LABORATORIES
QUALITY MANUAL

Version No: 8

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This manual is issued under the authority of:

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1. Manual Introduction

a) The Saudi Food and Drug Authority (SFDA) was established under the Council of Ministers resolution no (1) dated 07/01/1424 H, as an independent body corporate that directly reports to the chairman of board of directors, the minister of health. The Authority objective is to ensure safety of food and drug for human and animal, safety of biological and chemical substance as well as electronic products as well as to set mandatory standards specifications thereof, whether they are imported or locally manufactured. The control and/or testing activities can be conducted in the SFDA or other agency's laboratories.

b) This manual has been written to give to any interested party an overview on all lab management system and more detailed information have given in related quality documents provided in annex.

c) The SFDA Laboratories established a Quality Management System to include all operations associated with its internal management because the SFDA Laboratories are not directly responsible for field sampling.

d) All personnel associated with the SFDA Laboratories are bound by the requirements set forth in the policies, processes, procedures and standard operating procedures included or referenced in this document.

e) The sections, appendixes and other information in this document are generally arranged according to the contents in Quality Systems to facilitate the audit process and ISO/IEC 17025:2017 requirements are presented in the text supported by appendixes containing information on Quality Control and Quality Assurance requirements.

f) The purpose of the SFDA Laboratories is to establish and execute a set of management policies, procedures and practices that together providing a foundation for producing analytical results that are consistent and meet the data quality needs of our customer's field.

g) The quality management system of SFDA Laboratories lays down to fulfill the requirements of the international standard ISO/IEC 17025:2017.

h) The SFDA Laboratories operates under Saudi Food and Drug Authority (SFDA) mission by driving focus of the laboratory's efforts and purpose for being.

i) The primary mission of the SFDA Laboratories is to support SFDA programs that require long term, consistent, analytical data of known quality for use in national assessment and trends analysis.

j) To this end, the laboratories use its three most important strengths (people, quality and safety) to provide consistent, high quality analytical data, new analytical methods.

k) This version of quality manual is unified to all SFDA Laboratories and superseded all quality manuals previous versions, and all document effected will be updated according to the last version.

2. Quality Policy

a) The general policy of the SFDA Laboratories is to provide analytical results that meet established standards for consistency, accuracy, defensibility and fitness for purpose, and to ensure that the data obtained are suitable for decision making to providing the best possible value to our customers.

b) Special test emphasis has to be paid to the accuracy when the analytical result approaches the maximum permissible limit.

c) Our commitment to customers is professional, confidential, honest and forthright service, adhering to the highest levels of business ethics.

d) Consistently high standards are achieved through the diligent application of Quality System that documents the approved standard for each operation performed by qualified Laboratories Analysts and personnel.

e) All staff has to know their responsibilities and strictly follow their job description and is well motivated to maintain the high quality of analytical services. They are always free from any undue commercial, financial and any other pressure which might influence their technical judgment. The SFDA and management of laboratory do not make pressures on lab staff and they are completely free to exercise their professional judgment. The lab doesn't differentiate between full time employees and contract personnel and all are treated equally. Supervision, training and competence are documented for all staff.

f) SFDA employees must not be engaged in any activities that may affect the trust in their independence of judgment and integrity in relation to the laboratories testing activities.

g) The quality program ensures:
   a. Customer samples integrity from time of reception to customer acceptance of the final data.
   b. Customer samples are analyzed using our validated test methods on properly maintained and calibrated instruments.
   c. The data has been consistently characterized, quantified, validated and checked to our high quality standards.

h) All samples are analyzed in under quality control analysis system. The result of batch quality control samples is used to assess the sample data quality and are provided to clients with sample results.

i) Our key quality policies meet or exceed the requirements of international standards ISO/IEC 17025:2017 and accreditation body. Analytical processes that laboratories employ are audited internally by SFDA auditors, and externally by accreditation body. In addition, all processes are continually reviewed to ensure adherence and improvement upon the Quality System.

3. General Requirements

3.1.Impartiality

SFDA Labs should act to impartiality in all activities. The SFDA labs have no direct contact with external costumers. It is the policy of SFDA laboratories, which is stated in the initial contract, signed by the employ through HR department that the staff must not take any funds or gifts from customers, either directly or indirectly, for illegal payments of any kind, including bribes or "kickbacks" of funds. They take care with respect to the sharing with customers, vendors or others of certain types of information such as pricing data, avoid any conflict of interest that jeopardize our customer relationship (e.g. providing consulting/test or services, sharing confidential customer information that may impact our customer's business or reputation, participating in activities that could conflict with the best interest of SFDA or our customers, etc.).

