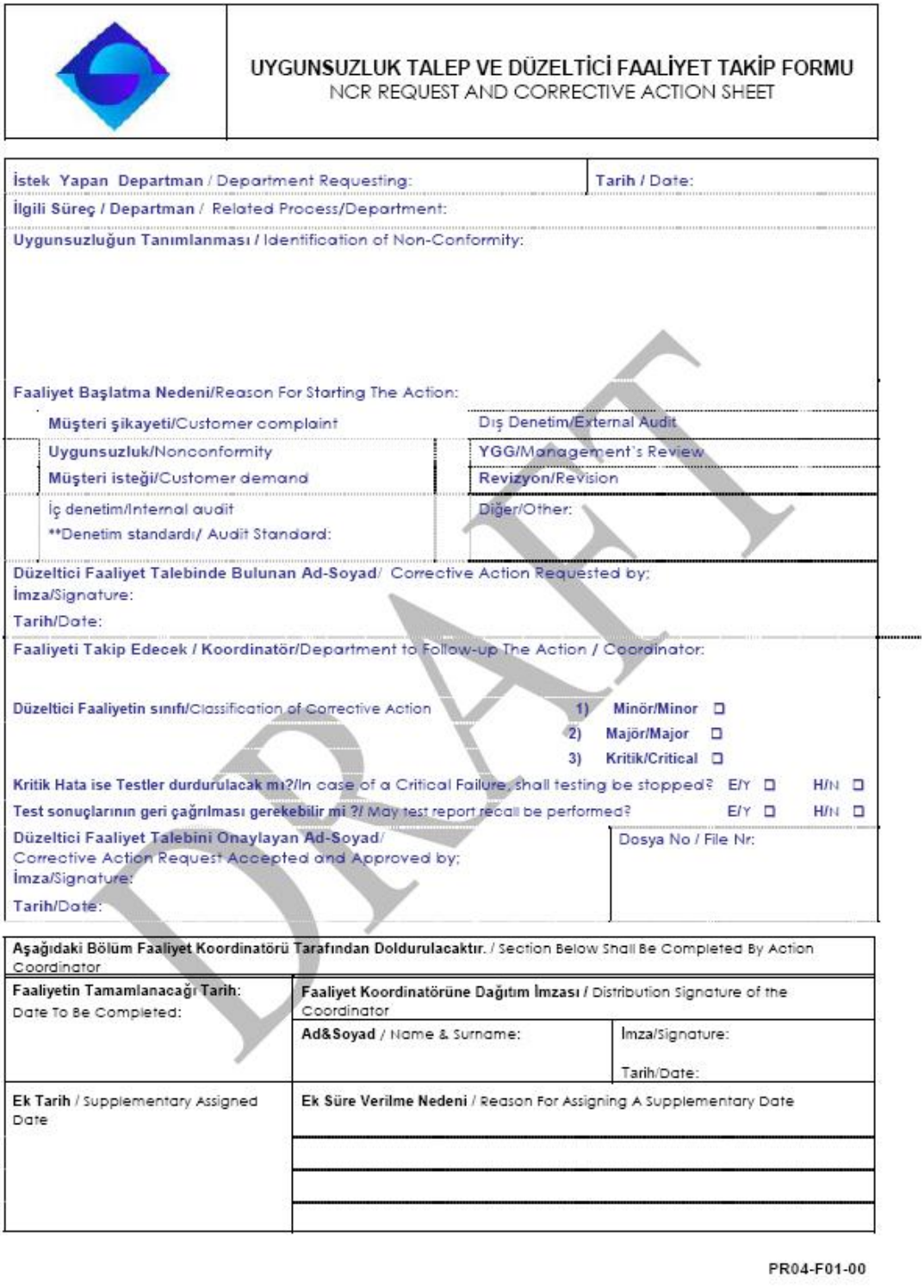
Figure C3. Sample form for Customer Complaint Evaluation Report

C.4. PR 04 Draft Procedure for Handling Nonconformities

Scope: The purpose of this instruction is to define the method for evaluating the nonconformities according to EN 17025 standard.

Evaluation of Nonconformity and Classification**;** When nonconforming product is determined, Nonconformity sheet shall be filled up. Nonconformities are determined according to their criticality. In case of an undefined nonconformity determined during processes, defect criticality shall be described and corrective action initiated. Classification of nonconformity: Major, minor and defect classifications will be used for nonconformity classifications.

- **Major Nonconformity:** It's nonconformity to prove that an element of Quality Management System does not work or the system is not effective on personnel and there is a need for a Corrective Action.
- **Critical Mistake:** Such a mistake to show that any element of Quality Management System does not work or if repeated would cause a major mistake or a recall from the market. In case of any critical mistake, a Corrective Action is taken and a short due date is assigned.
- **Minor Nonconformities:** Initiated after nonconformity, which is not related to the system but mistakes of personnel and not observed frequently



UYGUNSUZLUK TALEP VE DÜZELTİCİ FAALİYET TAKİP FORMU
NCR REQUEST AND CORRECTIVE ACTION SHEET

İstek Yapan Departman / Department Requesting: | **Tarih** / Date:

İlgili Süreç / Departman / Related Process/Department:

Uygunsuzluğun Tanımlanması / Identification of Non-Conformity:

Faaliyet Başlatma Nedeni/Reason For Starting The Action:

Müşteri şikayeti/Customer complaint	Dış Denetim/External Audit
Uygunsuzluk/Nonconformity	YGG/Management's Review
Müşteri isteği/Customer demand	Revizyon/Revision
İç denetim/Internal audit	Diğer/Other:
**Denetim standardı/ Audit Standard:	

Düzeltici Faaliyet Talebinde Bulunan Ad-Soyad/ Corrective Action Requested by:
İmza/Signature:
Tarih/Date:

Faaliyeti Takip Edecek / Koordinatör/Department to Follow-up The Action / Coordinator:

Düzeltici Faaliyetin sınıfı/Classification of Corrective Action
1) **Minör/Minor** ☐
2) **Majör/Major** ☐
3) **Kritik/Critical** ☐

Kritik Hata ise Testler durdurulacak mı?/In case of a Critical Failure, shall testing be stopped? E/Y ☐ H/N ☐
Test sonuçlarının geri çağrılması gerekebilir mi ?/ May test report recall be performed? E/Y ☐ H/N ☐

Düzeltici Faaliyet Talebini Onaylayan Ad-Soyad/
Corrective Action Request Accepted and Approved by;
İmza/Signature:
Tarih/Date:

Dosya No / File Nr:

Aşağıdaki Bölüm Faaliyet Koordinatörü Tarafından Doldurulacaktır. / Section Below Shall Be Completed By Action Coordinator

Faaliyetin Tamamlanacağı Tarih: Date To Be Completed:	**Faaliyet Koordinatörüne Dağıtım İmzası** / Distribution Signature of the Coordinator	
	Ad&Soyad / Name & Surname:	İmza/Signature: Tarih/Date:
Ek Tarih / Supplementary Assigned Date	**Ek Süre Verilme Nedeni** / Reason For Assigning A Supplementary Date	

PR04-F01-00

Figure C4. Sample form for Nonconformity Request and Corrective Action Report

C.5. PR 05 Draft Procedure for Corrective Actions

Scope: The purpose of this procedure is to plan and execute the necessary Corrective Actions by evaluating the data derived from internal and external audits, customer complaints, statistical process controls, nonconforming product controls, literature, service reports, maintenance reports, scrap or rejected product reports.

Evaluation of Nonconformity and Classification: Internal or external audits, customer complaints, Management's Review, control of nonconforming product, FMECA analysis, published literature, service reports, maintenance reports, scrap or reject reports, concessions in production, reports from the marketing function, reports from personnel, returned product, solicited information on new or modified products, published reports of failures of similar products and warranty claims, failures in the system or processes.

- At the end of Internal and External Audits; Corrective Action is initiated at the end of audits in case of any major nonconformity or any minor problems requiring system improvement.
- A Corrective Action shall be initiated because of a customer complaint or a demand; Lab Director analyzes 3 months period performance reports and would initiate a Corrective Action on critical customer complaints stressing on the same product group.
- Management Review Meeting; During Management Review Meeting, Corrective Actions shall be started according to system, products, customer complaints or demands and changes that could affect the Quality Management System.
- Corrective Actions shall be started including the following reasons; published literature, service reports, maintenance reports, scrap or reject data, concessions in production, reports from the marketing function, returned product, solicited information on new or modified products, published reports of failures of similar products and warranty claims
- Action is initiated at the end of Nonconforming Product Control

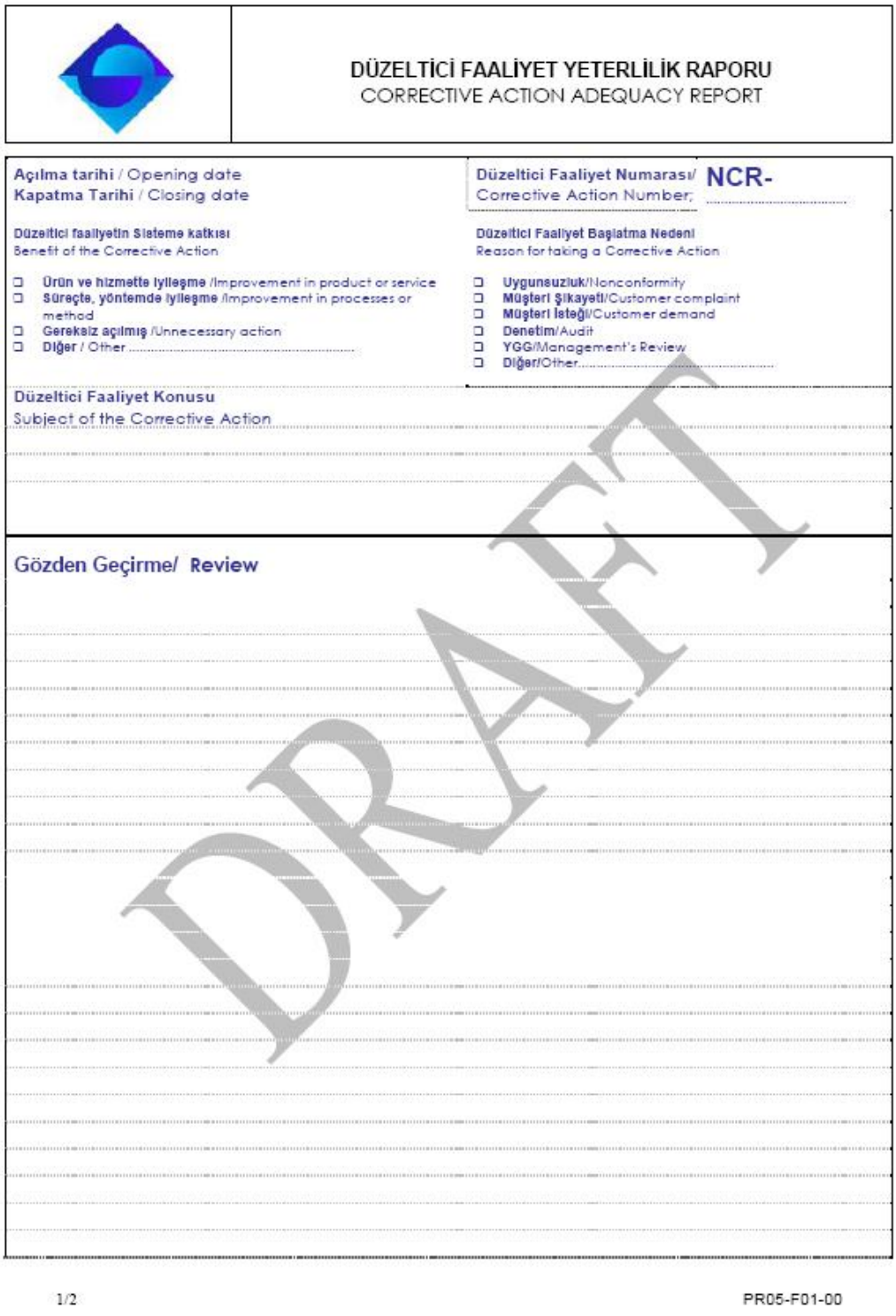
Corrective Action Process /Action Planning: When the Corrective Action request is accepted, action task is started in the mean time.

- Decision is given on an action plan.

- In one or two days, Related Study Leaders meet again in the mean time to review action plan for subjects that need urgent solutions.
- A coordinator who is capable of the subject is attained. Corrective Action Request form is given to coordinator in return of his/her signature.
- A due date is determined for completion of the action.
- Decisions taken in the meeting are communicated to related persons and non-attending staff via mail or in return of a distribution signature.

Documentation and Monitoring the Corrective Action**:** Related problems about prepared action plan are controlled by the Action Coordinator for monitoring. In each consecutive meeting, application of the plan and level of the progress from previous meeting is reviewed.

Review of the Corrective Action: Laboratory Director gives the decision for "Closing the Action" considering the tasks performed on Corrective Action shall prevent the recurrence of the problem. At the stage of "Closing the Action", Laboratory Director prepares an Adequacy Report for closing the action. If the Corrective Action cannot be completed at the assigned due date, a supplementary date is assigned and on the form, coordinator writes the reasons for supplementary date.



DÜZELTİCİ FAALİYET YETERLİLİK RAPORU
CORRECTIVE ACTION ADEQUACY REPORT

Açılma tarihi / Opening date
Kapatma Tarihi / Closing date

Düzeltici Faaliyet Numarası/ NCR-
Corrective Action Number;

Düzeltici faaliyetin Sisteme katkısı
Benefit of the Corrective Action

- ❑ **Ürün ve hizmette iyileşme** /Improvement in product or service
- ❑ **Süreçte, yöntemde iyileşme** /Improvement in processes or method
- ❑ **Gereksiz açılmış** /Unnecessary action
- ❑ **Diğer** / Other .....

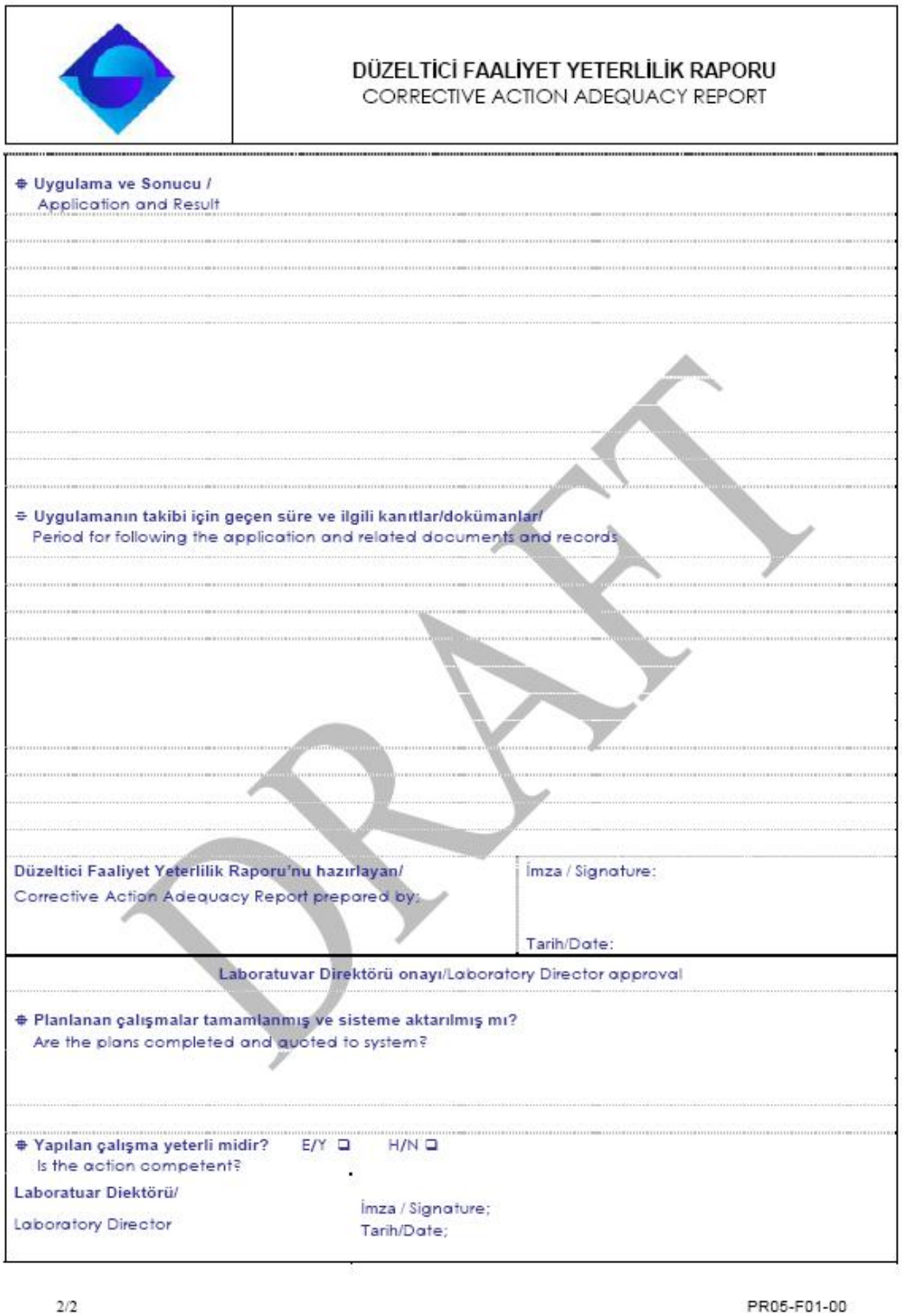
Düzeltici Faaliyet Başlatma Nedeni
Reason for taking a Corrective Action

- ❑ **Uygunsuzluk**/Nonconformity
- ❑ **Müşteri Şikayeti**/Customer complaint
- ❑ **Müşteri İsteği**/Customer demand
- ❑ **Denetim**/Audit
- ❑ YGG/Management's Review
- ❑ **Diğer**/Other.....

