JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPRIETORSHIP LLC

QUALITY MANAGEMENT SYSTEM – MANUAL

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0. Introduction

Company Address-	JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC P.O Box 145843 Mussafah West, MW-5 ABU DHABI, UAE	
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E-mail	jacob@jacobptp.com	
Number of Employees	12	
Shift Operations	**Start Time**	**End Time**
General Shift	8:00 AM	5:30 PM

Legal Compliance Areas
JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC has following recognitions / Certifications from Governmental agencies: ▪ Commercial license

1 Scope

The scope of this quality management system manual is to demonstrate JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC's ability to consistently provide Laboratory services that meet customer and applicable statutory and regulatory requirements. This quality management system manual will provide the information about how JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC's enhances customer satisfaction through the effective application of the system.

2 Normative references

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

TERM	DEFINITIONS
	JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC
Audit	An audit is a systematic evidence gathering process. Audits must be independent and evidence must be evaluated objectively to determine how well audit criteria are being met. There are three types of audits: first-party, second-party, and third-party. First-party audits are internal audits while second and third party audits are external audits.
Audit criteria	Audit criteria are used as a reference point and include policies, requirements, and other forms of documented information. They are compared against audit evidence to determine how well they are being met. Audit evidence is used to determine how well policies are being implemented and how well requirements are being followed.
Audit evidence	Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, requirements, and other documented information.
Audit findings	Audit findings result from a process that evaluates audit evidence and compares it against audit criteria. Audit findings can show that audit criteria are being met (conformity) or that they are not being met (nonconformity). They can also identify best practices or improvement opportunities.
Audit program	An audit program (or programme) refers to a set of one or more audits that are planned and carried out within a specific time frame and are intended to achieve a specific audit purpose.
Characteristic	A characteristic is a distinctive feature or property of something. Characteristics can be inherent or assigned and can be qualitative or quantitative. An inherent characteristic exists in something or is a permanent feature of something while an assigned characteristic is a feature that is attributed or attached to something.
Competence	Competence means being able to apply knowledge and skill to achieve intended results. Being competent means having the knowledge and skill that you need and knowing how to apply it. Being competent means that you're qualified to do the job.
Complaint	In the context of ISO 9001, a complaint refers to an expression of dissatisfaction with a product or service and is filed by a customer and received by an organization. Whenever a customer lodges a complaint, a response is either explicitly or implicitly required.
Concession	A concession is a special approval that is granted to release a nonconforming product or service for use or delivery. Concessions are usually restricted to a specific use and limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.
Conformity	Conformity is the "fulfilment of a requirement". To conform means to meet or comply with requirements and a requirement is a need, expectation, or obligation. There are many types of requirements

	including customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.
Context of the organization	An organization's context is its business environment. It includes all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.
Continual improvement	Continual improvement is a set of recurring activities that are carried out in order to enhance performance. Continual improvements can be achieved by carrying out audits, self-assessments, and management reviews. Continual improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions.
Contract	A contract is a binding agreement between two or more parties.
Correction	A correction is any action that is taken to eliminate a non conformity. However, corrections do not address root causes. When applied to products, corrections can include reworking products, reprocessing them, regarding them, assigning them to a different use, or simply destroying them
Corrective action	Corrective actions are steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations don't happen again.
Customer	A customer is anyone who receives products or services (outputs) from a supplier. Customers can be either people or organizations and can be either external or internal to the supplier organization. Examples of customers include clients, consumers, users, guests, patients, purchasers, and beneficiaries.
Customer satisfaction	Customer satisfaction is a perception. It's also a question of degree. It can vary from high satisfaction to low satisfaction. If customers believe that you've met their requirements, they experience high satisfaction. If they believe that you've not met their requirements, they experience low satisfaction
Data	The term data is defined as any facts about an object.
Defect	A defect is a type of nonconformity. It occurs when a product or service fails to meet specified or intended use requirements.
Design and development	Design and development is a process (or a set of processes) that uses resources to transform general input requirements for an object into specific output requirements.
Determination	To determine means to find or to identify the value of a characteristic
Documented information	The term documented information refers to information that must be controlled and maintained and its supporting medium. Documented information can be in any format and on any medium and can come from any source.
Effectiveness	Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are actually carried out and planned results are effective if these results are actually achieved.