If a risk to impartiality is identified, the laboratory demonstrates how it eliminates or minimizes such risks

3.2.Confidentiality

The lab managers shall ensure that customer confidential information and proprietary rights are respected and protected (i.e. the laboratory personnel shall not copy or otherwise reproduce any customer provided confidential or proprietary document, the returned samples were taken from the original sample and stored, maintain good communication with the customer). The lab managers ensure and protect laboratory reports, records, documents and electronic data of the instruments, equipment and the physical security of the laboratory staff. The test reports may be issued by electronic data transfer such as electronic mail as appropriate confirmation of receipt by customer. The only printed out test reports and signed are legally valid.

4. Structure Requirements

4.1.Legal identity

4.1.1. SFDA LABs is part of Research and Laboratories Sector of the SFDA which was established under the Council of Ministers resolution no (1) dated 07/01/1424 H, as an independent body corporate that directly reports to The President of Council of Ministers, the chairman of board of directors, the minister of health. The Authority objective is to ensure safety of food and drug for human and animal, and safety of biological and chemical substance as well as safety and effectiveness medical devices.

The functions of the SFDA Labs are:

- To ensure quality & efficacy of drugs beside safety. As drugs should be effective, of known quality & safe.
- To protect the community from the risks of the consumption of unsafe food, drug, and medical devices.
- To provide scientific and technical assistance as a reference body in analytical results of samples.
- To enhance the social cooperation with governmental, private, and international partners in the field of laboratories.

4.1.2. The vision of SFDA is to be the leading regional Drug Regulatory Authority for pharmaceuticals and safety of cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

4.1.3. The mission of SFDA is to protect public health by ensuring safety and quality through administration of a national regulatory system which is consistent with international best practice. Through this mission, also provides accurate and scientific-based information to the public and healthcare professionals.

4.2. Organization chart

The Organization Chart showing the general lines of management responsibilities and the place of

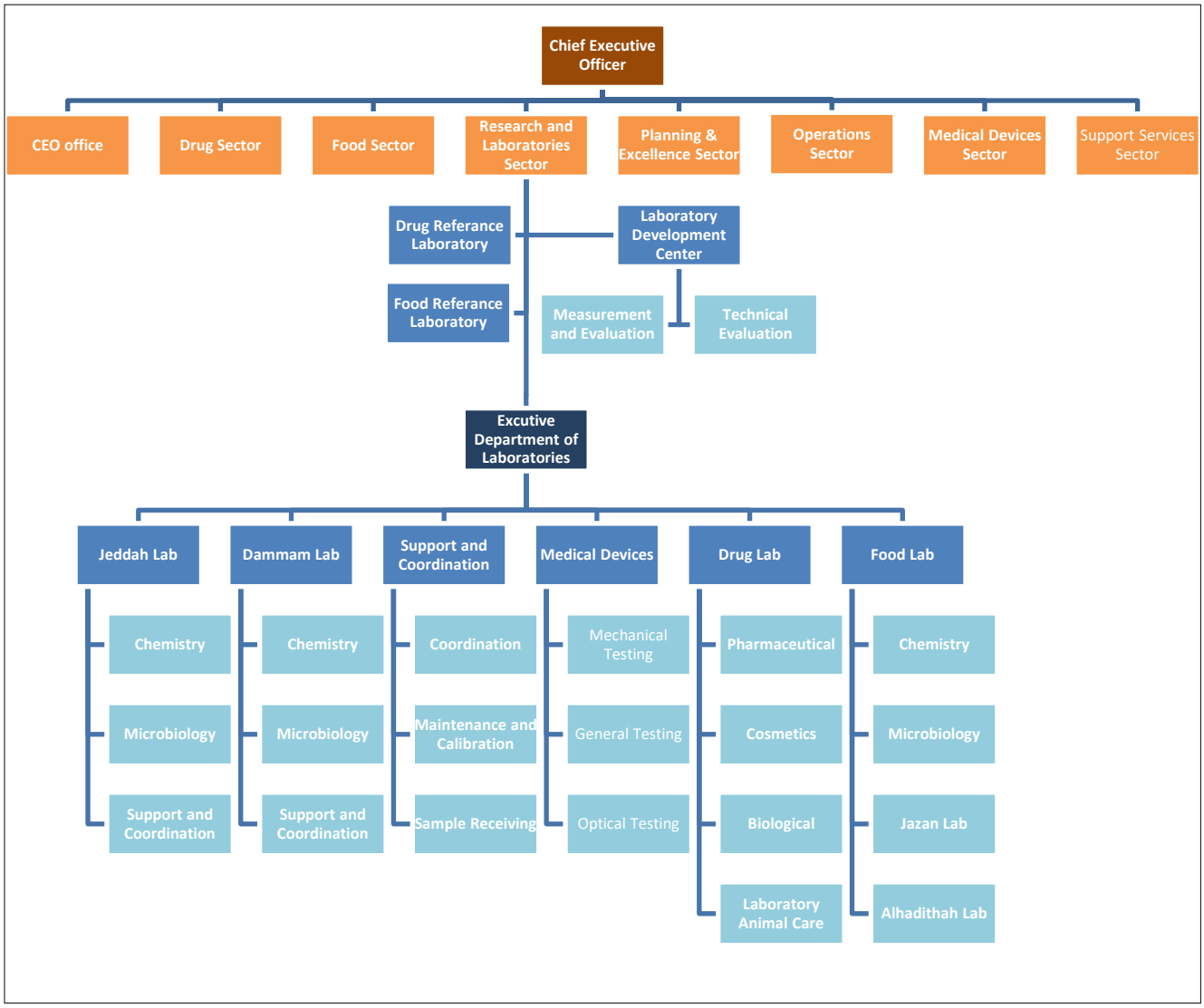

Figure 1 : Organisational chart diagram

Chief Executive Officer

a) Approval of Quality Manual.