Düzeltici Faaliyet Konusu
Subject of the Corrective Action

Gözden Geçirme/ Review

Figure C5. Sample form for Corrective Action Adequacy Report - Continued



DÜZELTİCİ FAALİYET YETERLİLİK RAPORU
CORRECTIVE ACTION ADEQUACY REPORT

❖ Uygulama ve Sonucu /
Application and Result

❖ Uygulamanın takibi için geçen süre ve ilgili kanıtlar/dokümanlar/
Period for following the application and related documents and records

Düzeltici Faaliyet Yeterlilik Raporu'nu hazırlayan/
Corrective Action Adequacy Report prepared by:

İmza / Signature:

Tarih/Date:

Laboratuvar Direktörü onayı/Laboratory Director approval

❖ Planlanan çalışmalar tamamlanmış ve sisteme aktarılmış mı?
Are the plans completed and quoted to system?

❖ Yapılan çalışma yeterli midir? E/Y ❑ H/N ❑
Is the action competent?

Laboratuar Diektörü/
Laboratory Director

İmza / Signature;
Tarih/Date;

2/2

PR05-F01-00

Figure C5. Sample form for Corrective Action Adequacy Report

C.6. PR 06 Draft Procedure for Preventive Actions

Scope: The purpose of this procedure is to plan and perform Preventive Actions.

Evaluation of Preventive action and Classification;

- Preventive Action: Actions determined to eliminate the causes of potential nonconformities in order to prevent their occurrence.
- Major Preventive Action: Initiated as a potential nonconformity, showing accurate evidence that an element of Quality Management System is not working or lack of system exists.
- Minor Preventive Action: Initiated before a potential nonconformity occurs, which not related to the system but mistakes of personnel and not observed frequently.

Reasons for initiating a Preventive Action: Preventive Actions shall be started including the following reasons; published literature, service reports, maintenance reports, scrap or reject data, concessions in production, reports from the marketing function, returned product, solicited information on new or modified products, published reports of failures of similar products and warranty claims

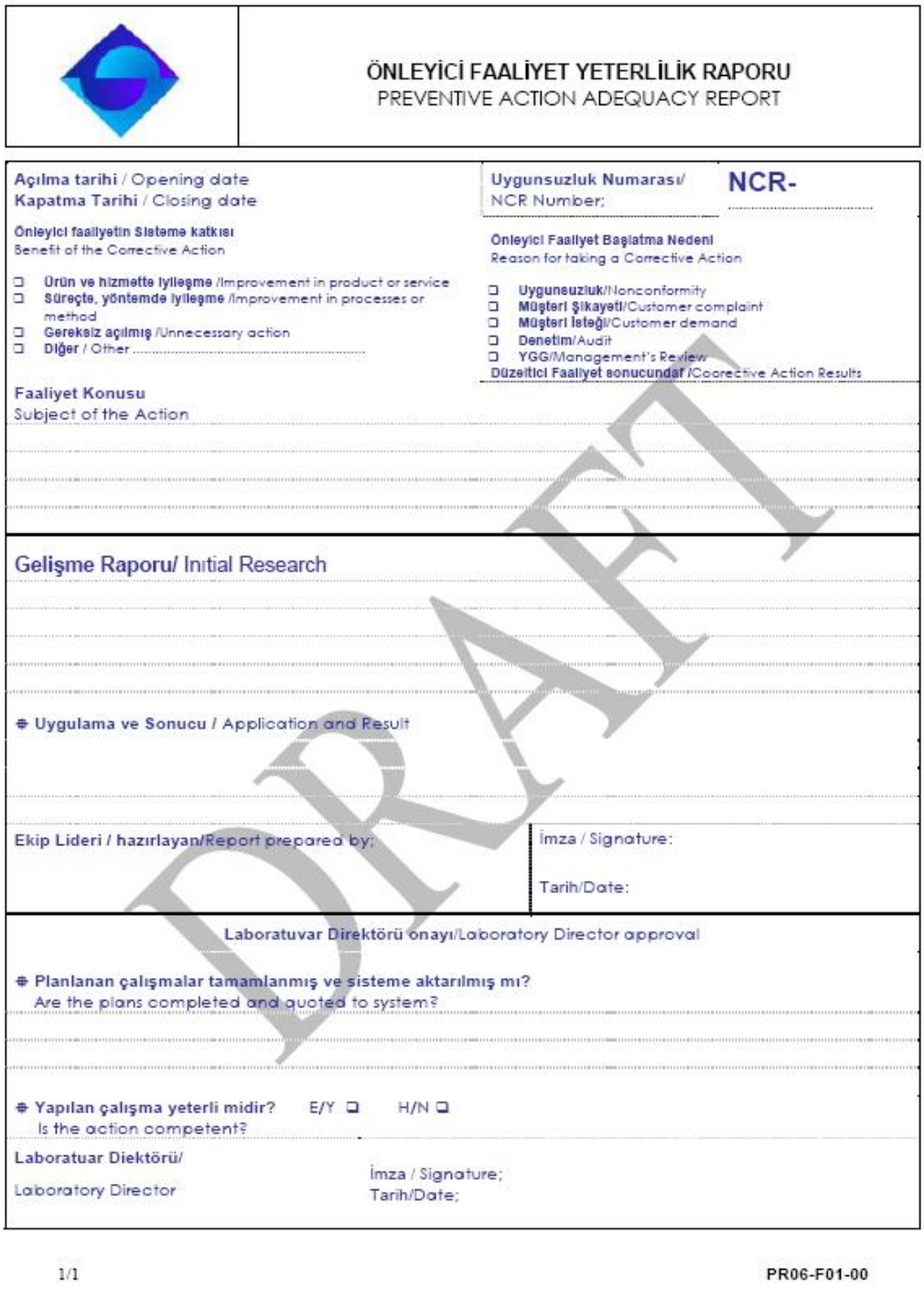
- As a result of statistical evaluations on nonconformities, customer complaints, failures, a Preventive Action shall be started at Management's Review Meeting.
- A Preventive Action shall be initiated because of a customer complaint or a demand
- Lab Director analyzes 3 months period performance reports and would initiate a Preventive Action on critical customer complaints stressing on the same product group.
- Management Review Meeting; During Management Review Meeting, Preventive Actions shall be started according to system, products, customer complaints or demands and changes that could affect the Quality Management System.
- Action may be initiated at the end of Nonconformity report.

Preventive Action Process - Action Planning: When the Preventive Action request is accepted, action task is started in the mean time.

- Decision is given on an action plan.
- In one or two days, Department Managers meet again in the mean time to review action plan for subjects that need urgent solutions.
- A coordinator who is capable of the subject is attained. Preventive Action Request form is given to coordinator in return of his/her signature.
- A due date is determined for completion of the action.
- Decisions taken in the meeting are communicated to related persons and non-attending staff via mail or in return of a distribution signature.

Documentation and Monitoring the Preventive Action: Related problems about prepared action plan are controlled by the Action Coordinator for monitoring. In each consecutive meeting, application of the plan and level of the progress from previous meeting is reviewed.

Review of the Preventive Action: Laboratory Director gives the decision for "Closing the Action" considering the tasks performed on Preventive Action shall prevent the recurrence of the problem. At the stage of "Closing the Action", Laboratory Director prepares an Adequacy Report for closing the action. If the Preventive Action cannot be completed at the assigned due date, a supplementary date is assigned and on the form, coordinator writes the reasons for supplementary date.



ÖNLEYİCİ FAALİYET YETERLİLİK RAPORU
PREVENTIVE ACTION ADEQUACY REPORT

Açılma tarihi / Opening date
Kapatma Tarihi / Closing date

Uygunsuzluk Numarası/ NCR Number: **NCR-**

Önleyici faaliyetin Sisteme katkısı
Benefit of the Corrective Action

- ❑ **Ürün ve hizmette iyileşme** /Improvement in product or service
- ❑ **Süreçte, yöntemde iyileşme** /Improvement in processes or method
- ❑ **Gereksiz açılmış** /Unnecessary action
- ❑ **Diğer** / Other .....

Önleyici Faaliyet Başlatma Nedeni
Reason for taking a Corrective Action

- ❑ **Uygunsuzluk**/Nonconformity
- ❑ **Müşteri Şikayeti**/Customer complaint
- ❑ **Müşteri İsteği**/Customer demand
- ❑ **Denetim**/Audit
- ❑ **YGG**/Management's Review

Düzeltici Faaliyet sonucundaf /Coorective Action Results

Faaliyet Konusu
Subject of the Action

Gelişme Raporu/ Initial Research

Uygulama ve Sonucu / Application and Result

Ekip Lideri / hazırlayan/Report prepared by:

İmza / Signature:

Tarih/Date:

Laboratuvar Direktörü onayı/Laboratory Director approval

Planlanan çalışmalar tamamlanmış ve sisteme aktarılmış mı?
Are the plans completed and quoted to system?

Yapılan çalışma yeterli midir? E/Y ❑ H/N ❑
Is the action competent?

Laboratuar Diektörü/
Laboratory Director

İmza / Signature;
Tarih/Date;

DRAFT

1/1 PR06-F01-00

Figure C6. Sample form for Preventive Action Adequacy Report

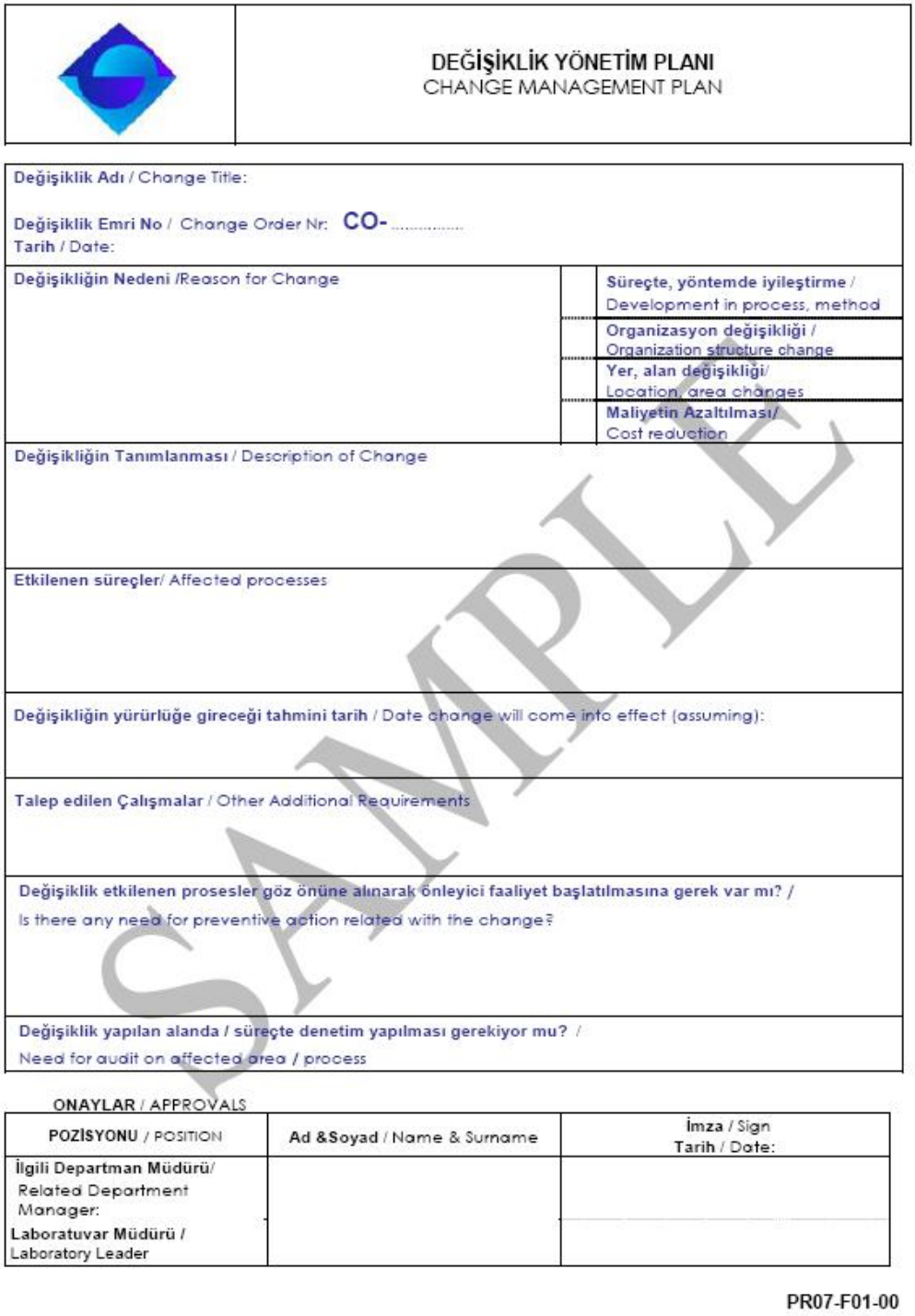
C.7. PR 07 Draft Procedure for Change Management

Scope: Purpose of this procedure is to define methods to control changes about Laboratory Quality Management System. This procedure covers changes, which may affect Quality System Management tasks; organization changes, appointments, changes related to production area, personnel changes.

Change request Evaluations**:** All types of engineering change recommendations of employees are delivered to Quality Representative with Change Recommendation Sheet. In case of acceptance of recommendation, change information is recorded on Change Log and numbering performed as shown below: All details of change described on Recommendation Sheet shall be transferred to Change Work Plan. Plan is distributed to all Board members for notification and work planning. For changes initiating from a process, Related Study Leaders are responsible from filling up the Change Requesting page of the Change Work Plan, and sent to Q. Representative. Quality Representative is responsible from notifying all related departments from the change, and provides to complete work plan with due date. Change meetings shall be held at least once a week for evaluating the change work plans of ongoing changes, commenting on new changes and recording additional studies (if required). Quality Representative is responsible from following the completion status of all issues on the Change Work Plan. Change Close-out Report is prepared by Quality Representative, and send for Laboratory Director approval. The effective date of change recorded on Change Log.

Minor changes: Any changes like spelling mistakes or any attempt to correct meaning integrity shall be put into practice with the approval Laboratory Director. Revision rules of documents are described in Document Control Procedure.

File Retention: Change documents are completed regarding the items determined on Change Study Plan. Item with all additional information and all control reports related to the change shall be filed in the Laboratory Director. Quality Representative is responsible for retaining all the documentation for every change initiated under the



DEĞİŞİKLİK YÖNETİM PLANI
CHANGE MANAGEMENT PLAN

Değişiklik Adı / Change Title:

Değişiklik Emri No / Change Order Nr: **CO-**.....
Tarih / Date:

Değişikliğin Nedeni /Reason for Change		
		Süreçte, yöntemde iyileştirme / Development in process, method
		Organizasyon değişikliği / Organization structure change
		Yer, alan değişikliği/ Location, area changes
		Maliyetin Azaltılması/ Cost reduction

Değişikliğin Tanımlanması / Description of Change

Etkilenen süreçler/ Affected processes

Değişikliğin yürürlüğe gireceği tahmini tarih / Date change will come into effect (assuming):

Talep edilen Çalışmalar / Other Additional Requirements

Değişiklik etkilenen prosesler göz önüne alınarak önleyici faaliyet başlatılmasına gerek var mı? /
Is there any need for preventive action related with the change?

Değişiklik yapılan alanda / süreçte denetim yapılması gerekiyor mu? /
Need for audit on affected area / process

ONAYLAR / APPROVALS

POZİSYONU / POSITION	**Ad &Soyad** / Name & Surname	**İmza** / Sign **Tarih** / Date:
İlgili Departman Müdürü/ Related Department Manager:		
Laboratuvar Müdürü / Laboratory Leader		

PR07-F01-00

Figure C75. Sample form for Change Management Report

C.8. PR 08 Draft Procedure for Control of Records

Scope: The purpose of the procedure is to describe the methods for identification, collection, indexing, filling, storage, maintenance, retrieval, retention time and disposition of quality records.

Rules for Archiving Quality Records: Each newly published form that is publicized by Quality Representative is added to Controlled Document Master List. Related personnel keep all quality records in file through their use. When it is time for archiving, prepared documents or materials are placed determined place in the archive.

Quality records shall be archived at least within the periods determined in Institute archives. Disposition of quality records shall be decided by taking into consideration all the regulatory standards. Approval shall be taken from Laboratory Director.