Feedback	The term feedback is used to refer to a comment or an opinion expressed about a product or service or an interest expressed in a product or a service. It may also be used to refer to the customer complaints-handling process itself.
Improvement	Improvement is a set of activities that organizations carry out in order to enhance performance (get better results). Improvement can be achieved by means of a single activity or by means of a recurring set of activities.
Information system	In the context of this ISO 9001 standard, an information system is a network of communication channels used within an organization.
Interested party	An interested party is anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An interested party is a person, group, or organization that has an interest or a stake in a decision or activity.
Management	The term management refers to all the activities that are used to coordinate, direct, and control organizations. These activities include developing policies, setting objectives, and establishing processes to achieve these objectives. In this context, the term management does not refer to people. It refers to what managers do.
Measuring equipment	Measuring equipment includes all the things needed to carry out a measurement process. Accordingly, measuring equipment includes instruments and apparatuses as well as all the associated software, standards, and reference materials.
Nonconformity	Nonconformity is a non fulfilment or failure to meet a requirement. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization or interested parties.
Objective	An objective is a result you intend to achieve. Objectives can be strategic, tactical, or operational and can apply to an organization as a whole or to a system, process, project, product, or service. Objectives may also be referred to as targets, aims, goals, or intended outcomes.
Objective evidence	Objective evidence is data that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or using other suitable methods.
Policy	A policy is a general commitment, direction, or intention and is formally stated by top management. A quality policy statement should express top management's commitment to the implementation and improvement of its quality management system and should allow managers to set quality objectives.
Product	A product is a tangible or intangible output that is the result of a process that does not include activities that are performed at the interface between the supplier (provider) and the customer.
Quality	The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfils a set of requirements. An object is any entity that is either conceivable or perceivable and an inherent characteristic is a feature that exists in an object
Quality management system	A quality management system (QMS) is a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, practices, procedures, plans, rules, roles, responsibilities, relationships,

	contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.
Quality objective	A quality objective is a quality result that you intend to achieve. Quality objectives are based on or derived from an organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.
Quality policy	A quality policy should express top management's commitment to the quality management system (QMS) and should allow managers to set quality objectives. It should be based on ISO's quality management principles and should be compatible with your organization's other policies and be consistent with its vision and mission.
Risk-based thinking	Risk-based thinking refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives. Risk-based thinking replaces what the old standard used to call preventive action.
Service	A service is an intangible output and is the result of a process that includes at least one activity that is carried out at the interface between the supplier (provider) and the customer.
Supplier	A supplier is a person or an organization that provides products or services. Suppliers can be either internal or external to an organization. Internal suppliers provide products or services to people within their own organization while external suppliers provide products or services to other organizations.
Top management	The term top management normally refers to the people at the top of an organization. It refers to the people who provide resources and delegate authority and who coordinate, direct, and control organizations.
Validation	Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment.
Verification	Verification is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved.

4 Context of the Organization

4.1 Understanding the Organization and its Context

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC determined the internal and external issues which have ability to affect on achieving its intended results of its quality management system. conducted a detailed analysis by considering the external and internal issues, and maintained. JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC is planned to periodically review this data during the management review meeting.

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC considered the positive and negative issues, which rose from external or internal origin while understanding the context. The main sources of issues from external origin are already identified by and are from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
The internal issues which identified are related to values, culture, knowledge and performance of the organization.

4.2 Understanding the Needs and Expectations of Interested Parties

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC documented and maintained the expectation of the interested parties which may affect or potential effect on ability to consistently provide Laboratory services that meet customer and applicable statutory and regulatory requirements. maintained a document which contains the interested parties and the interest of them; will review and monitor this information Semi-annually.

Refer: Procedure for Understanding the Context of Organization

4.3 Determining the Scope of the Quality Management System

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC considered the external and internal issues, requirements of relevant interested parties in its operation in providing Laboratory services while determining the scope of its Quality Management system. And the following services are included under the scope of :

- Quality and Standardization Certificates Issuing Services
- Proficiency Testing Provider Services (PTP)

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC applied all the requirements of ISO 9001:2015 as they are applicable within the determined scope of its quality management system.