President Assistance of Laboratories & Research Sector

a) Budget approval – sector level.

b) Strategic plans approval – sector level.

c) Annual report approval – sector level.

d) Approval of major processes changes.

e) Approving the Executive departments needs for employees recruitments.

f) Ensuring the overall continuity of work within the sector.

Executive Director of Laboratories (EDL)

a) Budget approval – EDL level.

b) Strategic plans approval – EDL level.

c) Annual report approval – EDL level.

d) Suggestion of major processes changes related to the EDL.

e) Feedback on the QMS appropriateness – EDL level.

f) Approving the departments needs for employees recruitments.

g) Approval of technical documents.

h) Ensuring the maintenance of laboratories accreditation.

i) Ensuring the overall continuity of work within the EDL.

Executive Department of Organization Excellence (EDOE)

a) Review of quality manual.

Laboratories Development Center (LDC)

a) Monitors and advice on the performance of the quality management system.

b) Coordinate with other QRs in the laboratories.

c) The authority to delegate responsibilities to the centers' staff.

d) Conducting internal audit:
- Organizing and conducting the audits;
- Choosing auditors who are independent of the specific activities being audited;

- Extended to verify that all corrective actions required by audits have been completed;
- Defining audit criteria and scope for each audit;
- Ensuring that the results of the audits are reported to relevant management.

e) Responsible for receiving customer Feedback.

f) Coordinate Training Needed.

g) Review all documents.

h) Responsible for receiving and verifying the complaint from customers.

National References laboratories (NRL)

a) Providing definite confirmation for the test results of local labs in case of disputes or request.

b) Providing training and workshops in the reference activities for the labs.

c) Method development, ring trails and method validation.

d) Conducting PT trails and statistically reporting the results.

e) Scientific and technical assistance.

f) Providing some reference materials, if needed.

Support and Coordination (Sample Receiving, Purchasing, Maintenance and Calibration)

a) Prepare lists of laboratory equipment for the analysis and inventory periodically and determine the operational status.

b) Preparation, planning, coordination and follow-up of maintenance programs (periodic and emergency) and calibration of laboratory equipment and supervision of their implementation.

c) Preparation of plans to determine the need of the executive management of laboratories and their departments of materials, machinery, spare parts and consumables necessary for maintenance.

d) Maintain the continuity of lab work by maintaining all the equipment required for maintenance.

e) Technical evaluation of the equipment to be replaced and the actual need.

f) Preparing manuals for maintenance, calibration and safety programs for laboratory equipment.

g) All samples for SFDA labs should be received first in the samples receiving section

h) Coordinate purchasing requests from laboratories.

Lab Manager (LM)

a) Authority to sign the test reports.

b) Authority to delegate responsibilities to lab staff.

c) Oversee budgeting in the lab.

d) Make sure that staff members are informed about quality management system.

e) Strategic plans approval – department level.

f) Annual report approval – department level.

g) Suggestion of major processes changes related to the department.

h) Approving the sections needs for employees recruitments.

i) Ensuring the maintenance of laboratory accreditation.

j) Ensuring the overall continuity of work within the department.

Section Head (SH)

a) Supervision on tests conduction and its related work in the unit.

b) Supervision and applying quality system requirement in the unit.

c) Prepare plan for analyst training.

d) Request and follow up unit needs.

e) Ensure the technician competence.

f) Identify non-conformities, prepare and evaluate of corrective actions.

g) Review final test results.

Quality Representative (QR)

a) Appointed by lab manager and has direct access to the Laboratories Development Center and to the highest level of management in the laboratories at which decision are made on laboratories policy or resources.

b) Coordinates the activities required to meet quality standards.

c) Monitors and advice on the performance of the quality management system.

d) Cooperates with staff in the lab to ensure that the quality assurance and quality control systems are functioning properly.

e) Has direct access to the section heads.

f) Recommend to the lab manager that a task be stopped or that results not be forwarded if non-compliance with the quality management rules established in this manual is noticed.

g) Where appropriate, the QR advise on changes and their implementation and provides training, tools and techniques to enable others to achieve quality.

h) Coordinate personnel file as specified in (6.2.1 b).