Retention of Documents: Study Leaders shall arrange documents or materials in boxes such that documents or materials shall be prevented from damages during their retention time. List shall be used for recording the type of the file, its number, and label of the material or documents boxed. Lists shall be kept in the related departments. On the archive box label, this information is recorded; Department abbreviation-year that documents belongs to and numerically increasing numbers, these numbers are reset each year. Box number, shelf code, contents, date interval is recorded to form, and box is placed to specified place according to recorded information.

KALİTE KAYITLARI ARŞİV İZLEME LİSTESİ
LIST OF ARCHIEVED RECORDS

Kutu No Box No	Tarih Aralığı Time Period	Raf Yeri Shelf Address	Dosya / Doküman Adı Name of File / Document	İmha Tarihi Date of Destructions

PR08-F01-00

Figure C8. Sample form for Archived Records

C.9. PR 09 Draft Procedure for Internal Audits

Scope: The purpose of this procedure is to specify the methods of internal auditing and to perform an internal audit providing information on the qualifications and effectiveness of EN/ISO 17025.

General: Auditor sends detailed audit plans and questionnaire to related departments at least two weeks before the audit. If the department to be audited believes that auditor will be biased, they have right to object. Quality Representative can change the auditor by evaluating this objection. Auditor can not be selected from the department under the same organizational chart. The Quality Auditor prepares/updates an audit checklist for systematic examination of the area to be audited, informs the Manager of the department being audited at the start of the audit, and reviews observations with the Department Manager. Section Responsible – Study Leaders: Responsible for preparing for the audits in conformity with questionnaires and assisting the auditors and initiate corrective, preventive action and allow auditors to terminate procedure on time.

Preparation before auditing: Quality Representative prepares annual audit plans in December. This plan requires all departments / processes/systems included in the Quality Management System to be examined at least once a year and specify the lead audit. Number of audits may depend on the frequency of corrective actions and changes in the organizational structure. Annual audit plan is sent to related department managers/process owners. Unplanned audits can be performed cause of outputs of design controls, corrective actions, customer complaint results, change control studies or departmental audits for improving their effectiveness of their processes. Documentation and rules of internal audit process shall be used

Audit Questionnaires and Audit Sampling Plans: During audit, questions shall have a basis of ISO 17025: 2005 related sections and have a relationship between the scopes of the processes. Besides, question list contains audit-sampling plans for audit investigation activities. Auditor should execute the audit taken into consideration of these sampling plans.

Audit Process: Internal audit starts with a pre-audit conference. The following items should be considered in an opening meeting, as appropriate:

- introduction of participants and their roles,

- confirmation of the audit objectives, scope and criteria,
- confirmation of timetables,
- methods and procedures to be used to conduct the audit,
- confirmation of formal communication links between the audit team and the auditor,
- confirmation that resources needed by the audit team are available,
- confirmation of work safety, emergency and security procedures for the audit team,
- method of reporting including any grading of non-conformities.

Auditing: Audit begins and proceeds in the direction of questionnaires. However, questionnaires do not limit, but direct the auditing. Questions not included in the list can also be asked. Results of previous audit can be checked.

Audit Evidence: Document and report numbers and document names can be added to notes, which are clear, readable and taken during the audit, and called as audit evidence. Audit evidences shall be legible; report includes not only the inappropriate situations but also the appropriate ones. Audit is concluded with a wrap-up meeting with the department management to discuss all findings that were identified during the audit. All responses to the findings will be documented on Meeting Report and reviewed before issuing the audit report. Department manager is asked to determine the period of completing findings. Auditors document these actions and their deadlines

Preparation of Audit Evaluation Technical Report: The Auditor reviews the data gathered, verifies important details, and writes an audit report. Technical report includes any positive, negative, improvement potential points about the department; also minor, major nonconformities and critical mistakes are implied. For major nonconformities and critical mistakes, corrective actions shall be started. A search for the causes of minor nonconformities is performed and if necessary, Quality Representative starts a preventive action.

- Minor Nonconformity: It’s a nonconformity, which has not been met in previous audit or nonconformity about filing, keeping the documents, nonconformity related to mistakes of workers but not the system, not repeated often, and no need corrective action

- Major Nonconformities: It's nonconformity to prove that an element of QAS does not work or the system is not effective on personnel, and need for a corrective action
- Critical Nonconformity: Such a mistake to show that any element of QAS does not work or if repeated would cause a major mistake or to cause a recall from the market. In case of any critical mistake, a corrective action shall be started and a very short term is given to complete the corrective action.

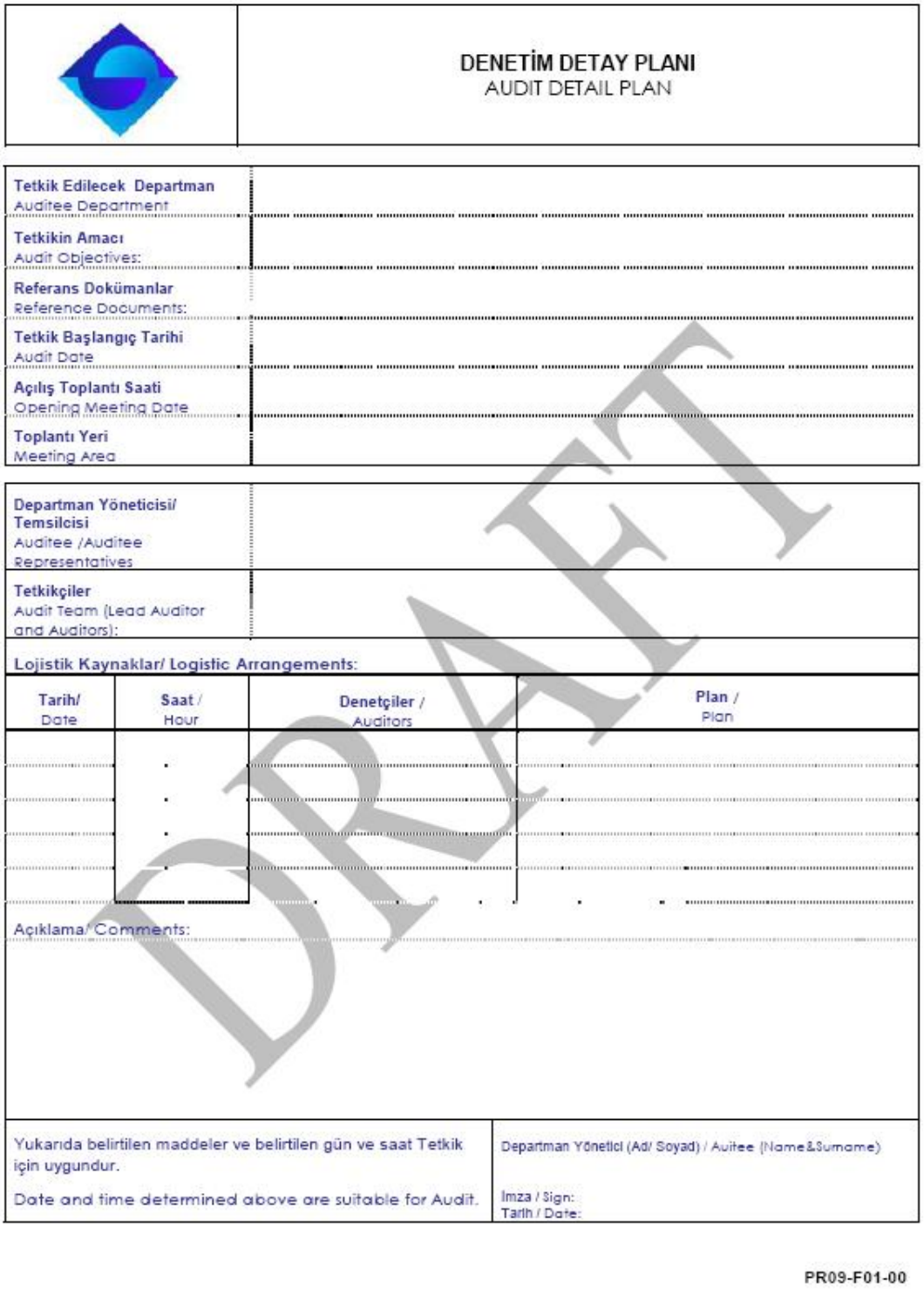
Major issues, critical non-conformances, trends and gross non-conformances are to be reported Laboratory Director on Management Review Meeting. If a re-audit is required, approximately eight weeks from completion date of the initial assessment, the auditor shall perform a reassessment of the department. Results of the original assessment, the results of the re-assessment (if appropriate), execution and completion of the corrective actions, and any response received from responsible individuals will be listed in the Audit Close-Up Report.

Scoring the Audit Findings**:** In the Audit Questionnaires, there is a scoring section. The scoring is performed as follows:

NA Not applicable
0 No action (Critical Error)
1 Not fulfilled (Critical error, or major fault)
2 Partially fulfilled (minor fault)
3 Fulfilled

If any nonconformity is evaluated as a major or a critical mistake, then a corrective action is started and activities for solving the problem shall be monitored.
The appropriate Management staff member shall be responsible for developing a schedule for correcting deficiencies cited in the audit report and submitting same within five working days to Laboratory Director.

Included in the correction schedule shall be the responsible individual, and the date when corrective action will be completed. The Laboratory Director shall act as arbiter, if necessary, to judge validity of the deficiency, responsible individual and reasonable date to complete the corrective action. The audit log file shall include a copy of current audits, list of areas to be audited during the 12-month period, and list of areas audited to date.



DENETİM DETAY PLANI
AUDIT DETAIL PLAN

Tetkik Edilecek Departman Auditee Department	
Tetkikin Amacı Audit Objectives:	
Referans Dokümanlar Reference Documents:	
Tetkik Başlangıç Tarihi Audit Date	
Açılış Toplantı Saati Opening Meeting Date	
Toplantı Yeri Meeting Area	

Departman Yöneticisi/ Temsilcisi Auditee /Auditee Representatives	
Tetkikçiler Audit Team (Lead Auditor and Auditors):	

Lojistik Kaynaklar/ Logistic Arrangements:

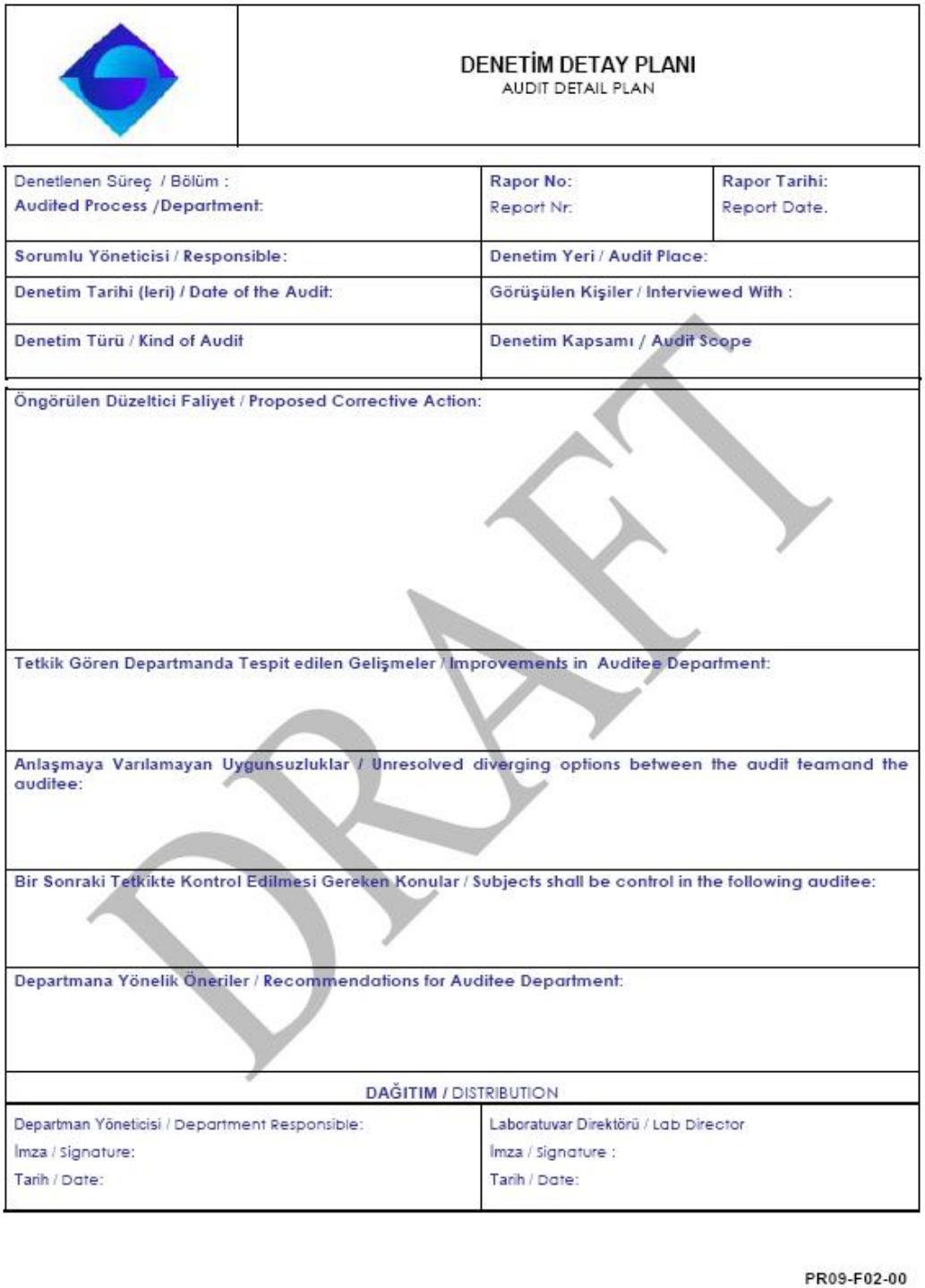
Tarih/ Date	Saat / Hour	Denetçiler / Auditors	Plan / Plan

Açıklama/ Comments:

Yukarıda belirtilen maddeler ve belirtilen gün ve saat Tetkik için uygundur. Date and time determined above are suitable for Audit.	Departman Yönetici (Ad/ Soyad) / Auitee (Name&Surname) İmza / Sign: Tarih / Date:

PR09-F01-00

Figure C9. Sample form for Audit Detail Plan



DENETİM DETAY PLANI
AUDIT DETAIL PLAN

Denetlenen Süreç / Bölüm : Audited Process /Department:	Rapor No: Report Nr:	Rapor Tarihi: Report Date.
Sorumlu Yöneticisi / Responsible:	Denetim Yeri / Audit Place:	
Denetim Tarihi (leri) / Date of the Audit:	Görüşülen Kişiler / Interviewed With :	
Denetim Türü / Kind of Audit	Denetim Kapsamı / Audit Scope	
Öngörülen Düzeltici Faliyet / Proposed Corrective Action:		
Tetkik Gören Departmanda Tespit edilen Gelişmeler / Improvements in Auditee Department:		
Anlaşmaya Varılamayan Uygunsuzluklar / Unresolved diverging options between the audit teamand the auditee:		
Bir Sonraki Tetkikte Kontrol Edilmesi Gereken Konular / Subjects shall be control in the following auditee:		
Departmana Yönelik Öneriler / Recommendations for Auditee Department:		
DAĞITIM / DISTRIBUTION		
Departman Yöneticisi / Department Responsible: İmza / Signature: Tarih / Date:	Laboratuvar Direktörü / Lab Director İmza / Signature : Tarih / Date:	

PR09-F02-00

Figure C10. Sample form for Audit Report

C.10. PR 10 Draft Procedure for Equipment Management

Scope: The purpose of this quality system procedure is to describe the method for safe usage, maintenance and documentation for the equipment in BME Laboratory. Covers all the equipment in BME Laboratory.

Numbering of Equipments: First, machine, device and equipments are defined letters that indicates the equipment type and usage place. The latest number in the equipment list is given to the equipment.

Labelling: The identification numbers should be applied in a readily visible location on a major surface of equipment. When size or application makes it impractical to use the identification label, the equipments shall permanently be marked in a manner that provides traceability for the calibration status.

Receiving the Equipment: All laboratory equipment and equipment sent outside the Laboratory and received back shall be pre-checked by the related Study Leader. This pre-check covers the normal operating conditions of the equipment. The detail description of pre-check is given in Procedure for Procurement.

The equipment that is not in use for a period of 6 months shall be maintained, calibrated and/or verified. The document of this kind shall be kept in equipment files.

Equipment Acceptance Testing: Acceptance tests should be performed on every laboratory test and calibration equipment usage prior to routine service. The Study Leader should be directly involved in the equipment acceptance testing phase to ensure that the equipment meets the specifications indicated in the purchase agreement. The content of the guidelines should be determined by management with participation from the Study Leader but the following elements are considered essential:

- a list of the equipment specifications and tolerances;
- the conformance standards and the tolerance limits for each parameter to be tested;
- a list of the equipment required to test each parameter;
- a detailed method (protocol) of testing for each parameter;
- a schedule for the completion of each test;

- a list of the persons authorized to perform or witness the acceptance tests; and
- a list of the persons responsible for authorizing the acceptance of each test.

The report on the acceptance tests results should contain all of the information listed above including the actual data with graphs, charts and in conformance with the procedures. This report should be retained as part of the equipment performance log book and used to compare with future QC test results to assess the continued acceptability of the equipment's performance and estimate the equipment's remaining useful life.