4.4 Quality Management System and Its Processes

To implement the quality management system, JPTPS has managed to:

- Identify the inputs required and the outputs expected from these processes;
- Determine the sequence and interaction of these processes
- Determine criteria and methods required to ensure the effective operation and control of these processes
- determine the resources needed for these processes and ensure their availability;
- assign the responsibilities and authorities for these processes;
- address the risks and opportunities as determined
- Implement actions necessary to achieve the planned results and continual improvement

5 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management is fully committed to quality and demonstrates its commitment to the development and continually improvement of the quality management system by:

- taking accountability for the effectiveness of the quality management system;
- ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization
- ensuring the integration of the quality management system requirements into the organization's business processes;
- promoting the use of the process approach and risk-based thinking;
- ensuring that the resources needed for the quality management system are available;
- communicating the importance of effective quality management and of conforming to the quality management system requirements;
- ensuring that the quality management system achieves its intended results;
- engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- promoting improvement;
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

JPTPS Top management determines appropriate customer and applicable statutory and regulatory requirements to comply consistently. The top management determined and addressed the risks and opportunities that can affect conformity of Laboratory services and the ability to enhance customer satisfaction. The business risk assessment related to the Management are already identified and documented in JPTPS.

5.2 Policy

5.2.1 Establishing the Quality Policy

JACOB PROFICIENCY TESTING PROVIDER SERVICES-SOLE PROPERTIES LLC has established and documented its policy for quality and ensures that it:

- is appropriate to the purpose and context of the organization and supports its strategic direction;
- provides a framework for setting quality objectives;
- includes a commitment to satisfy applicable requirements;
- includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The quality policy is communicated and enforced through management reviews, training, and displays in English at appropriate locations within JPTPS. Management Representative conducts regular sessions with existing employees and new employees to ensure that all understands quality policy. The quality policy is displayed in the organization profile and uploaded in the organization's website. The quality policy is reviewed at least once in a year, in the management review meetings for its continuous suitability and improvement

5.3 Organizational Roles, Responsibilities and Authorities

The responsibilities and authorities for relevant roles are assigned in JPTPS and it is documented as Organization Chart.
The responsibility and authority of different personnel within the organization shall be detailed in the Job Description issued to each personnel performing the jobs affecting the product quality. (Refer: Job Descriptions)

A brief description of responsibilities for effective implementation of the Quality System is as given below:

Sl No.	Personnel	Responsibilities for Quality Activities
1.	MANAGING DIRECTOR	Quality Policy, Management Review, Contract Review, Legal Requirement Review, Risk Register. Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented
2.	Management Representative	Quality System, Internal Quality Audit, Handling of Customer Complaints, Training, Maintenance of Quality Record. Reporting on the performance of the quality management system and on opportunities for improvement in particular to top management
3.	Marketing Head	ensuring the promotion of customer focus throughout the organization
4.	Laboratory manager	Ensuring the processes is delivering their intended outputs.
5.	Senior Supervisor	Ensuring the processes is delivering their intended outputs.

6 Planning

6.1 Actions to Address Risks and Opportunities

The top management of JPTPS planned the Quality Management system based on the identified risks and opportunities to

- give assurance that the quality management system can achieve its intended results;
- enhance desirable effects;
- prevent, or reduce, undesired effects;
- Achieve improvement.

The risk assessment prepared will be used as the guiding document while planning the Quality management system. JPTPS planned some actions to address all these identified risks and opportunities; and to integrate it with the quality management system activities.

Most of the risks are planned to remove through regular training and proper monitoring and control operations.

Refer: Risk Assessment

6.2 Quality Objectives and Planning to Achieve Them

Top management has established quality objectives at appropriate functions and levels within JPTPS. These objectives are defined in measurable terms and are the interpretation goals of policy deployment in each department. The objectives are

consistent with the quality policy and the commitment to continual improvement and meeting requirements for Laboratory services. Top management established quality objectives for each department in order to remove the negative issues as much as possible.

Top management will try to achieve above quality objectives in coming years to secure the rights of its customers.

Refer: Quality Objective

6.3 Planning of changes

Top management has established a proper planning to carry out the changes in Quality management System, if it is necessary to change it. And the planning for the changes are based on the

- the purpose of the changes and their potential consequences;
- the integrity of the quality management system;
- the availability of resources;
- the allocation or reallocation of responsibilities and authorities.