5. Resource requirements

5.1.General

The laboratory has available facilities, equipment, systems and support services necessary to manage and perform its laboratory activities. Many factors determine the correctness and reliability of tests performed by LM. These factors include contributions from:

a) Personal
b) facilities and environmental conditions;
c) equipment;
d) measurement traceability;
e) Externally provided products and services.

5.2.Personnel

a) Laboratories management ensure that laboratory personnel have the knowledge, skills and abilities to perform their duties. Competence is based on education, experience, demonstrated skills and training. Staff records contain the documentation of personnel education, experience, skills and training for the position held.
   b) Trainees undergo a training program in accordance with the laboratories' "personnel and training procedure – P-009".
c) For in house training, an experienced analyst serves as the trainer. Trainees perform test analysis when training is completed and competency has been demonstrated. The trainee is considered competent after the specified criteria have been successfully met.

5.2.1. Qualification and Training

a) All staff members of the lab are selected and appointed to the recruitment rules of SFDA.
b) Personnel files, including job description, training records and other essential information are kept confidential in the office of QR.
c) staff is familiar with the latest technical and scientific developments and other subjects related to their work including:

1. Staff members of laboratories are encouraged to keep updated with the technical and scientific developments of their field with regularly reading the scientific literature, self-training and attending scientific workshops.
2. Internal seminars and lectures are regularly organized within laboratories to present new ideas, technical and scientific developments and to deepen and update the knowledge of laboratories members in the subjects included in the training programs.
3. SFDA Laboratories organize various training programs for the staff and the laboratories managers inform the laboratories employees about the relevant courses and recommend the participation.
4. Laboratories members may also request permission to attend internal or external training courses, technical or scientific seminars, conferences or workshops.

5. Applications requested will be discussed and decided by the management on a case by case basis depending on its relevance to work programs and availability of time and funds.

d) The copies of diplomas and certificates of education and attendance of training workshops, seminars or scientific conferences and the list of publications are kept in the personnel files stored in the quality manager office.
e) The external and internal trainings are recorded by the section head and approved by lab manager of the laboratories on the training record sheets and kept in the archive.
f) The staff members are responsible for submitting the new information at the latest in each year to section head for updating the personal files.
g) The laboratories managers assign an experienced staff of the lab as responsible analyst to introduce the structure, procedures of the laboratory to the new member. The introduction procedure and training is described in quality documents.
h) No member of the laboratories is allowed to undertake any critical test or operate without supervision any piece of equipment that the laboratories managers considers significant to the performance of project until the person has been fully trained and the responsible person in-charge of training and section head are satisfied that the training has been satisfactorily completed, the new member is proficient in carrying out the procedure and that fact is recorded in writing.
i) The new member and responsible analyst in-charge of training sign the records of internal proficiency tests and the authorization to perform analytical procedures which are kept together with the evaluation records in personnel file in the archive.
j) The equipment record sheets record the names of laboratories members who are authorized to use the equipment defined as significant to the performance of the relevant analyses.
k) Laboratories members receiving training in a procedure or the use of equipment which is significant to the performance of the analyses may only undertake the procedure or use of equipment whilst under the direct supervision of fully trained staff nominated by laboratory quality manager.
l) It is the combined responsibility of the individual being trained and the person providing the training to ensure that training records are up dated at the earliest opportunity.

5.2.2. Employees and Contracted Personnel

The laboratory utilizes the skills and talent of both full time employees and contract personnel. The requirements of the management system are administrated equally to both categories. No differentiation is made between the two categories of workers. Supervision, training and competence are documented for all technical and key support personnel.

5.2.3. Job Descriptions

The laboratories maintain active job descriptions for managerial, technical and key support personnel involved in tests. Job descriptions are established based on current duties and technologies utilized.

5.2.4. Management Authorization

The laboratories management authorizes identified personnel to:

a) Perform testing and calibration.
b) Issue test reports.

c) Give opinions and interpretations.
d) Operate particular types of equipment.
Records of authorizations, demonstration of competence, education, training and experience are maintained by the laboratories and dated. Training files are maintained and include these records.

5.2.5. Staff absence

a) The laboratory manager appoints one of the professional staff members of the laboratory as deputy of laboratory manager for the period of his leave or duty travel. The deputy of laboratory manager has the same rights and responsibilities as the laboratory manager except quality assurance issues in relation to his own activities. The latter issues are referred to the quality manager. In case of doubt, the deputy of laboratory manager may consult and seek advice from the SFDA laboratories managers as appropriate.

b) Any person has responsibility in the lab should have a deputy in case of absence, this deputy has all authority to perform all tasks that responsible person should do except quality assurance issues in relation to position activities. related procedure “Personnel procedure – P-009”.

5.3.Facilities and Environmental Conditions

The laboratories environmental conditions facilitate the correct performance of analytical testing. Test methods used by the laboratories include instructions addressing applicable environmental conditions.

The laboratories monitor critical environmental conditions to ensure that results and the quality of the measurement are not adversely affected or invalidated.