Assessment of need for installation qualification of the test equipment is given in PR 12. Also, the purpose of installation validation is to insure that the equipment operates correctly and meets the following criteria:

- the standards of design, construction and functioning,
- the purchase contract specifications; and/or,
- the original equipment manufacturer specifications.

Calibration: Calibration of equipment is performed as per Procedure for Laboratory Equipment Calibration.

Equipment Usage Authorization: Only authorized personnel can use Laboratory Equipment. The usage of the equipment by unauthorized personnel is restricted by the authorization lists near the equipment and equipment file.

Equipment Usage: Equipment usage by authorized personnel shall be performed as per Usage Instruction prepared for all equipment.

Equipment Maintenance: Related Study Leader shall control usage, authorization, maintenance, calibration and/or verification of the equipment, she/he is responsible for. The Annual Laboratory Equipment Maintenance Calendar shall relate to the purpose of the analysis or test, environmental influences, the physical location of the equipment, and the level of operator skills. Maintenance not planning shall be recorded in Equipment Maintenance Form. Planned maintenance process of the equipment shall be reviewed

Limitation of the Adjustment: If the equipment is operated with the software program, all technical information shall be used to maintain highest-level security for the adjustment of parameters.

Transportation of the Equipment: Laboratory Equipment cannot transported anywhere without the approval of related Study Leader. All safety precautions for the device itself and personnel shall be taken. For the transport of stable devices and devices validated, Procedure for Change Control shall be applied. For the equipment sent outside the BME plant, waybill shall be prepared. It is strictly forbidden to send the equipment without the waybill.

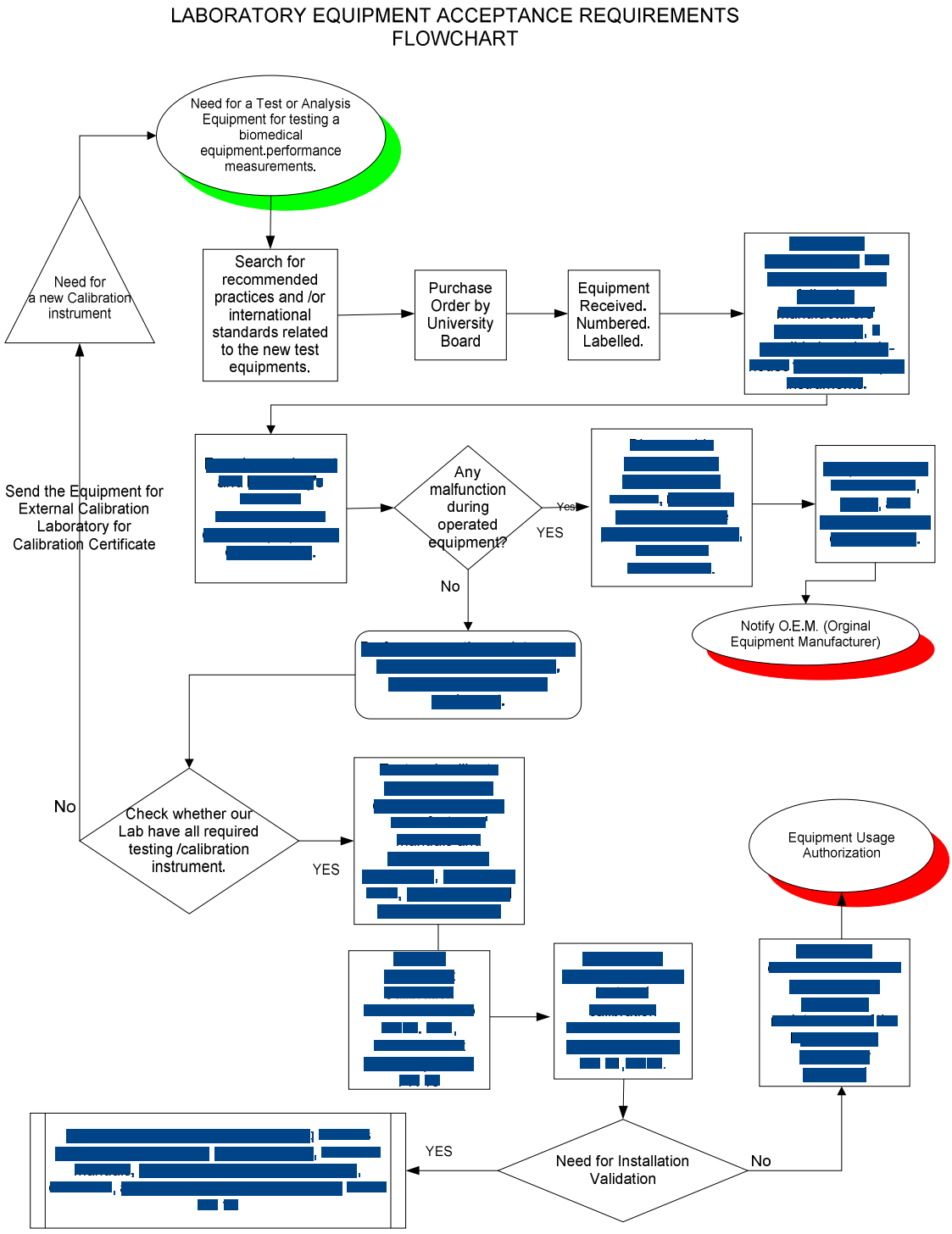


Figure: C11. Flowchart of test equipment Laboratory Acceptance Method.

C.11. PR 11 Draft Procedure for Uncertainty of Measurements

Scope: This quality management procedure covers the general topics and responsibilities of the measurement and evaluation of the measurement uncertainties.

General Principles of Uncertainty Measurement, Determining Uncertainty Source: Measurand that uncertainty to be calculated shall be analyzed. All the inputs and affects of the measurand shall be listed. Quantity of the measurand, constants of the measurement, related calibration standard values, sampling methods, all data related to the measurement device, place where measurement realized and all related affects of the operators shall be examined under this topic.

Grouping of the Measurement Uncertainty Sources; while grouping the measurement uncertainty sources, list of the measurand analysis shall be used. Components affecting the measurement uncertainty are;

Measurement Method; Measurement process method and all related affects inside this method shall be evaluated under this topic.

- calibration method (comparative calibration, direct measurement, etc.),
- reference standard used,
- measurement number,
- sampling methods shall be evaluated under “measurement method” topic.

Measurement Device; Components related to the measurement device shall be evaluated under this topic.

- repeatability of the measurement device,
- reproducibility of the measurement device,
- hierarchy of the measurement device,
- sensibility of the measurement device indicator,
- slipping of the measurement device shall be evaluated under this topic.

Measured Object; Physical properties of the measured object shall be evaluated under this topic.

- expansion coefficient of metal,
- surface smooth,
- straightness,

- parallelism shall be evaluated under this topic.
- operator / who makes measurement,
- the personnel who make measurement are a very important component of the measurement uncertainty.

components like,

- reading errors,
- parallax errors,
- applying wrong force
- holding the measurement device/reference wrong
- using the measurement device/reference wrong,
- making wrong acceptance through measuring,
- being tired shall be evaluated under this topic.

Environment Conditions;

- environment temperature,
- environment pressure,
- relative humidity,
- vibration,
- lightning,
- magnetic area,
- local gravity,
- density of the air shall be evaluated under this topic.

Calculating Uncertainty**:** While making uncertainty calculations, it shall be evaluated as Type A or Type B. Grouped uncertainty sources shall be used. Source shall be decided as Type A or Type B. After making this decision, uncertainty of each source shall be calculated. Statically information shall be used through uncertainty calculations and uncertainty shall be calculated by using standard deviations. Standard deviations shall be used at measurement uncertainty because units of each measurement sources are different from each other. By calculating Standard deviations, they became without unit and mathematical calculations can be made over them. After calculating the Standard deviations of each uncertainty sources one by one, they shall be attached as the last step. Total uncertainty of the measurement shall be calculated.

Calculating Type A Uncertainties: It covers uncertainties that can be calculated statically. It covers the data of the repeatability measurements. Type A uncertainties shall be mathematically calculated because they determined from repeatability measurements.

Calculating Type B Uncertainties: It covers uncertainty sources that cannot be evaluated statically. They are random errors. They are the components that cannot be determined by repeatability measurements. These errors do not give the same results under same conditions; they change as quality and/or way.

General Uncertainty Calculation: Calculating the average directly without making mathematical modelling at Type A is the difference between Type A and Type B uncertainty calculations. Mathematical modelling shall be done at Type B uncertainties because there are no statically data, and then arithmetic average calculation shall be done. Mathematical modelling shall be done for each measurement uncertainty source at Biomedical Laboratory because uncertainty measurement sources do not separate from each other by straight lines and can change the type class according to the measurand or measurement process.

Mathematical Modelling: Preceding information, experiences and statically data of the system shall be used while making mathematical modelling. One of the three modelling type shall be chosen while making mathematical modelling. Statically specifications of the measurand shall be focused through choosing the model.

- Normal Distribution (Gauss Distribution): Values of the graphic are separated around the average value. Realizing probability of the measured values is more around at the average value and becomes less as getting far from the average value.
- Triangle Distribution: Values of the graphic are separated around the average value. However, the probability for having any measurement result is not in this graphic type. There are limits for the probability of having the measurement results. Also the probability of having the measurement result is not same for every value. Probability of having the result is becoming less while getting far from the average value.
- Rectangle Distribution: Values of the graphic are separated around the average value. However, probability of having any measurement result is not in this type graphic. Probability of having any result is equal. Also there is a limit for measurement results.

Uncertainties of Certificates / Documents**:** They are Type B uncertainties and having no statistical data. They shall be calculated from tables, certificates.

Arithmetic Average: After making mathematical modelling, arithmetic average shall be calculated. Measurements shall be done in the same conditions and they shall be independent from each other.

Standard Deviation: Standard deviation shall be calculated after the calculation of arithmetic average. Standard deviation shows how far the measurement results distributed from the average value. The purpose of standard deviation is comparing a measurement with another one.

Total Uncertainty Calculation**:** For calculating the "Total Measurement Uncertainty", all factors shall be statistically combined. Calculation on standard deviations shall be done pectoral because they are not arithmetic. Vectoral sum of the standard deviation shall be performed.

Calculation of Functional Uncertainties: Statistical method determined below shall be performed if ala the inputs are independent but a part of the total function. These kinds of uncertainties are mostly seemed at chemical measurements. Uncertainty calculated while preparing concentration of liquid is a functional uncertainty. Two independent uncertainties are taking place at concentration formula. While calculating this kind of uncertainties, fractional differentiation shall be used. While calculating total measurement uncertainty, before differentiation calculation, uncertainties of ala components shall be calculated as determined above. Then differentiation shall be used for total uncertainty calculation. If there is only multiple/division process in the function, uncertainty calculation shall be done as determined below.

Calculation Of Expanded Measurement Uncertainty**:** After combining ala factors affects to the measurand, Expanded Measurement Uncertainty shall be found by calculating confidence level. Confidence level shall be added to the uncertainty result according to principle. The principle is the result of uncertainty calculated from statistical methods cannot be given at only one point. So, probability range for having the result inside infinitive measurements shall be determined.

Confidence level calculation shall be done according to the Sigma Rule. Measurements performed at our Laboratory are accepted at ±2 ó means %95-confidence level. Total Measurement Uncertainty shall be multiplied by 2 for having Expanded

Measurement Uncertainty. Expanded Measurement Uncertainty shall be given at certificates and reports.

Documentation Of Measurement Uncertainty**:** Calculated uncertainties shall be documented understandable at reports. Measurement results and calculation method of the measurement results and inputs shall be documented at reports. All uncertainty components and calculation methods of these components shall be determined at reports. The reason of using and usage way of all constants and correction values used at calculations shall be determined. There is no need for this kind of explanation if they are not used. Expanded Measurement Uncertainty shall be given at the report. The ratio of performed on the expanded uncertainty shall be determined too.

C.12. PR 12 Draft Procedure For Test Method Selection And Validation

Scope. This procedure covers selection of test methods and method validation for developed test methods that will be applied in BME Laboratory.

General: All newly acquired medical devices, and/or used medical devices, entering a healthcare facility should have an inventory criteria review and acceptance test performed on it prior to being placed into clinical use. The inventory criteria review evaluation is a guide for establishing the levels of inspections and maintenance that is appropriate for specific medical devices. Whereas, an acceptance test is designed to insure that the equipment is performing within the manufacturer's specifications and comply the appropriate safety standards. Performance testing is also designed to periodically re-evaluate the equipment performance, as the equipment will tend to deteriorate as it ages over time and use.

Test Method Selection for Biomedical Devices: The test method selection is descried in the following flowchart for biomedical devices. The quantitative and qualitative tests are defined after the international laws and standards searched. Sample for customer medical device performance testing; biomedical equipment is given in Appendix E.

Test method selection can be differing for biomedical imaging devices. Radiation safety compliance testing and the methods of compliance testing are must for the manufacturers. All radiation producing medical devices is in compliance with the applicable laws. Test instructions and test reports shall be prepared separately in accordance with the applicable laws and approved by the Laboratory Director. Sample for customer medical device; imaging device is given in Appendix E.

Monitoring of Test Results Statistically: Sponsor test results for the Functional test service shall be reported in conformity with quality manual Section for Test Reports. Test results shall be reviewed by monitoring validity of test results once a year. The resulting data for a year shall be filed in such a way that trends are detectable and statistical techniques shall be applied to the reviewing of the results. the end of the year, study leaders shall show the changes of test results by the drawing a graph between test result and test number. If the test results out of upper or lower control limits, Study Leader shall research and report these nonconformities to sponsor as a end of year report, if requested by the sponsor.

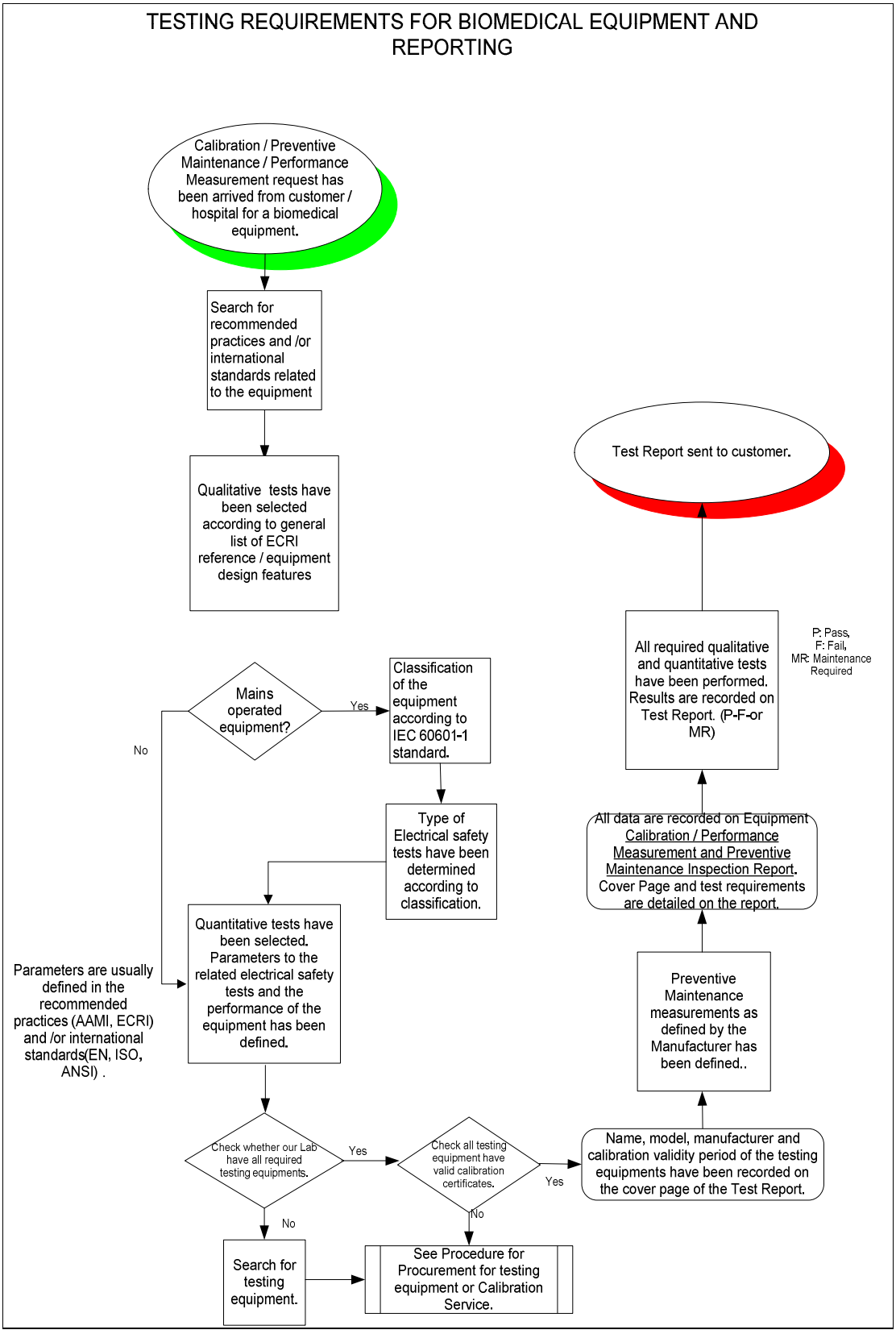


Figure C.12: Flowchart for Determination of Testing requirements for biomedical equipments

C.13. PR13 Draft Procedure For Test Quality

Scope: The purpose of this instruction is to define; responsibility, authority and management during monitoring the validity of test results based on sponsor request.