7. Support
7.1 Resources
7.1.1 General

Top Management determined and provided the resources needed for the establishment, Implementation, maintenance and continual improvement of the quality management system based on:

- the capabilities of, and constraints on, existing internal resources;
- What needs to be obtained from external providers

Top management of JPTPS created the organization chart that shows the structure of its organization and the relationships and relative ranks of its parts and positions.

7.1.2 People
7.1.3 Infrastructure

Top Management determined and provided the persons and Infrastructure necessary for the effective implementation of its quality management system and for the operation and control of its processes. The top management is always made available the new and modern software and electronic equipment to its people who required it. For the Laboratory requirement, JPTPS management appointed a proper management with necessary quantity of vehicle.

7.1.4 Environment for the operation of processes

Top management provided a suitable environment of combination of human and physical factors, such as social, psychological and physical, for the operation of its processes.

7.1.5 Monitoring and Measuring Resources
7.1.5.1 General
7.1.5.2 Measurement Traceability

7.1.6 Organizational Knowledge

Top Management of JPTPS determined the knowledge necessary for the operation of its processes and to achieve conformity of Laboratory services and it is maintained update on any new changes. Organizational knowledge is knowledge specific to JPTPS; it is generally gained by experience. It is information that is used and shared to achieve the Quality objectives. This organizational knowledge normally obtained from the:

- internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes);
- External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

Top management always maintained to have competent persons to be hired in the organization for doing work under its control that affects the performance and effectiveness of the quality management system. Top management preferred to hire the persons are competent on the basis of appropriate education, training, or experience. And provide training to the employees for improving the competency and maintain a record of it. The evaluation of the effectiveness of training is also conducted.

Top management determined to conduct a competency evaluation for all the employees at the time of joining and maintained a record of it.

Refer: Resource Management Procedure

7.3 Awareness

The training programme for the whole organization is planned by JPTPS top management to ensure the awareness of the employees working under the control of it. A planning process is being implemented which ensures the proper training, awareness and competence development of people. JPTPS ensured the whole employees must be aware about the following details:

- The quality policy;
- Relevant quality objectives;
- Their contribution to the effectiveness of the quality management system, including the :benefits of improved performance;

- The implications of not conforming with the quality management system requirements.

Refer: Resource Management Procedure

7.4 Communication

JPTPS has established and maintains a procedure for internal and external communication between various levels and functions regarding the quality management system and its effectiveness. This ensures that the quality policy, goals, procedures, and records are properly communicated to relevant persons on time to keep them fully aware.

The communication procedure was clarifying the following details:

- On what it will communicate;
- When to communicate;
- With whom to communicate;
- How to communicate;
- Who communicate

7.5 Documented information
7.5.1 General

The documented information of JPTPS include, documented information required by this ISO 9001:2015 and documented information determined by the organization as being necessary for the effectiveness of the quality management system.

The quality management system documentation includes:

- Documented statements of a quality policy and quality objectives.
- A quality manual
- Documented procedures
- Business Risk Assessment
- Organizational Knowledge

7.5.2 Creating and Updating

The top management of JPTPS determined the some criteria for creating and updating the documented information.
For the identification and description documented information, it decided to include a title, date and reference number.

SN	PUPOSE	ACTION/DETAILS
1	Identification and description	A title, date and reference number
2	Format	English
3	Media	Paper and Electronic
4	Suitability and adequacy	Review - By the Quality Manager Approval– MANAGING DIRECTOR

7.5.3 Control of Documented Information

The top management of JPTPS determined to control the documented information required by the quality management system and by this International Standard. To ensure that documented information of internal and external origin determined by JPTPS to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and JPTPS has established a procedure for controlling documents used in its quality management system. This control ensures that:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

8 Operation

8.1 Operational Planning and Control

The top management of JPTPS determined and planned to implement and control the processes needed to meet the requirements for the provision of Laboratory services to its valued customers. While creating the plan, the Top management and operations department considered the following criteria to meet the requirements of customers.

a) Determined the requirements for the Laboratory services;
b) Establishing criteria for:
   1) The processes;
   2) The acceptance of Laboratory services;
c) Determining the resources needed to achieve conformity to the service requirements;
d) Implementing control of the processes in accordance with the criteria;
e) Determining, maintaining and retaining documented information to the extent necessary:
   1) To have confidence that the processes have been carried out as planned;
   2) To demonstrate the conformity of services to their requirements.