5.3.1. Monitoring

Environmental conditions requiring monitoring include, but are not limited to:

a) Room temperature and humidity.
b) Biosafety hoods.
c) Air sampling for microbiological contamination in microbiology areas.
d) Air filter of air conditions.
e) Metal contamination on benches and hoods in laboratories performing metal analysis.
f) Microbiological contamination on bench surfaces and hoods in microbiology laboratories.

Where environmental controls are needed the environmental conditions are recorded.
Testing activities are stopped when the environmental conditions invalidate the test results or adversely affect quality control.

5.3.2. Cross contamination

Separate areas are maintained for incompatible activities. Measures taken to prevent cross contamination include but are not limited to:

a) Chemistry laboratories are separated from microbiology laboratories.
b) Sample receiving and storage are conducted in designated areas.
c) Separate storage for standards and reference materials and cultures.
d) Microbiology media preparation and sterilization are separated from work areas.

5.3.3. Access

Laboratories are limited access areas and controlled.

5.3.4. Housekeeping

Laboratories areas are maintained clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratories operations.

Related procedure “Facilities and Environmental Conditions - P-010”.

5.4.Equipment

5.4.1. General

a) All Equipment and its software used for testing must be capable of achieving the accuracy required and must comply with specifications relevant to the tests concerned.

b) Before being placed into service, Equipment must be calibrated or checked to assure that it meets the lab requirements.

c) Regularly asked for introduction and training on software and use of equipment.

d) Related procedure “Equipment - P-013”.

5.4.2. Equipment Operation

Any equipment must be used only by persons with appropriate training. A responsible person must be assigned for each an equipment to take care of the maintenance. They must be well familiar with the operation and maintenance of the Equipment and name of the responsible persons of all equipment must be mentioned in the Equipment file. The assigned person must take care that:

a) The equipment functions properly for the intended purpose.
b) The calibration and testing of the equipment are made according to the schedules and records made into the equipment file.
c) After service the equipment is tested and calibrated if required.
d) New users are sufficiently trained.

All equipment used in the laboratories must be in good working order and there must be evidence of this. The assigned person must take care that the equipment has file and that it is properly used.

5.5.Metrological traceability

SFDA has established traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or CRM linking them to relevant primary standards of the SI units of measurement. When using external calibration services where traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by theses laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. The Equipment - P-013 gives more details.

5.6. Externally provided products and services

a) There should be a procedure which includes approved vendor list used to select and purchase services and supplies. This procedure is used for procurement, reception. Consumable materials shall be stored according to the appropriate test method.

b) Only services and supplies of the required quality shall be used. These quality requirements should be outline in detail in procedures and will identify the appropriate minimum specifications when necessary.

c) Requests should be recorded on purchasing request and contain data describing the product specifications. This record reviewed and approved for technical content prior to release by the appropriate persons.

d) The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and management system under which they were produced.

e) Where necessary supplies will be analyzing on those impurities or contaminants that may affect in the test.

f) If the manufacturer does not provide certificates or items do not have quality data, then the laboratory should reject the purchased items.

g) The laboratory shall evaluate suppliers of consumables, supplies and services that may affect the quality of testing.

h) Records shall be maintaining of these evaluations and a list of approved suppliers, only chemicals and supplies suitable for laboratory use shall be ordered.

i) The laboratories evaluate and select the suppliers on the basis to meet the requirement of ISO/IEC 17025:2017. The laboratories keep and maintain records of all approved suppliers and subcontractors.

j) Related procedure “Externally provided products and services – P-003”.

6. Process requirements

6.1. Review of requests, tenders and contracts

a) The customer should be informed of any deviation from the agreed requests or contracts.

b) If the contract needs to be amended after work has commenced, the same contract review processes shall be repeated. Any amendments shall be communicated to all relevant and affected personnel

c) The results of this process are discussed and documented as part of the laboratory’ annual management review.

d) The lab has the authority to reject the customer request according to the lab requirements.

e) Related procedure “Review of Customer Requests – P-002”.

6.2. Selection, verification and validation of methods

6.2.1. General

a) The scope of test technologies and associated method source routinely used are identified in the laboratory documentation.

b) The laboratory must use appropriate analytical methods and procedures for all tests within its scope.

c) The laboratory prefers to use methods published either in international, regional or national standards or by reputable technical organization or in relevant scientific texts or journal.

d) Laboratory developed methods or methods adopted by the lab may also be used only if they are appropriate for the intended use and if they are validated.

e) Deviation from Standard Operating Procedures (SOP) is not allowed.

f) All international, national or other recognized test methods used by the lab have to be validated and rewritten as internal Standard Operating Procedures (SOP) before applied for analysis.

g) The lab maintains procedure for estimation of the measurement uncertainty.

h) Related procedures "Validation of Analytical Methods – P-011".