Verification**:** Tests shall be replicated by using the same or different methods in the scope of measurement management system validation study. Retesting shall be performed for retained samples in the scope of measurement management system validation study. The process shall be applied as per PR 12 Procedure for Test Method Validation

Validation: Validation is the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. For developed test methods that will be used in the compliance testing of the sponsor's biomedical devices shall be validated. Validation process shall be initiated with the Master Plan. Validation Master Plan is an annual Schedule that indicates the validation time. At the 12^{th} of each year, Validation Master Plan shall be prepared for next year by Quality representative.

Validation Method Summary: Each step or groups of related steps, in the validation package shall be signed and dated by the person(s) performing the evaluations. All equipment test instrumentation used in validation studies to monitor key process parameters or to generate test data shall be calibrated before and after the validation studies are conducted. Validation studies are organized in the following order:

- coordination meeting,
- preparation and approval of validation protocol,
- preparation and approval of required SOP'S,
- training required for validation process is given,
- performing validation process,
- data collecting, recording, evaluation, and reporting,
- evaluation of validation studies, preparation of final report.

Preparation of Validation Protocol**:** Validation protocol shall cover minimum the following information and be prepared before the validation tests.

- test method expected or required uncertainty and intended use,
- method to demonstrate the capability of the test method within the specified test range.
- calibration requirements,
- intercomparisions including the use of reference materials and reference methods,
- qualification of the staff,
- acceptance criteria.

Method Validation: Method validation may be the combination of validation procedures given below:

- utilization of calibration,
- intercomparisions including the use of reference materials and reference methods,
- well qualified staff and their professional judgment,
- simulation and modelling,
- other approaches.

The selection of validation procedures can also be justified on a cost-benefit basis as long as the fitness-for-purpose is maintained. Different validation methods can be characterized as “scientific” or “comparative”. Basic Validation Methods:**; t**he definitions for the basic validation methods, used in validation approaches are given below:

Repeatability (of results of measurements): Closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement. These conditions are called repeatability conditions. Repeatability conditions include:

- same measurement procedure,
- same observer,
- same measuring instrument, used under the same condition,
- same location,
- repetition of a short period of time.

Reproducibility (of results of measurements): Closeness of the agreement between the results of measurements of the same measurand conditions carried out under changed conditions of measurement. A valid statement of reproducibility requires specification of the conditions changes. These changes conditions may include

- principle of measurement,
- method of measurement,
- observer,
- measuring instrument,
- reference standard,
- location,
- conditions of use,
- time.

Uncertainty (of measurement): Parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. The details of the uncertainty in measurement are given in 270108 Procedure for Measurement Uncertainty.

Comparative Approach: The test method is assessed by comparing its results to those obtained by means of another already validated test method, which has been developed for the same purposes. If this is not possible the performance characteristics of the method may be assessed through interlaboratory comparisons. The method is valid if the result obtained by different laboratories fall within the expected uncertainty limit. Deviations beyond such limits may indicate lack of control of influencing parameters. The causes of this behaviour should be clarified and the method is to be redefined accordingly.

The “fast” validation methods must be used in many cases, the capability of use professional judgment in assessing whether the validation is comprehensive enough becomes pronounced. However even when talking about simplified or fast validation procedures, the validation must be done with such a dept that the method is fit for intended use and acceptable to the customer and/or authorities. In case the fast validation is applied, there is no need for preparation of master plan and protocol; only final report describing the validation and the results is sufficient.

Rules for Deviations: Deviations from the requirements of this procedure must be documented, justified, signed and dated by the initiator and shall be included as an addendum to the validation document package prior to final review and approval.

Rules for Revalidation: The primary intent of the revalidation program will be to reconfirm the operational consistency of the test method and to broaden the base on which operating parameters are validated.

Revalidation shall be performed under the following conditions.

- when there is a change in the actual test method that may affect quality.
- when there is an investigation of a negative trend in quality indicators.
- when the test is transferred from one facility another.
- when scope of application of the test has changed.
- when there are changes identified for specific tests.

C.14. PR 14 Draft Procedure For Laboratory Equipment Calibration

Scope: This procedure outlines and describes responsibilities and proceeding for calibration of Laboratory Equipment.

General: Calibration documents of inspection, measurement and test equipments are prepared and their continuity is ensured. The consistency of inspection, measurement and test equipments uncertainty with allowed deviations is ensured.

All inspection, measurement and test equipments that affect the test are identified and are calibrated in determined intervals or just before usage and the operation is documented.

Desired accuracy and measurements for devices are determined.

After the inspection for calibration, test and measurement equipments are marked with a label that shows calibration status of device. Usage of nonconforming inspection, test and measurement equipments is prevented. Completed calibration records are preserved in Laboratory devices folders.

Request For Calibration and/or Maintenance: Measurement equipment is recalibrated after any event that causes doubt as to whether or not the accuracy established at the last periodic calibration can still be obtained. When the user suspects discrepant measuring equipment, it shall request examination of the equipment by the Calibration Specialist, starting the apparent discrepancy. After examination, the Study Leader takes necessary steps for correction.

Monitoring of Calibration: Annual Verification and Calibration Plans for measuring equipment are prepared and performing and monitoring of the activities is carried by Study Leader.

Cleaning and Minor Repairs: The department, that uses the measuring equipment, is responsible for cleaning the equipment under normal conditions. It is the responsibility of the department to clean their own measuring equipment and tooling as necessary during normal use. Cleaning does not include disassembly or removal of sealed access door or covers. Prior to calibration, the equipment is operated and checked and the and its status is recorded on the Calibration Record. Cleaning is performed as necessary and all switches, knobs, dials, and functions used in the assigned application are checked for tightness and normal operation. Minor discrepancies, such as loose knobs or components, are corrected

by the Study Leader at the time of the calibration

Calibration Instructions: If calibration procedure is required detailed /specific operations, it is prepared for each type of measuring equipment to be calibrated, indicating the standard to be used and detailed instructions for calibration. If a detailed calibration does not performed, calibration operation is explained on the verification/calibration form. The instructions are reviewed on two-year schedule and revised as required.

Definition of Calibration Points: Calibration/verification is performed at least for three points that cover minimum, maximum, range of test values. The calibration points can be increased in conformity with related department requests.

Evaluation of Calibration Reports: Calibration results are recorded on verification/calibration report, which is included at least following information:

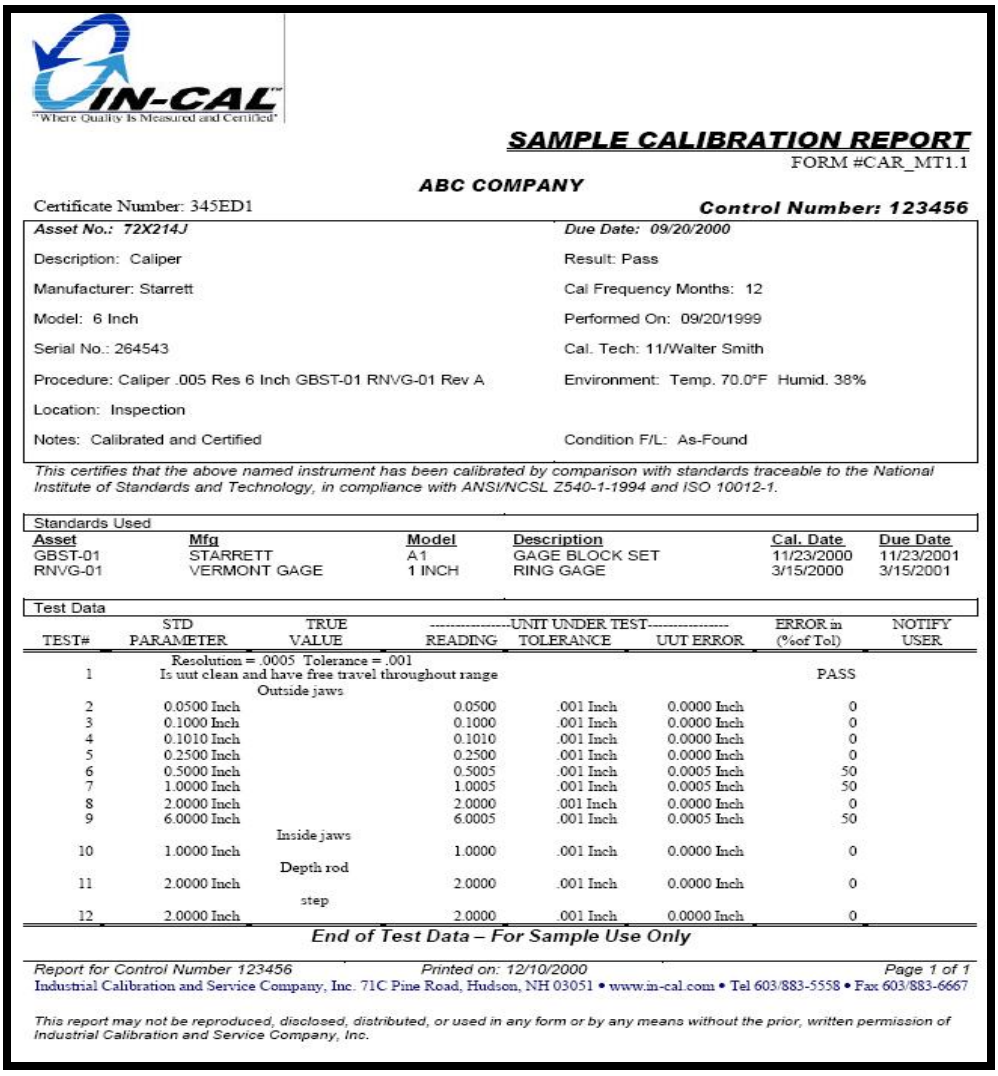
- calibration/verification report no,
- measuring equipment name and identification number,
- calibrator name and identification number,
- calibrator report no,
- calculated total measurement uncertainty after the calibration,
- verification/calibration date,
- next verification/calibration date,
- related calibration/verification document no,
- ambient temperature and humidity during the calibration/verification,
- allowed standard deviation for measuring device,
- calibration/verification results,
- decision that is given after the calibration/verification,
- personnel name, title and signature that has performed and approved calibration/verification.

Calibration Labels: Calibration labels are applied to each unit of measuring equipment at the time of calibration, in a readily visible location on a major surface, preferably the front. Labels are written legibly and covered with transparent band to prevent being wiped away. There are five types of calibration labels.

- For Use; Green “Use” label is attached the device that its calibration results are in defined error limits for usage after the calibration.
- Limited Calibration; An orange “Limited Calibration” label will be affixed to

instruments not meeting full manufacturer's specifications but that is usable within the limited calibration, or is not fully calibrated, as use does not require all functions of the instrument to be calibrated. Additionally, a label will be affixed to the instrument describing the limitation of the calibration and showing the instrument's accountability number or other identifying number.

- Not Use; Red "Not Use" label attached when the damage on the equipment prevents its usage occurs. The device is sent back to user, user takes action to stop its usage (service is called for/sent to service.)
- "NO CALIBRATION REQUIRED" label is attached to all equipment that do not need calibration.



IN-CAL
"Where Quality Is Measured and Certified"

SAMPLE CALIBRATION REPORT
FORM #CAR_MT1.1

ABC COMPANY

Certificate Number: 345ED1 — **Control Number: 123456**

Asset No.: 72X214J	*Due Date: 09/20/2000*
Description: Caliper	Result: Pass
Manufacturer: Starrett	Cal Frequency Months: 12
Model: 6 Inch	Performed On: 09/20/1999
Serial No.: 264543	Cal. Tech: 11/Walter Smith
Procedure: Caliper .005 Res 6 Inch GBST-01 RNVG-01 Rev A	Environment: Temp. 70.0°F Humid. 38%
Location: Inspection	
Notes: Calibrated and Certified	Condition F/L: As-Found

This certifies that the above named instrument has been calibrated by comparison with standards traceable to the National Institute of Standards and Technology, in compliance with ANSI/NCSL Z540-1-1994 and ISO 10012-1.

Standards Used

Asset	Mfg	Model	Description	Cal. Date	Due Date
GBST-01	STARRETT	A1	GAGE BLOCK SET	11/23/2000	11/23/2001
RNVG-01	VERMONT GAGE	1 INCH	RING GAGE	3/15/2000	3/15/2001

Test Data

TEST#	STD PARAMETER	TRUE VALUE	UNIT UNDER TEST: READING	TOLERANCE	UUT ERROR	ERROR in (%of Tol)	NOTIFY USER
	Resolution = .0005 Tolerance = .001						
1	Is uut clean and have free travel throughout range					PASS	
	Outside jaws						
2	0.0500 Inch		0.0500	.001 Inch	0.0000 Inch	0	
3	0.1000 Inch		0.1000	.001 Inch	0.0000 Inch	0	
4	0.1010 Inch		0.1010	.001 Inch	0.0000 Inch	0	
5	0.2500 Inch		0.2500	.001 Inch	0.0000 Inch	0	
6	0.5000 Inch		0.5005	.001 Inch	0.0005 Inch	50	
7	1.0000 Inch		1.0005	.001 Inch	0.0005 Inch	50	
8	2.0000 Inch		2.0000	.001 Inch	0.0000 Inch	0	
9	6.0000 Inch		6.0005	.001 Inch	0.0005 Inch	50	
	Inside jaws						
10	1.0000 Inch		1.0000	.001 Inch	0.0000 Inch	0	
	Depth rod						
11	2.0000 Inch		2.0000	.001 Inch	0.0000 Inch	0	
	step						
12	2.0000 Inch		2.0000	.001 Inch	0.0000 Inch	0	

End of Test Data – For Sample Use Only

Industrial Calibration and Service Company, Inc. 71C Pine Road, Hudson, NH 03051 • www.in-cal.com • Tel 603/883-5558 • Fax 603/883-6667

Figure C13: Sample Calibration Report-

C.15. PR 15 Draft Procedure For Measurement Traceability

Scope: The purpose of this instruction is to define; responsibility, authority and management for measurement traceability.

Elements of Traceability: Traceability is characterized by a number of essential elements;

- An unbroken chain of comparisons going back to a standard acceptable to the parties, usually a national or international standard.
- Measurement uncertainty; The measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated.
- Documentation; Each step in the chain must be performed according to documented and generally acknowledged procedures; the results must equally be documented.
- Competence; The laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence
- Reference to SI units; The “appropriate” standards must be primary standards for the realization of the SI units.
- Reference materials can take the position of physical reference standards. It is equally important that such reference materials are traceable to relevant SI units. Certification of reference materials is a method that is often used to demonstrate traceability to SI units.
- Recalibrations: Calibrations must be repeated at appropriate intervals; the length of these intervals depends on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment)

Traceability of In-house Calibration: An in-house calibration system ensures that all measuring and test equipment used in a company is calibrated regularly against its own reference standards. Biomedical Calibration Laboratory reference standards shall have traceability of measurement by being calibrated at an accredited calibration laboratory or a National Metrology Institute. The in-house calibration shall be evidenced by a calibration label. Calibrations and measurements made by the laboratory are traceable to the SI Units.

National measurement standards may be;

- Primary standards, which are primary realizations of the SI units,
- agreed representations of SI units based on fundamental physical constants,
- they may be secondary standards which are standards calibrated by another national metrology institute.

Traceability of External Calibration: Traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to ISO17025, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported. Where traceability of measurements to SI units is not possible, the same requirements for traceability to, certified reference materials, agreed methods or consensus standards are required as for calibration laboratories.

Traceability of Reference Materials**:** Reference materials shall, where possible, is traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

APPENDIX D. BIOMEDICAL CALIBRATION LABORATORY EQUIPMENT LIST and TEST SCOPE

D.1. Biomedical Calibration Laboratory Equipment List

Equipment	Manufacturer	Model	Serial Nr	Applications	Type	Calib. Status
Aerosol Particle Counter	LASAIR	LASAIR II 310		Clean Air Measurements	Measurement Equipment	B. U.
Aluminium Step Wedge	RMI	117		X-Ray Unit	Test Equipment	Not valid
Beam Alignment Test Tool	Nuclear Associates	07-662	794349	X-Ray Unit	Test Equipment	Not valid
Checkmate Pneumatic Verification Stand	BEAR MEDICAL	Model-1		Anesthesia Machine, Medical Gases, Suction Unit (Aspirator)	Measurement Equipment	NETES
Collimator Test Tool, Test Cassette Overlay [62-95 kVp]	Nuclear Associates	C7-603	1290	X-Ray Unit	Test Equipment	Not valid
D.C. Power Supply Dual Tracking x 5	GOODWILL		GPG-3030D	Lab	Measurement Equipment	B. U.
Defibrillator Analyzer	BIO-TEK	QED 6	90621	Defibrillator	Measurement Equipment	B. U.
Defibrillator Analyzer	DYNATECH-NEVADA	PEI 3100		Defibrillator	Measurement Equipment	B. U.
Defibrillator Analyzer	DYNATECH-NEVADA	PEI 3101		Defibrillator	Measurement Equipment	B. U.
Densitometer	RMI	2-331	23941	X Ray Film Bath	Measurement Equipment	B. U.
Dental QA Phantom	RMI	501 A		Mobile X-Ray Unit	Phantom	
Diathermy Analyzer	BIO-TEK	901		Diathermy Machine	Measurement Equipment	B. U.
Digital kVp meter II	Victorian	07-473	C 349	Fluoroscopy Machine, X-Ray Unit	Measurement Equipment	T. A. E. K.