8.2 Requirements for Products and Services

8.2.1 Customer communication

JPTPS has defined and implements effective liaison with customers, with the aim of meeting customer requirements. JPTPS has defined communication requirements relating to:

a) Providing information relating to Laboratory services;
b) Handling enquiries, contracts or orders, including changes;
c) Obtaining customer feedback relating to products and services, including customer complaints;
d) Handling or controlling customer property;
e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Services

JPTPS measures the needs of customers and determines:

- Requirements specified by the customer including the requirements for submitting and post-submitting activities
- Requirements not stated by the customer but necessary for specified or intended use
- Statutory and regulatory requirements related to the product
- The organization can meet the claims for the products and services it offers.

8.2.3 Review of the Requirements for Products and Services

The management reviews the customer requirements related to the service demanded. The management ensures the review prior to commitment to provide Laboratory services to the customer during review management ensures that:

- Laboratory services and documentation requirements are clearly defined Where the customer provides no written statement of requirement, the order requirements are confirmed before acceptance
- Contract or order requirements differing from those previously expressed, e.g. in a tender or quotation, are resolved

The results of reviews and subsequent follow-up actions are recorded. JPTPS ensures that relevant documentation is amended on changes in service requirements. The changed requirements are communicated to all relevant personnel.

8.2.4 Changes to Requirements for Products and Services

When the requirements for services are changed, the top management of JPTPS ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements. This information will be communicated to each consultant by the Laboratory manager.

8.3 Design and Development of Products and Services

This clause was excluded from the manual as per the scope of activities of JPTPS

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

JPTPS top management determined that. externally provided processes, products and services conform to requirements. JPTPS top management determined the controls to be applied to externally provided processes, services when:

a) Services from external providers are intended for incorporation into the organization's own products and services;
b) Services are provided directly to the customer(s) by external providers on behalf of the organization;
c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

8.4.2 Type and Extent of Control

JPTPS top management determined that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming Laboratory services to its customers.

JPTPS top management determined to:

a) Ensure that externally provided processes remain within the control of its quality management system;
b) Defined both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) Took into consideration:
    1) The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
    2) The effectiveness of the controls applied by the external provider;
d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for External Providers

JPTPS top management determined the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, services to be provided;

b) the approval of:
   1) Laboratory services;
   2) Methods, processes and Documents;
   3) The release of Documents and services;
c) Competence, including any required qualification of persons;
d) The external providers' interactions with the organization;
e) Control and monitoring of the external providers' performance to be applied by the organization;
f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

JPTPS top management determined to implement Laboratory service provision under controlled conditions.
Controlled conditions shall include, as applicable:
   a) The availability of documented information that defines:
   b) The availability and use of suitable monitoring and measuring resources;
   c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
   d) The use of suitable infrastructure and environment for the operation of processes;
   e) The appointment of competent persons, including any required qualification;
   f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
   g) The implementation of actions to prevent human error;
   h) The implementation of release, delivery and post-delivery activities.

8.5.2 Identification and Traceability

JPTPS top management determined to use suitable means to identify outputs when it is necessary to ensure the conformity of documentation and Laboratory services.
JPTPS top management determined to identify the status of outputs with respect to monitoring and measurement requirements throughout service provision.

8.5.4 Preservation

JPTPS top management determined to preserve the outputs during Laboratory service provision, to the extent necessary to ensure conformity to requirements.

8.5.5 Post-delivery Activities

JPTPS top management determined to meet requirements for post-delivery activities associated with the services.

In determining the extent of post-delivery activities that are required, JPTPS top management considered:
a) Statutory and regulatory requirements;
b) The potential undesired consequences associated with its services;
c) The nature, use and intended lifetime of its services;
d) Customer requirements;
e) Customer feedback.

8.5.6 Control of Changes

JPTPS top management determined to review and control changes for service provision, to the extent necessary to ensure continuing conformity with requirements. JPTPS top management determined to retain documented information describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

JPTPS top management determined to implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

JPTPS top management determined to retain documented information on the release of products and services. The documented information shall include:
a) Evidence of conformity with the acceptance criteria;
b) Traceability to the person(s) authorizing the release.