6.2.2. Selection of methods

a) Laboratories methods are selected to meet the customer's needs and when the customer does not specify the method to be used, a standard method is preferred for use.

b) If a standard method is not found the laboratories may use either a non-standard method or modify a method for use with the concurrence of the customer. The non-standard or modified method must be validated.

c) The laboratories inform the customer when the method proposed is considered to be the incorrect choice for the intended purpose.

6.3. Validation and verification of methods

a) Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

b) The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified.

c) Validation of test methods does not include procedures for sampling, handling and transportation of the test samples.

d) All methods will be validated appropriately and rewritten as internal standard operating procedures (SOP) before applied and used.

6.4. Sampling

Not applicable

6.5. Handling of test items

SFDA labs have Procedure P-014 "Handling of test items" for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items, including all Customer

supplied product and provisions necessary to protect the integrity of the test item, and to protect the interests of SFDA and the customer.

Labs use LIMS for identifying test items. The identification is retained throughout the life of the item at labs.

6.6.Technical Records

Staff records, equipment calibration and verification reports are retained in accordance with the laboratory's control of records procedure, Related procedures "control of records – P-006".

a) The records contain sufficient information to establish an audit trail.
b) The records of each test contain sufficient information in order to repeat the test under conditions as close as possible to the original. This information includes factors that affect uncertainty and any environmental conditions that affect the test.
c) Records are kept for the identity of the personnel responsible for performance of each test and for checking the results.
d) Observation, data and calculations are recorded at the time they are made and are identifiable to the activity performed. Method numbers and titles are used to provide traceability of records to activities.

6.7 Evaluation of measurement uncertainty

a) The laboratories have and apply procedure for Evaluation of Measurement Uncertainty – P-016 and "Estimation of Measurement Uncertainty for Quantitative Determinations for Microbiology Section P-015".

b) The application of details in cases where the nature of the test method may preclude rigorous, metrological and statistically valid, calculation of uncertainty of measurement is addressed in the procedure.

c) An attempt is made to identify all the components of uncertainty and make a reasonable estimation of the measurement uncertainty. This estimation is based on knowledge, experience and validation data of the performance of the method and on the measurement scope. If needed as a part of the laboratory data, the uncertainty estimation is reported according to the procedure.

6.8.Ensuring the validity of results

a) The laboratories have quality control procedures to validate the results of tests undertaken according to these procedures.

b) The monitoring data is recorded in such a way that trends may be detected, for example, statistical process control charts.

c) Monitoring activities are planned and evaluated.

d) Related procedures "Ensuring the validity of results P – 012".

e) Monitoring techniques may include, but are not limited to the following:

1. Scheduled use of certified reference materials and internally generated reference materials.

2. Scheduled participation in inter laboratory comparison and/or proficiency testing and calibration programs as described in the quality documents.
3. Replicate tests using the same or different methods.
4. Retesting of reference materials and retained customer sample.
5. Correlation of results from tests conducted for different characteristics of a sample.

6.9.Reporting of results

The results of each test or series of tests carried out by labs is reported accurately, clearly, unambiguously and objectively.
The results are reported via LIMS which can be printed as Test Report that includes all the information requested by the customer and necessary for the interpretation of the testing results and all information required by the test procedure used.
The related procedures "Reporting of results and discision rule – P-018 provides rules for labs in relation to reporting results and reporting of compliance or non-compliance with specified requirements and legal or regulatory requirements.

6.10. Complaints

The laboratories management are committed to the efficient and fair resolution of service complaints and the provision of quality customer service. All complaints received from the customers or other parties about the laboratory's activities shall be documented, handled and resolved in appropriate way for proper investigation. Records must be maintained of all complaints, investigations and corrective actions undertaken by the laboratories.

The laboratory has procedure describing the process for the receipt, register and dealing with customer's complaints and comments. Refer to the procedure "Handling of complaints – P-004" for more detail.

6.11. Nonconforming work

6.11.1. The laboratory has a policy and procedure for control of non-conforming work. This procedure will be implemented when any aspect of the testing work, or the results of this work, does not conform to requirements of the management system or the customer needs. For more details, refer to procedure "Control of Non-Conformities and Corrective actions – P-005".

6.11.2. The laboratory retains records of nonconforming work and actions.

6.11.3. Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action.

6.12. Control of data and information management

The laboratory has access to the data and information needed to perform its activities. Calculations and data transfers are subject to appropriate checks in a systematic manner before reported. LIMS is managed and maintained through the IT department.

7. Management system requirements

7.1.Options

7.1.1. General

SFDA Lab has a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. SFDA labs implemented a management system in accordance with Option A.

As a minimum, the management system of the lab addresses the following:

- management system documentation;
- control of management system documents;
- control of records;
- actions to address risks and opportunities;
- improvement;
- corrective actions;
- internal audits;
- Management reviews.