Table D.1. List of Laboratory Equipment – Continued

Equipment	Manufacturer	Model	Serial Nr	Applications	Type	Calib. Status
Digital Mammography kVp meter	RMI	232		Mammography	Measurement Equipment	T. A. E. K.
Digital Multimeter (5 1/2 digit)		DP-100		Lab	Measurement Equipment	NETES
Digital Sound Meter	AZ	8921	2997689	Infant Intensive Care Incubator	Measurement Equipment	B. U.
Digital X-Ray Timer	Nuclear Associates	07-457	C 139	X-Ray Unit	Measurement Equipment	T. A. E. K.
Dosimeter [0-200 mR]	Nuclear Associates	138	029459	X-Ray Unit	Measurement Equipment	B. U.
DSA Phantom	RMI	171		Digital Angio Equipment	Phantom	Not valid
Dual Colour Sensitometer	RMI	2-234	14118	X Ray Film Bath	Measurement Equipment	B. U.
Economy CT Phantom	RMI – GAMMEX	RMI 463		CT (Computerized Tomography)	Phantom	Not valid
Electrical Safety Analyzer	BIO-TEK	601 PRO	90612	Electrical Safety	Measurement Equipment	B. U.
Electrometer	KEITHLEY Instruments		610 B	Lab	Measurement Equipment	B. U.
Electrometer (Solid State)	KEITHLEY Instruments		610 C	Lab	Measurement Equipment	B. U.
Electrosurgical Analyzer	NEURODYNE-DEMPSEY	443		Electrocoter	Measurement Equipment	B. U.
European Spine Phantom	QRM	ESP-203-08		Bone Densitometer	Phantom	Not valid
Film-Screen Contact Test Tool	RMI	143 C		X-Ray Unit	Test Equipment	Not valid
Focal Spot Test Tool	Nuclear Associates	07-591	791194	X-Ray Unit	Test Equipment	Not valid
Function Generator	HP		3311	Lab	Measurement Equipment	B. U.
Function Generator x 5	GOODWILL		GFG-8019G	Lab	Measurement Equipment	B. U.
Gas Indicator Vaporizer	RIKEN	18		Anesthesia Vaporization	Measurement Equipment	Self Calib.

Table D.1. List of Laboratory Equipment – Continued

Equipment	Mark	Model	Serial Nr	Applications	Type	Calib. Status
Grid alignment Test Tool	RMI	144		X-Ray Unit	Test Equipment	Not valid
High-contrast Resolution Test Tool	RMI	141	141-4467	Fluoroscopy Machine	Test Equipment	
HVL Attenuator Set	RMI	115 A		X-Ray Unit	Test Equipment	Not valid
Infusion Pump Analyzer	DYNATECH-NEVADA	404 A		Infusion Pump	Measurement Equipment	B. U.
Low-contrast Resolution Test Tool	RMI	151		Fluoroscopy Machine	Test Equipment	B. U.
Mammography Accreditation Phantom	RMI	156		Mammography	Test Equipment	Not valid
Mammography Film-Screen Contact Test Tool	RMI	157 A	3366	Mammography	Test Equipment	Not valid
Micro spector	NEURODYNE-DEMPSEY	449		Electrical Safety	Measurement Equipment	B. U.
Multiparameter Simulator	BIO-TEK	Lion Heart III	90544	ECG Machine, Patient Monitor	Measurement Equipment	B. U.
Phototimer Consistency Test Tool for mammography	RMI	159		Mammography	Test Equipment	Not valid
Precision LCR Meter 20 Hz-1MHz	HP		4284-A	Lab	Measurement Equipment	B. U.
Rad. Check plus external detector	Nuclear Associates	06-528		X-Ray Unit		B. U.
RAD-CHECK Plus, Dosimeter	Nuclear Associates	06-526	C 346	X-Ray Unit, Scopy	Measurement Equipment	T. A. E. K.
Slit Camera	RMI			Mammography	Test Equipment	Not valid
Static Electric Detector	KEITHLEY Instruments		2501	Lab	Measurement Equipment	B. U.
Storage Oscilloscope	Tektronix	TDS 120	B071658	Calibration	Measurement Equipment	NETES
Tachometer	AMETEK	050500003		Centrifuge	Measurement Equipment	B. U.
The Individual Mammography Phantom	RMI	154 D		Mammography	Phantom	Not valid
Equipment	Mark	Model	Serial Nr	Applications	Type	Calibration.
Wide-range kVp Test Cassette	Nuclear Associates	07-466		Fluoroscopy Machine, X-Ray Unit	Test Equipment	Not valid
X-Ray Resolution Test Pattern	Nuclear Associates	07-527		X-Ray Unit	Test Equipment	Not valid

Table D.1. List of Laboratory Equipment

D.2. Test Scope And Standards Used

Biomedical Equipment Name	Standards/Procedures used in Calibration and QC Measurements
Anesthesia Machine	ECRI 400-20010301-01, ECRI 436-20010301-01
Anesthesia Machine (Complete w/MR)	ECRI 400-20010301-01, ECRI 436-20010301-01
Anesthesia Monitor	ECRI 450-20010301-03
CT (Computerized Tomography)	AAPM Report No.39
Defibrillator	ECRI 476-20010301-01
Fluoroscopy Machine	ECRI 473-20010301-01
Interventional Angiography	ECRI 472-20010301-01
Patient Monitor	ECRI 420-20010301-01, ECRI 434-20010301-01, ECRI 409-20010301-01, ECRI 451-20010301-01,ECRI 425-20010301-01
Bone Densitometer (DXA)	ANZBMS, Accreditation Guidelines for Bone Densitometry.
LASER camera	BRH Compliance Guidance for Radiographic Quality Control
Mammography Unit	ECRI 467-20010301-01, AAPM Report No.4
Magnetic Resonance Imaging (MRI)	AAPM Report No.28
Automatic Film Bath	Photogram. Quality Assurance In Diagnostic Radiology, Nuclear Medicine And Radiation Therapy
Pulse Oximeter	ECRI 451-20010301-01
X-Ray Unit	ECRI 473-20010301-0, AAPM Report No.4
X-Ray Unit, Mobile	ECRI 468--20010301-01
X-Ray Unit/Lung	ECRI 473-20010301-01
Sterilizer	AAMI ST-46, ISO 17665
Sphygmomanometer	ECRI 424-20010301-01
Ultrasound Scanner	ECRI 474-20010301-01, AAPM Report No.8
Radian Warmer	ECRI 419-20010301-01
Billirubine Bed	ECRI 469-20010301-01
ECG Recorder	ECRI 410-20010301-01
Phototherapy Machine	ECRI 469-20010301-01
Compressor	ECRI 483-20010301-01
Infant Intensive Care Incubator	ECRI 415-20010301-01
Laminar Air Flow System	ISO 14644
Physiological Monitor	ECRI 420-20010301-01, ECRI 434-20010301-01, ECRI 409-20010301-01, ECRI 451-20010301-01,ECRI 425-20010301-01
Humidifier - Nebulizator	ECRI 431--20010301-01
Respirator Monitor	ECRI 453-20010301-01
Transport - Incubator	ECRI 415-20010301-01
Ventilator	ECRI 458-20010301-01
Automatic X-Ray Film Processor	Brh Photogr. Quality Assurance In Diagnostic Radiology, Nuclear Medicine And Radiation Therapy
Radiotherapy Treatment Planning	AAPM Report No. 64

Table D.2. List of Biomedical Equipment can be tested in BME.

APPENDIX E. TEST METHOD SELECTION FOR IMAGING DEVICES – SAMPLE FOR X-RAY UNIT

As a part of this project, I wanted to implement some of the draft procedures for to illustrate how to use them. For this reason, PR 12, “Procedure for Test Method Selection” given in Appendix C is used for test method selection of X-Ray Unit.

As you know, most healthcare facilities and also hospitals do not have a medical physicist, x-ray engineer, biomedical engineer or a suitably trained radiographic technologist on staff to make the required QC performance evaluation measurements.

When request for Inspection of Performance, Calibration Measurements and Preventive Maintenance for a biomedical device is accepted by our Institute, a testing program is designed to ensure that equipment fulfil the requirements. Performance measurement control begins with the radiology equipment used to produce the image, and continues with the routine evaluation of the image processing facilities.

Normally, a good Performance measurement program involves essentially three steps:

1. Acceptance testing which is the establishment of a performance baseline for the equipment.
2. Routine performance evaluation whereby the diagnosis of changes in equipment performance before they become radiographic apparent.
3. Error correction whereby the correction and verification of causes of deterioration in equipment performance is resolved

In this Appendix section, we tried to explain how to select methods for performance and calibration measurements for imaging devices in the basis of “Routine performance evaluation” testing. I applied method selection which is briefly summarized in Appendix C12. So, I found international standards and laws for radiographic systems.

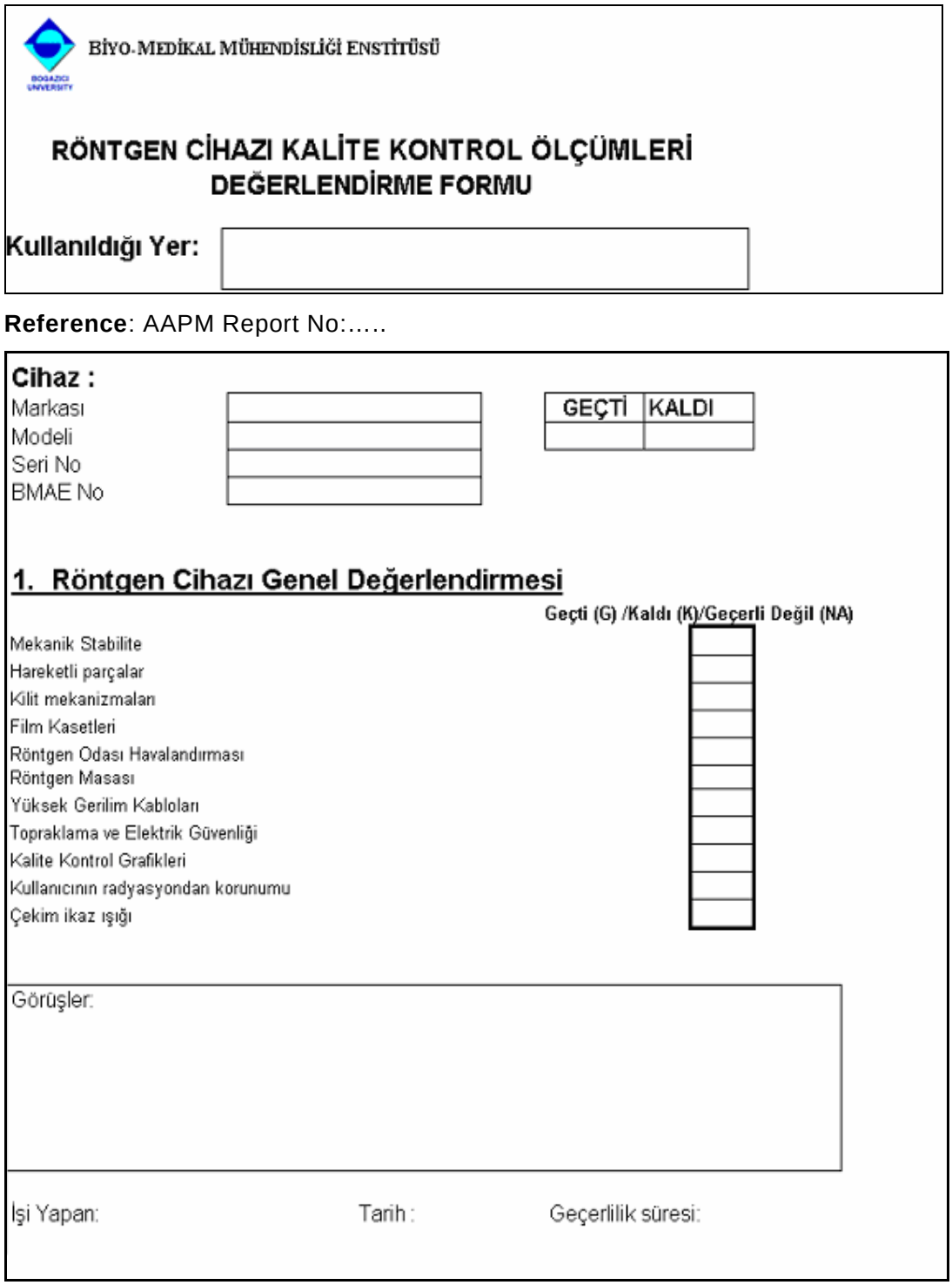
There are several organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), the American College of Medical Physics (AMCP) and the American Association of Physicists in Medicine (AAPM) who have developed guidelines for QC programs in radiography and other imaging modalities. The Joint Commission on Accreditation of Healthcare Organizations also considers radiology quality assurance and quality control programs to be critical elements during their survey.

By the help of RMI Quality Assurance Handbook and applied laws, quantitative tests can be defined and test instruction can be prepared for to detail testing criteria.

The instructions and block diagrams shall contain and illustrate the data collecting process. The tests will be performed the KV accuracy, mA linearity, timer accuracy, half-value layer, exposure reproducibility and the exposure linearity. The list of the test is;

1. Focal spot size.
2. Automatic fluoroscopic collimation.
3. Kilovolt peak (kVp) accuracy.
4. Exposure timer accuracy.
5. Milliampere-seconds (mAs) linearity.
6. Radiation dose rates.
7. Half value layer.
8. Phototimer reproducibility.

The qualitative tests generated from design features of equipment are recorded on the Test Report Cover Page as given in Figure E.1.



BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROL ÖLÇÜMLERİ DEĞERLENDİRME FORMU

Kullanıldığı Yer:

Reference: AAPM Report No:.....

Cihaz :

Markası	
Modeli	
Seri No	
BMAE No	

GEÇTİ	KALDI

1. Röntgen Cihazı Genel Değerlendirmesi

	Geçti (G) /Kaldı (K)/Geçerli Değil (NA)
Mekanik Stabilite	
Hareketli parçalar	
Kilit mekanizmaları	
Film Kasetleri	
Röntgen Odası Havalandırması	
Röntgen Masası	
Yüksek Gerilim Kabloları	
Topraklama ve Elektrik Güvenliği	
Kalite Kontrol Grafikleri	
Kullanıcının radyasyondan korunumu	
Çekim ikaz ışığı	

Görüşler:

İşi Yapan: Tarih : Geçerlilik süresi:

Figure E.1 Sample Test Report for X-Ray Unit.-Page 1-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

2. kVp Doğruluk Ölçümleri

GEÇTİ	KALDI

Test Cihazları :

Adı:	Digital kVp meter II
Markası	Victoreen
Modeli	07-473
Seri No	C 349

Fokal Spot	mAs	Tüp Mesafesi	Ayarlanan kVp	Ölçülen kVp	Aradaki Fark (% Değişim)	Uygun	
						Evet	Hayır

TA SINIRL/ % 5 veya 5 kVp'den hangisi daha büyükse.
(RMI Quality Assurance Handbook)

Figure E.1 Sample Test Report for X-Ray Unit.-Page 2-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

3. Poz Süresi Doğruluk Ölçümleri

GEÇTİ	KALDI

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

kVp	mAs	Tüp Mesafesi	Ayarlanan Poz Süresi	Ölçülen Poz Süresi	Aradaki Fark (% Değişim)	Uygun	
						Evet	Hayır

HATA SINIRI: ≤ +/- % 5 veya +/- 2 milisaniye'den hangisi büyükse
(RMI Quality Assurance Handbook)

Figure E.1 Sample Test Report for X-Ray Unit.-Page 3-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

4. Doz-mAs İlişkisi Ölçümleri

	GEÇTİ	KALDI
Doz-mAs Oranı		
Doz-mAs Linearitesi		

Test Cihazları :

Adı:	RAD-CHECK plus Dosimeter
Markası	Nuclear Associates
Modeli	06-526
Seri No	C 346

kVp	mAs	Tüp Mesafesi	Poz Süresi	Doz (mR)	mR/mAs	Uygun	
						Evet	Hayır
	Ortalama mR/mAs:						

HATA SINIRI: mAs Doğruluk Sınırı: +/- % 5; 80 kVp için mR/mAs=22.6 +/-%30 olmalıdır.
(RMI Quality Assurance Handbook)

Figure E.1 Sample Test Report for X-Ray Unit.-Page 4-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