8.7 Control of Nonconforming Outputs

8.7.1 JPTPS top management determined to ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.
JPTPS top management determined to take appropriate action based on the nature of the nonconformity and its effect on the conformity of documents and Laboratory services. This shall also apply to nonconforming services detected after delivery of services, during or after the provision of services.

JPTPS operation department shall deal with nonconforming outputs in one or more of the following ways:
a) Correction;
b) Informing the customer;
c) Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 JPTPS top management determined to retain documented information that:

a) Describes the nonconformity;
b) Describes the actions taken;
c) Describes any concessions obtained;
d) Identifies the authority deciding the action in respect of the nonconformity.

9 Performance Evaluations

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

JPTPS top management determined:
a) What needs to be monitored and measured;
b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) When the monitoring and measuring shall be performed;
d) When the results from monitoring and measurement shall be analysed and evaluated.

JPTPS top management determined to evaluate the performance and the effectiveness of the quality management system.
JPTPS top management determined to retain appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

JPTPS top management determined to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. JPTPS top management determined the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis and Evaluation

JPTPS top management determined to analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) Conformity of Laboratory services;
b) The degree of customer satisfaction;
c) The performance and effectiveness of the quality management system;
d) If planning has been implemented effectively;
e) The effectiveness of actions taken to address risks and opportunities;
f) The performance of external providers;

g) The need for improvements to the quality management system.

9.2 Internal audit

The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements have been met. JPTPS has established a process for performing internal audits in order to determine if the quality management system:

- Conforms to the requirements of this international standard
- Has been effectively implemented and maintained.

Addition of a requirement that the management team in the area being audited is responsible for "necessary corrections and corrective actions."

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

JPTPS plans audit program, which is based on the status and importance of the activities, areas or items to be audited, and the results of previous audits. JPTPS has documented and implemented internal audit process that covers the audit scope, frequency and methodologies, as well as the responsibilities, requirements for conducting audits, recording and reporting results to management.

Audits are performed by personnel other than those who performed the work being audited. The management takes timely corrective actions on deficiencies found during audit. Follow up actions includes the verification of the implementation of corrective action and the reporting of verification results.

9.3 Management review

9.3.1 General

JPTPS will review the quality management system after the complete execution of internal audit. These reviews ensure the continuing suitability, adequacy and effectiveness of the whole quality management system.
The review includes evaluation of the need for changes to quality management system, including quality policy and quality objectives.

9.3.2 Management review inputs

The management reviews include periodic review of current performance and improvement opportunities related to:

a) The status of actions from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system;
c) Information on the performance and effectiveness of the quality management system, including trends in:

1) Customer satisfaction and feedback from relevant interested parties;
2) The extent to which quality objectives have been met;
3) Process performance and conformity of products and services;
4) Nonconformities and corrective actions;
5) Monitoring and measurement results;
6) Audit results;
7) The performance of external providers;

d) The adequacy of resources;
e) The effectiveness of actions taken to address risks and opportunities (see 6.1);
f) Opportunities for improvement.

9.3.3 Management review outputs

The outputs from management review include actions related to:

a) Opportunities for improvement;
b) Any need for changes to the quality management system;
c) Resource needs.

Results of management reviews are recorded.

10 Improvement

10.1 General

JPTPS top management determined and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:
a) Improving documents and services to meet requirements as well as to address future needs and expectations;
b) Correcting, preventing or reducing undesired effects;
c) Improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1 When non-conformity occurs, including any arising from complaints, the organization determined to:
a) React to the nonconformity and, as applicable:
1) Take action to control and correct it;
2) Deal with the consequences;
b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
1) Reviewing and analysing the nonconformity;
2) Determining the causes of the nonconformity;
3) Determining if similar nonconformities exist, or could potentially occur;
c) Implement any action needed;
d) Review the effectiveness of any corrective action taken;
e) Update risks and opportunities determined during planning, if necessary;
f) Make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 JPTPS top management determined to retain documented information as evidence of:

a) The nature of the nonconformities and any subsequent actions taken;
b) The results of any corrective action.

10.3 Continual improvement

JPTPS top management determined to continually improve the suitability, adequacy and effectiveness of the quality management system. JPTPS top management determined to consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.