7.2.Management system documentation (Option A)

7.2.1.The management system documentation consists of different levels:

- documented statements of the quality and impartiality policy issued by the CEO of SFDA
- this quality manual
- Documented procedures required by all applicable standards such as ISO17025:2017 which detail the implementation of requirements and operation guidelines.
- Instructions: they detail specific quality or inspection information and specific instructions for performance or individual task.
- Records required by all applicable standards.
- When the term documented procedure appears within this quality manual, the procedure is established, documented, implemented and maintained.
- The lab maintains its documents on various media such as paper, electronic, magnetic, optical, etc.

7.2.2. The policies and objectives are acknowledged and implemented at all levels of the laboratory organization and address the competence, impartiality and consistent operation of the laboratory.

7.2.3. A list of the procedures, instructions and the quality records which are included in the management system, is maintained by the Quality manager.

7.2.4. The management system documentation is communicated to all relevant personnel. These documents are understood and implemented.

7.2.5. All personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities. The documents are available at the location needed.

7.3.Control of management system documents (Option A)

7.3.1. The lab is committed to use a documented management system to ensure that activities related to management system requirements are performed.

7.3.2. The laboratory has identified those documents and data that are directly related to customer contracts or the requirements of the documented management system. It is a requirement that the originator of each document carries out a formal review prior to approval and use. It is also a requirement that the correct documents are available at the relevant locations. Obsolete documents will be clearly identified as obsolete and managed in a way that positively prevents the incorrect information being referenced.

7.3.3. Data is held in various information systems for tracking business resource planning, service management, customer contacts, complaints and opportunities for improvement, software development, engineering documentation, internal and external standards and policies.

7.4.Control of records (Option A)

7.4.1. The lab is committed to record all activities with technical and managerial covering all actions and evidence.

7.4.2. Records are maintained for collection indexing, filing, storage, maintenance and disposal of quality and technical records. Quality records include reports from internal audits and management reviews as well as records of corrective and improvement actions whereas the technical records are that records related to the samples from laboratory entry date to exit date.

7.4.3. All records will be legible, stored properly, retained and readily retraceable in suitable environment to prevent damage or deterioration and to prevent loss. Retention periods of records are mentioned in procedures “control of records – P-006”.

7.4.4. The access to the quality or technical records is controlled by the authorized personnel where the laboratory director, Head of sections and the Quality manager or any other personnel assigned are allowed to access the records.

7.4.5. Records are stored in secured areas. The laboratory management system records may be kept in hard copy or electronic media this will be according to the nature of the records.

7.4.6. The laboratory has a procedure describing the protection and back-up of electronic records. The procedure also describes the safeguards in place to prevent unauthorized access to or amendment of electronic records.

7.4.7. The laboratory retains records of original observations, derived data and sufficient information to establish an effective audit performance, the records will be retained for a defined period as described in the procedures "control of records – P-006".

7.4.8. The record for each test contain sufficient information to facilitate, if possible, identification factors affecting the uncertainty and to enable the test results to be repeated under conditions as close as possible to the original.

7.4.9. The records include the identification of personnel responsible for the performance of the test and checking of results. The records contain sufficient information to establish an audit trail.

7.4.10. Observations, data, and calculations are recorded at the time they are made and identifiable to the activity performed. Method number is used to provide traceability of records to activities.

7.4.11. When mistakes occur in records, each mistake is lined out and not erased, made illegible or deleted and the correct values entered a long side. All alterations to records are signed or initialled by the person making the correction. In the case records stored electronically, measures governed by level of authority will be taken to avoid loss or change of the original data.

7.5.Actions to address risks and opportunities (Option A)

7.5.1. The laboratory considers the risks and opportunities associated with its activities in order to:

- Give assurance that the quality management system can achieve its intended results
- Enhance desired effects
- Prevent, or reduce, undesired effects;
- Achieve improvement

7.5.2. The laboratory established procedure procedures "Lab management of risks and opportunities – P-017" concerning the management of risks. The laboratory maintains a log of internal and external issues identified through planning, the risks and opportunities identified for those issues, and the requirements of Interested Parties. These issues, risks, and opportunities are monitored and reviewed periodically during Management Review to determine what, if any actions are required to meet the requirements of interested parties.

7.5.3. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

7.6.Improvements (Option A)

7.6.1. The laboratory management is committed to improve the effectiveness of the management system continually by taking opportunities for improvement and implementing any necessary actions.