5. Çıktı Kararlılığı Ölçümleri

GEÇTİ	KALDI

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

Çıkış Doz (mR)	kVp	mAs	Tüp Mesafesi	mR	mR/mAs	Uygun	
						Evet	Hayır

Ortalama:
Standart Sapma:
Değişim Katsayısı:

HATA SINIRI: +/- % 5'den küçük olmalı.
(RMI Quality Assurance Handbook)

Figure E.1 Sample Test Report for X-Ray Unit.-Page 5-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

SKOPİ CİHAZI KALİTE KONTROLÜ

6. X-ışını Yarı Tabaka Kalınlığı (HVL)

GEÇTİ	KALDI

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

kVp				
mA ayarı				
Poz süresi				
mAs				
Doz Ölçümleri (mR):				
Filtresiz, E(0a)				
1.0 mm Al Filtre, E(2)				
2.0 mm Al Filtre, E(3)				
2.5 mm Al Filtre, E(4)				
3.0 mm Al Filtre, E(5)				
4.0 mm Al Filtre, E(6)				
Filtresiz, E(0b)				
Ortalama E(0)				
Hesaplanan HVL				

$$HVL = [\, t_b \ln[\, 2\,E(a) / E\,(0)\,] - t_a \ln[\, 2\,E(b) / E(0)\,]\,] \;/\; \ln[\, E(a) / E(b)\,]$$

HATA SINIRI: HVL>=2.3 mm Al olmalı.
(RMI Quality Assurance Handbook)

Tüp Mesafesinin %'si				

HATA SINIRI: **Merkezleme Hatası Tüp Mesafesinin azami % 2'si olmalı. Kolimatör Hatası: Sol ve Sağ kenarlardaki toplam kayıklık veya üst ve alt kenarlardaki toplam kayıklık Tüp mesafesinin azami %2'si olmalı. (RMI Quality Assurance Handbook)**

Figure E.1 Sample Test Report for X-Ray Unit.-Page 6-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

7. Kolimatör ve X-ışını Hizalama Ölçümleri

GEÇTİ	KALDI

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

X-ışını Demeti Hizalaması

kVp				
Tüp Mesafesi				
mAs				
Kayıklık				
Tüp Mesafesinin %'si				

Kolimatör Ayarı

Kolimator (cm)		18x24	24x30	
Sol Kenarda Kayıklık				
Sağ kenarda Kayıklık				
Toplam Kayıklık				
Tüp Mesafesinin %'si				
Üst Kenarda Kayıklık				
Alt Kenarda Kayıklık				
Toplam Kayıklık				

Figure E.1 Sample Test Report for X-Ray Unit.-Page 7-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

8. Fokal - Spot Büyüklüğü Ölçümü

GEÇTİ	KALDI

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

Fokal Spot Büyüklüğü	İmalatçı tarafından Verilen Değer	Tüp mesafesi	kVp	mAs	Ayırd edilebilen En Küçük Çizgi Grubu	Ölçülen Fokal Spot	Aradaki Fark
Küçük					// /		
Büyük					// /		

HATA SINIRI: +/- 1 Gruptan küçük veya eşit olmalı.
(RMI Quality Assurance Handbook)

Figure E.1 Sample Test Report for X-Ray Unit.-Page 8-Continued.

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

RÖNTGEN CİHAZI KALİTE KONTROLÜ

9. Grid Hizalanması Ölçümleri

GEÇTİ	KALDI

İşi Yapan : Tarih :

Test Cihazları :

Adı:	
Markası	
Modeli	
Seri No	

Grid Hizalanması	kVp	Tüp Mesafesi	mA	Poz Süresi	Grid Oranı / Yoğunluk	Ölçülen Optik Yoğunluk				
						2	1	0	1	2

HATA SINIRI: Film üzerinde maksimum optik yoğunluk merkezden en fazla 2.5 cm uzaklıkta olmalı. (RMI Quality Assurance Handbook)

Figure E.1. Sample Test Report for X-Ray Unit.-Page 9

APPENDIX F. TEST METHOD SELECTION FOR BIOMEDICAL DEVICES – SAMPLE FOR SURGICAL ASPIRATOR

As I mentioned before, I aimed to give illustration of application of the draft procedures prepared as a result of this project. Consequently, I need to give another application example for identification of testing requirements for biomedical devices.

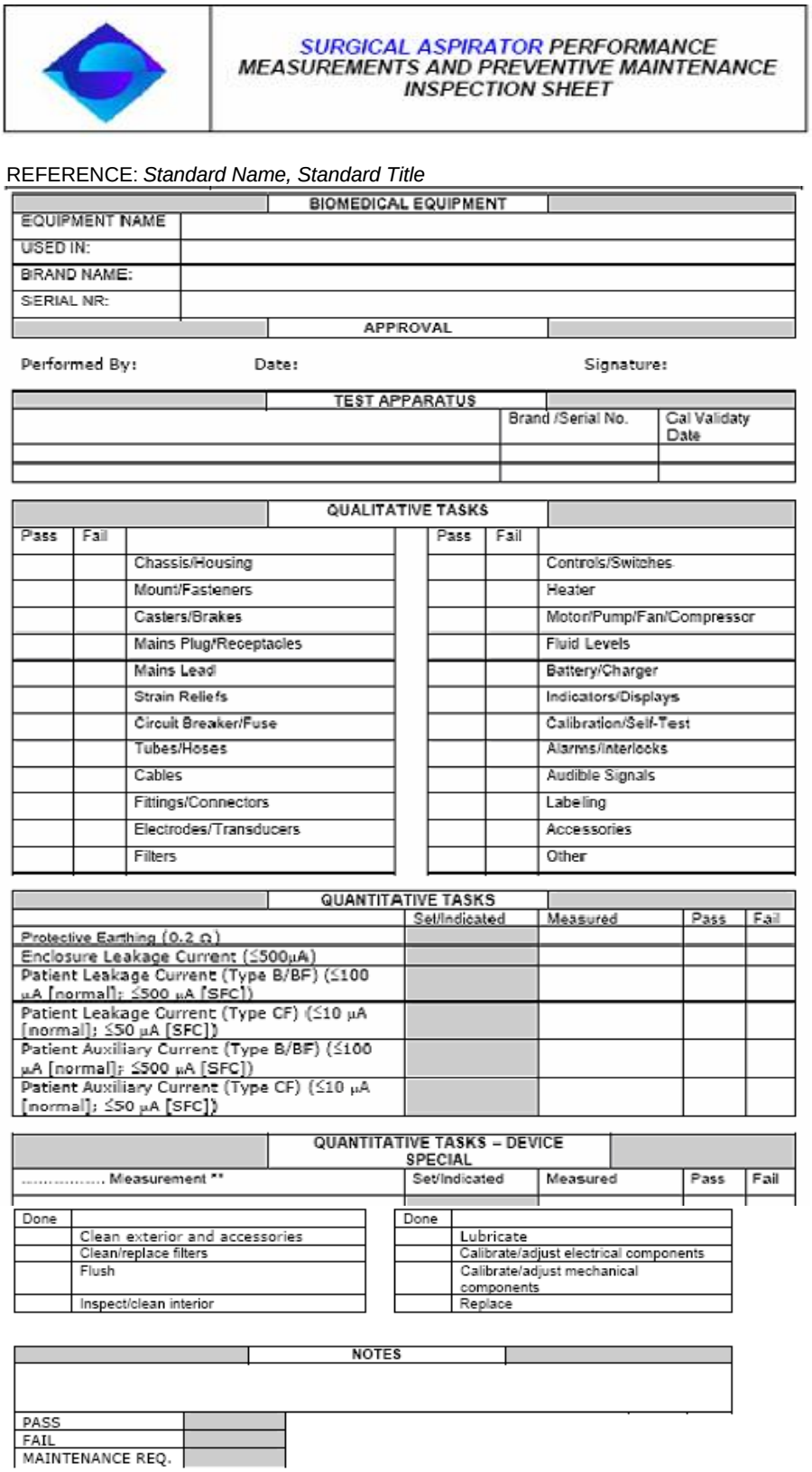
Besides, flowchart for test method selection given in Appendix C.12 is basically defines steps of selection for biomedical equipment. Following, you will find testing criteria determined for Surgical Aspirators.

For recording qualitative and quantitative test criteria, ECRI reference sheet can be used.

- Qualitative Tests
- Quantitative Tests
- Preventive Maintenance

Qualitative tests based on device design; be sure that you understand how to operate the equipment, the significance of each control and indicator. We shall skip tasks that are not relevant to the device being inspected. Most quantitative tasks are device specific. However, the electrical safety tests are common to all mains-powered devices. Most preventive maintenance tasks are device specific. Appropriate tasks are called out in the individual procedures or should be derived from device specifications and an understanding of the device's clinical application and design

The reference sheet prepared for this purpose is given below:



SURGICAL ASPIRATOR PERFORMANCE MEASUREMENTS AND PREVENTIVE MAINTENANCE INSPECTION SHEET

REFERENCE: *Standard Name, Standard Title*

BIOMEDICAL EQUIPMENT	
EQUIPMENT NAME	
USED IN:	
BRAND NAME:	
SERIAL NR:	
APPROVAL	

Performed By: Date: Signature:

TEST APPARATUS		
	Brand /Serial No.	Cal Validaty Date

QUALITATIVE TASKS					
Pass	Fail		Pass	Fail	
		Chassis/Housing			Controls/Switches
		Mount/Fasteners			Heater
		Casters/Brakes			Motor/Pump/Fan/Compressor
		Mains Plug/Receptacles			Fluid Levels
		Mains Lead			Battery/Charger
		Strain Reliefs			Indicators/Displays
		Circuit Breaker/Fuse			Calibration/Self-Test
		Tubes/Hoses			Alarms/Interlocks
		Cables			Audible Signals
		Fittings/Connectors			Labeling
		Electrodes/Transducers			Accessories
		Filters			Other

QUANTITATIVE TASKS				
	Set/Indicated	Measured	Pass	Fail
Protective Earthing (0.2 Ω)				
Enclosure Leakage Current (≤500μA)				
Patient Leakage Current (Type B/BF) (≤100 μA [normal]; ≤500 μA [SFC])				
Patient Leakage Current (Type CF) (≤10 μA [normal]; ≤50 μA [SFC])				
Patient Auxiliary Current (Type B/BF) (≤100 μA [normal]; ≤500 μA [SFC])				
Patient Auxiliary Current (Type CF) (≤10 μA [normal]; ≤50 μA [SFC])				

QUANTITATIVE TASKS – DEVICE SPECIAL				
..... Measurement **	Set/Indicated	Measured	Pass	Fail

Done		Done	
	Clean exterior and accessories		Lubricate
	Clean/replace filters		Calibrate/adjust electrical components
	Flush		Calibrate/adjust mechanical components
	Inspect/clean interior		Replace

NOTES	
PASS	
FAIL	
MAINTENANCE REQ.	

Figure F.1 Sample Biomedical Device Performance Measurement Reference Sheet

When our Laboratory takes a request for Performance Testing of biomedical equipment with the same reasons mentioned on Appendix F, we shall search for recommended practices and international standard.

For surgical aspirators, applied standards shall be;

- IEC 60601-1
- ISO 10079-1, -2, -3
- IEC 60601-1-1
- Related standards defined in IEC 60601-1: 1988, such as IEC 60695-2-2, IEC 60651, etc.

Assume that our testing equipment is a high volume/ high flow equipment, and then we can use ISO 10079-1: 1999, for determining quantitative tests. The classification given in Clause 5 of IEC 60601-1: 1988 applies and;

- according to mode of operation; COWSTL
- according to the degree of protection against harmful ingress of water: IPX5
- according to the type of protection against electric shock: Class 1
- according to the degree of protection against electric shock: CF-Type Equipment.

For all quantitative tests of a high volume/ high flow-electrically powered surgical aspirator, the requirements given in clauses of IEC 60601–1: 1988 applies, together with the additions given in ISO 10079–1: 1999 standard.

Required test apparatus, tasks and limits of the test results are given in the following test report.

SURGICAL ASPIRATOR PERFORMANCE MEASUREMENTS AND PREVENTIVE MAINTENANCE INSPECTION SHEET

REFERENCE: IEC 60601-1, ISO 10079-1

BIOMEDICAL EQUIPMENT	
EQUIPMENT NAME	SURGICAL ASPIRATOR
USED IN:	Medical suction equipment are non-surface contacting Class IIa electromechanical medical devices. They are used for removing fluids or particles from body cavities
BRAND NAME:	XXXX
SERIAL NR:	XXXX

APPROVAL

Performed By:

Date:

Signature:

TEST APPARATUS		
	Brand /Serial No.	Cal Validaty Date
Leakage current meter or electrical safety analyzer	BIOTEK / 601PRO	XXX
Ground resistance ohmmeter	BIOTEK / 601PRO	XXX

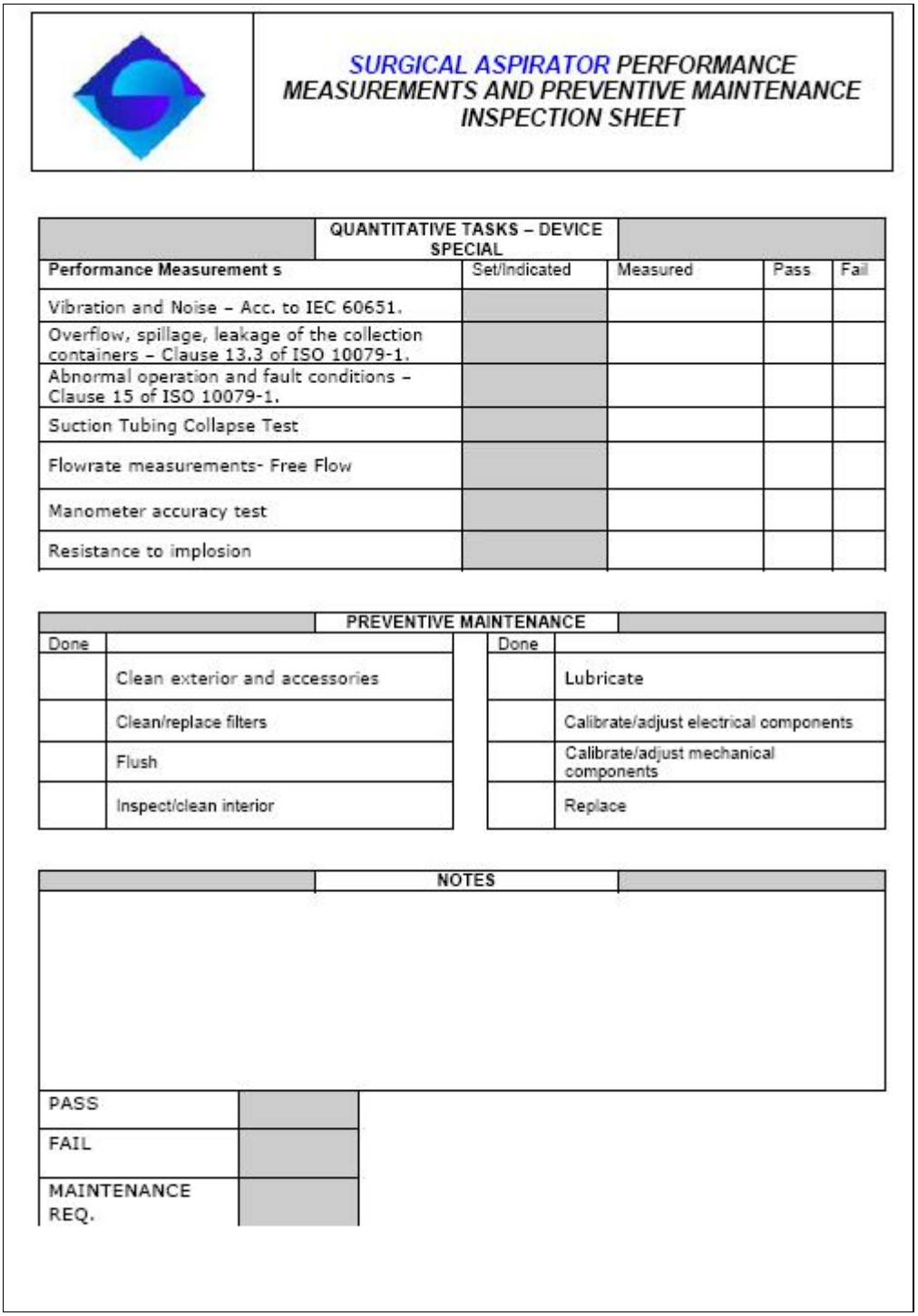
QUALITATIVE TASKS

Pass	Fail		Pass	Fail	
		Chassis/Housing			Controls/Switches
		Mount/Fasteners			
		Casters/Brakes			Motor/Pump/Fan/Compressor
		Mains Plug/Receptacles			Fluid Levels
		Mains Lead			
		Strain Reliefs			Indicators/Displays
		Circuit Breaker/Fuse			
		Tubes/Hoses			
		Cables			
		Fittings/Connectors			Labeling
					Accessories
		Filters			

QUANTITATIVE TASKS

Electrical Safety Tests	Set/Indicated	Measured	Pass	Fail
Protective Earthing (0.2 Ω)				
Enclosure Leakage Current (≤500μA)				
Patient Leakage Current (Type CF) (≤10 μA [normal]; ≤50 μA [SFC]) Addition: Clause 9.7 of ISO 10079-1				
Patient Auxiliary Current (Type CF) (≤10 μA [normal]; ≤50 μA [SFC]) Addition: Clause 9.7 of ISO 10079-1				

Figure F.2 Sample Surgical Aspirator Performance Measurement Reference Sheet-Continued.