7.6.2. The improvements will be taken according to the followings:

a) Management system regular reviews

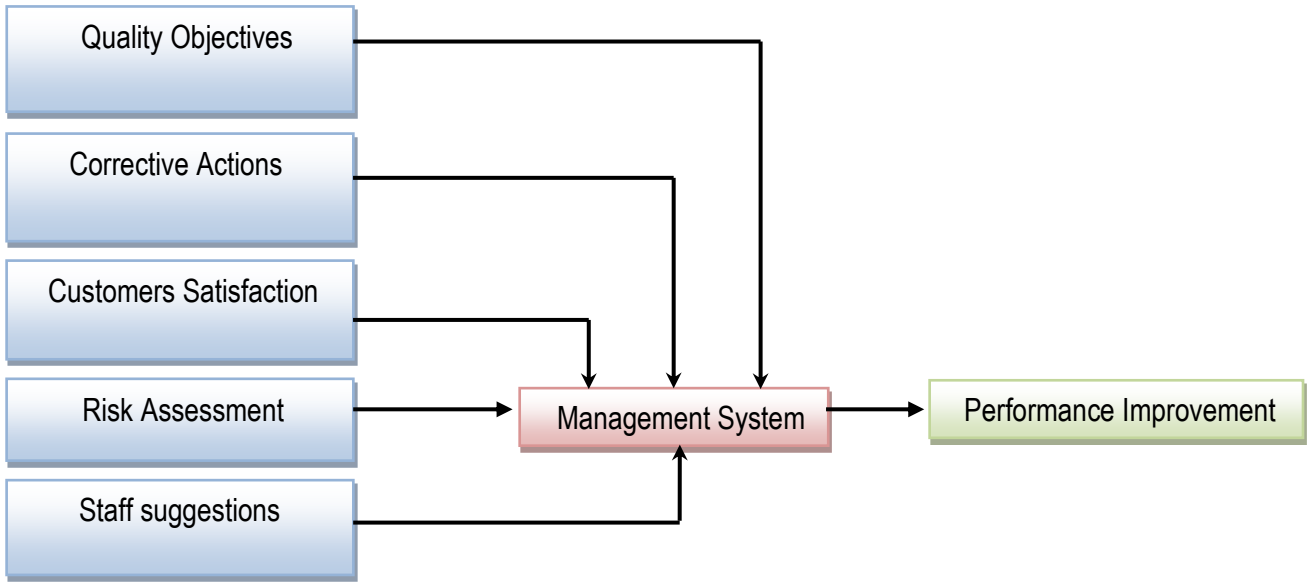

Figure 2 : Improvement resources diagram

b) Analysing quality objectives

Labs management ensures that quality objectives, including those needed to meet requirements of the customers are established at relevant functions and levels. The quality objectives are measurable and relate to the quality and impartiality policy statement.

c) Analysing of management system nonconformities

The Labs takes corrective actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. The causes of the nonconformities shall be studied carefully to selection of the appropriate corrective actions

d) Implementation of the staff suggestions

Lab management encourages staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions may be evaluated, implemented as appropriate and feedback provided to the staff.

e) Assessment of customers' feedback

SFDA labs seek feedbacks, both positive and negative, from its customers. The feedback analysed and used to improve the management system, laboratory activities and customer service as describe in procedure "Handling of Complaints – P-004".

f) Risk assessment

Lab management evaluates the impact of work processes and potential failures on laboratory processes as they affect laboratory personnel and customer's samples based on the failure mode and effect analysis.

7.7.Corrective action (Option A)

Corrective action is oriented at revising the laboratories management system policies, procedures and operating instructions in order to eliminate the root causes of quality problems. Corrective actions are used for example to resolve management system problems (non-conformities of internal or external audit, eliminate the poor quality service, customer complaint or internal quality failure). When a non-conforming testing work or departures from the policies and procedures in the management system or technical operation have been identified, an investigation must start to determine the root cause of the problem (cause analysis) and the responsible person must select the proper corrective action to be applied and follow up on the implementation and effectiveness of actions taken "Control of Non-Conformities and Corrective actions – P-005".

7.8.Internal audits (Option A)

7.8.1.Internal audits are conducted according to a schedule included in "Internal audit procedure – P-007".

Internal audits are conducted for activities to provide information on whether the management system:

a) Conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities;

— the requirements of this document;

b) Is effectively implemented and maintained.

7.8.2.A continuous program of internal auditing is conducted to ensure that quality and impartiality policy statement described in this quality manual is correctly and effectively implemented as defined by the laboratory procedures.

7.8.3.The internal audit program addresses all elements of the management system, including testing activities, the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.

7.8.4.When audit finding cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's results, the appropriate corrective action will be undertaken.

7.8.5.The customer will be notified in writing if investigations show that non-conformances affected the tests results.

7.8.6.The area of activity audited, the audit findings and corrective action(s) that arise from them are recorded according to "Internal audit procedure – P-007".

7.8.7.Lab management is keens to follow-up audit activities in order to verify and record the implementation and effectiveness of the corrective action taken. This follow-up is included as part of the internal audit and management review processes.

7.9. Management reviews (option A)

7.10. Labs management conduct management review periodically (at least annually) schedule basis as described in the procedure "management review – P-008". Review of the Lab's management system and testing activities is conducted to ensure their continuing suitability and effectiveness, including the stated policies and objectives related to the fulfilment of the ISO/IEC 17025 : 2017 and accreditation body requirements and to introduce any necessary changes or improvements.

End of the Document