SURGICAL ASPIRATOR PERFORMANCE MEASUREMENTS AND PREVENTIVE MAINTENANCE INSPECTION SHEET

QUANTITATIVE TASKS – DEVICE SPECIAL				
Performance Measurement s	Set/Indicated	Measured	Pass	Fail
Vibration and Noise – Acc. to IEC 60651.				
Overflow, spillage, leakage of the collection containers – Clause 13.3 of ISO 10079-1.				
Abnormal operation and fault conditions – Clause 15 of ISO 10079-1.				
Suction Tubing Collapse Test				
Flowrate measurements- Free Flow				
Manometer accuracy test				
Resistance to implosion				

PREVENTIVE MAINTENANCE			
Done		Done	
	Clean exterior and accessories		Lubricate
	Clean/replace filters		Calibrate/adjust electrical components
	Flush		Calibrate/adjust mechanical components
	Inspect/clean interior		Replace

NOTES

PASS	
FAIL	
MAINTENANCE REQ.	

Figure F.2 Sample Surgical Aspirator Performance Measurement Reference Sheet

APPENDIX G. DRAFT PROCEDURE APPLICATION– SAMPLE FOR HANDLING NONCONFORMITIES

For a detailed application of the draft procedures I decided to give an example for handling nonconformities and applying corrective actions. PR 04 and PR05, procedures are detailed the steps and approval system of a defined problem.

The following flowchart prepared for summarizing the actions.

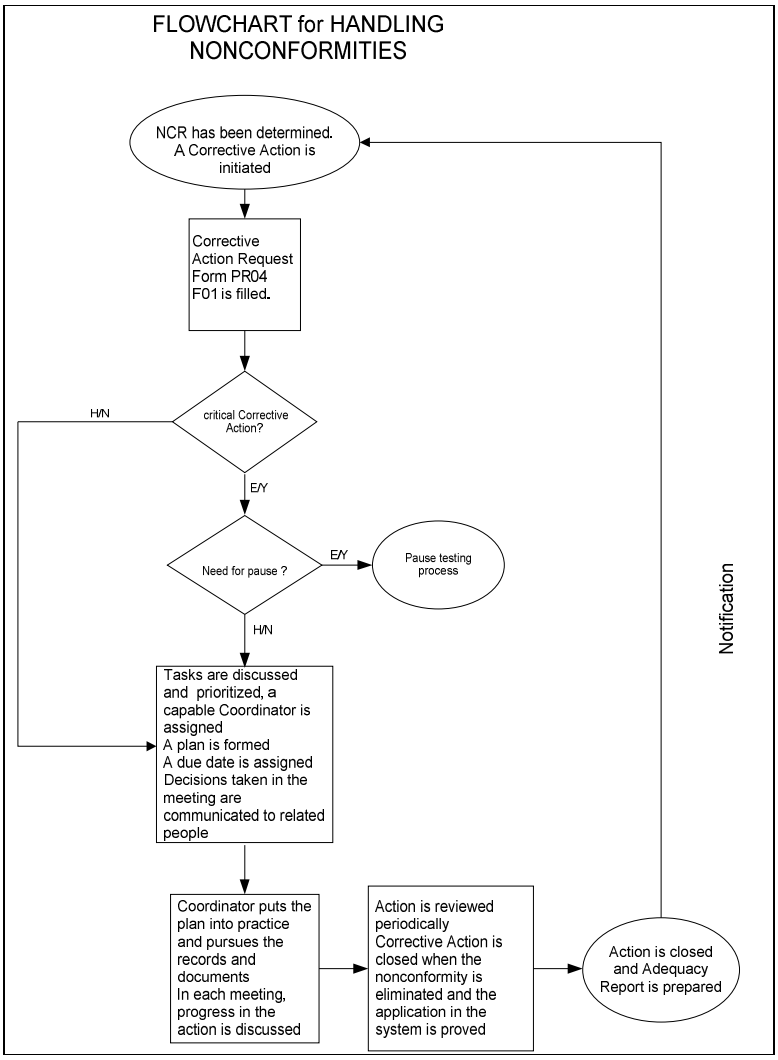
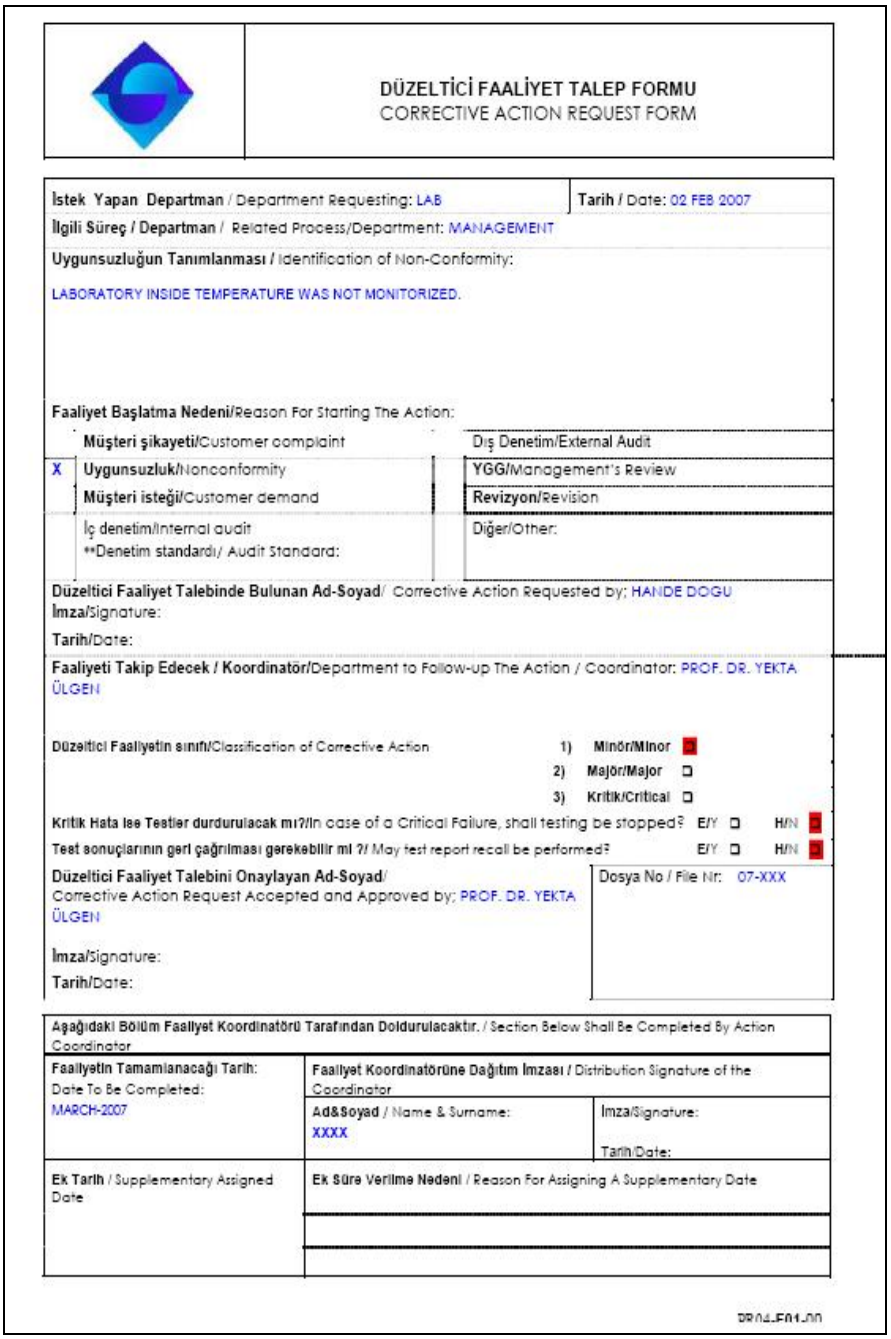


Figure G.1: Flowchart for Handling Nonconformities.

Besides, I prepared a “Corrective Action Request form” for recording the details of nonconformity (Sample is given in the Appendix C). I filled up the form for an example;



DÜZELTİCİ FAALİYET TALEP FORMU
CORRECTIVE ACTION REQUEST FORM

İstek Yapan Departman / Department Requesting: LAB | **Tarih** / Date: 02 FEB 2007

İlgili Süreç / Departman / Related Process/Department: MANAGEMENT

Uygunsuzluğun Tanımlanması / Identification of Non-Conformity:

LABORATORY INSIDE TEMPERATURE WAS NOT MONITORIZED.

Faaliyet Başlatma Nedeni/Reason For Starting The Action:

	Müşteri şikayeti/Customer complaint	Dış Denetim/External Audit
X	**Uygunsuzluk**/Nonconformity	**YGG**/Management's Review
	Müşteri isteği/Customer demand	**Revizyon**/Revision
	İç denetim/Internal audit **Denetim standardı/ Audit Standard:	Diğer/Other:

Düzeltici Faaliyet Talebinde Bulunan Ad-Soyad/ Corrective Action Requested by: HANDE DOGU
İmza/Signature:
Tarih/Date:

Faaliyeti Takip Edecek / Koordinatör/Department to Follow-up The Action / Coordinator: PROF. DR. YEKTA ÜLGEN

Düzeltici Faaliyetin sınıfı/Classification of Corrective Action
1) **Minör/Minor** ☒
2) **Majör/Major** ☐
3) **Kritik/Critical** ☐

Kritik Hata ise Testler durdurulacak mı?/In case of a Critical Failure, shall testing be stopped? E/Y ☐ H/N ☒
Test sonuçlarının geri çağrılması gerekebilir mi ?/ May test report recall be performed? E/Y ☐ H/N ☒

Düzeltici Faaliyet Talebini Onaylayan Ad-Soyad/ Corrective Action Request Accepted and Approved by: PROF. DR. YEKTA ÜLGEN
İmza/Signature:
Tarih/Date:

Dosya No / File Nr: 07-XXX

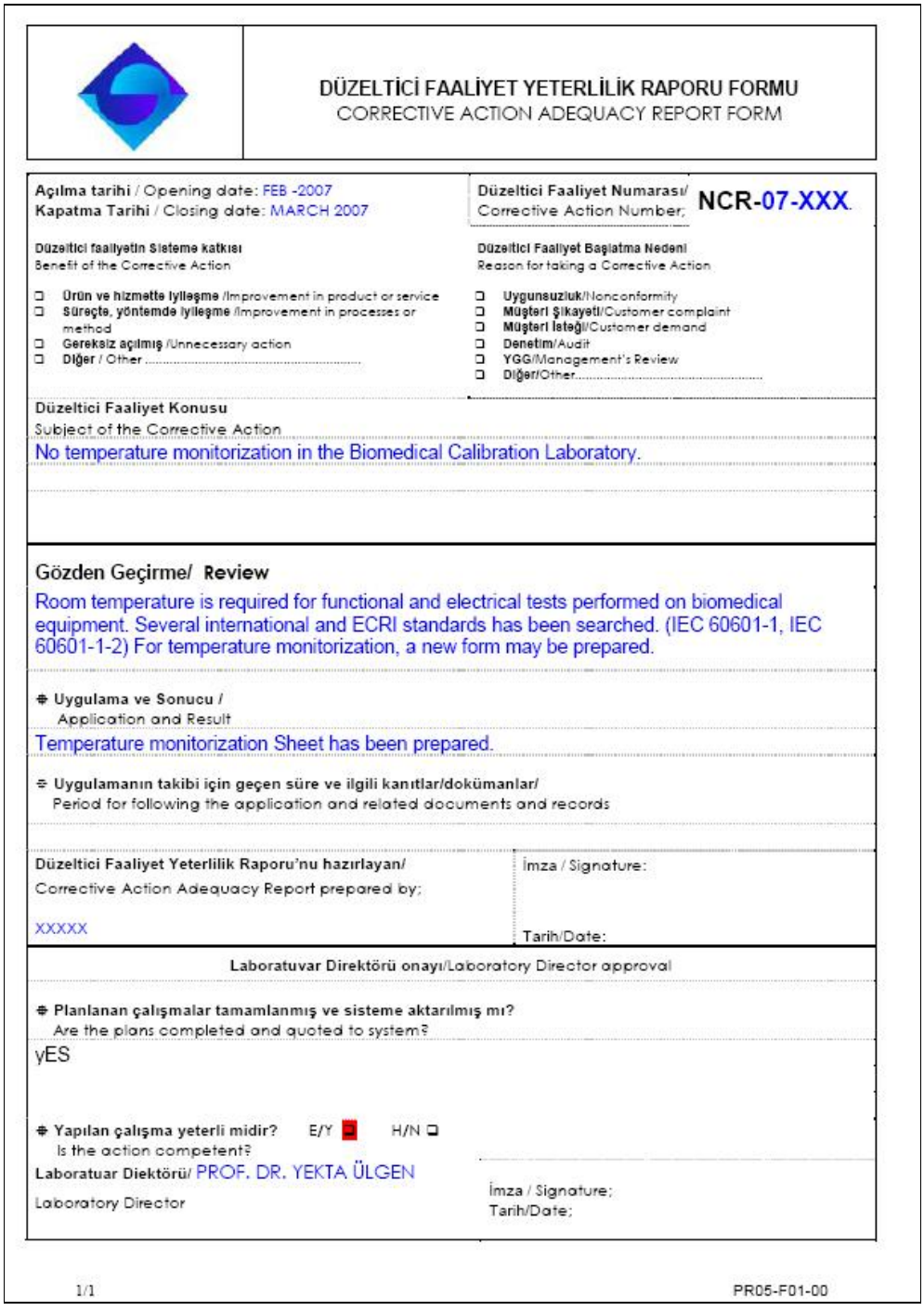
Aşağıdaki Bölüm Faaliyet Koordinatörü Tarafından Doldurulacaktır. / Section Below Shall Be Completed By Action Coordinator

Faaliyetin Tamamlanacağı Tarih: Date To Be Completed: MARCH-2007	**Faaliyet Koordinatörüne Dağıtım İmzası** / Distribution Signature of the Coordinator	
	Ad&Soyad / Name & Surname: XXXX	İmza/Signature: Tarih/Date:
Ek Tarih / Supplementary Assigned Date	**Ek Süre Verilme Nedeni** / Reason For Assigning A Supplementary Date	

PR04-F01-00

Figure G2: Sample Report for Handling Nonconformities

And when I followed up the PR 05, Corrective Action Procedure requirements step by step, I need to prepare "Corrective Action Adequacy Report." form. The following example shows us how to implement the system for the same problem "Monitorization of laboratory temperature".



DÜZELTİCİ FAALİYET YETERLİLİK RAPORU FORMU
CORRECTIVE ACTION ADEQUACY REPORT FORM

Açılma tarihi / Opening date: FEB -2007
Kapatma Tarihi / Closing date: MARCH 2007

Düzeltici Faaliyet Numarası/ Corrective Action Number: **NCR-07-XXX**

Düzeltici faaliyetin Sisteme katkısı
Benefit of the Corrective Action

- ❑ **Ürün ve hizmette iyileşme** /Improvement in product or service
- ❑ **Süreçte, yöntemde iyileşme** /Improvement in processes or method
- ❑ **Gereksiz açılmış** /Unnecessary action
- ❑ **Diğer** / Other .....

Düzeltici Faaliyet Başlatma Nedeni
Reason for taking a Corrective Action

- ❑ **Uygunsuzluk**/Nonconformity
- ❑ **Müşteri Şikayeti**/Customer complaint
- ❑ **Müşteri İsteği**/Customer demand
- ❑ **Denetim**/Audit
- ❑ **YGG**/Management's Review
- ❑ **Diğer**/Other.....

Düzeltici Faaliyet Konusu
Subject of the Corrective Action

No temperature monitorization in the Biomedical Calibration Laboratory.

Gözden Geçirme/ Review

Room temperature is required for functional and electrical tests performed on biomedical equipment. Several international and ECRI standards has been searched. (IEC 60601-1, IEC 60601-1-2) For temperature monitorization, a new form may be prepared.

Uygulama ve Sonucu /
Application and Result

Temperature monitorization Sheet has been prepared.

Uygulamanın takibi için geçen süre ve ilgili kanıtlar/dokümanlar/
Period for following the application and related documents and records

Düzeltici Faaliyet Yeterlilik Raporu'nu hazırlayan/
Corrective Action Adequacy Report prepared by:

XXXXX

İmza / Signature:

Tarih/Date:

Laboratuvar Direktörü onayı/Laboratory Director approval

Planlanan çalışmalar tamamlanmış ve sisteme aktarılmış mı?
Are the plans completed and quoted to system?

yES

Yapılan çalışma yeterli midir? E/Y ■ H/N ❑
Is the action competent?

Laboratuar Diektörü/ PROF. DR. YEKTA ÜLGEN
Laboratory Director

İmza / Signature;
Tarih/Date;

1/1 PR05-F01-00

Figure G3: Sample Adequacy Report for Handling Corrective Action.

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