4.4.1 Process Identification

Our QMS is that part of our overall management system which establishes documents and implements our quality policy, and related processes for providing products and services which meet or exceed customer requirements, and satisfies QMS requirements of ISO 9001:2015.

We have adopted the process approach advocated by ISO 9000:2005, by defining and managing:

- process inputs, controls, and outputs to ensure desired results are achieved, and
- interfaces between interrelated processes to ensure system effectiveness is achieved.

We have also developed Systems Procedures to help meet the specific needs of management and/or to meet management requirements of ISO 9001:2015 and other external standards and regulatory requirements.

We have developed appropriate Work Instructions (WI) to help implement general procedures (GP) and technical procedures (TPs) in the most effective and efficient manner possible.

The overall sequence of QMS processes and their (primary) interaction is depicted in our business process map (Figure 3).

Techniques and tools for process management are discussed in QM 9.1 *Performance Evaluation* - Monitoring, Measurement, Analysis and Evaluation.

Specific responsibilities for the sequence and interaction of our key QMS processes are detailed in the documented procedures, which contain deployment flow charts or narrative procedures depicting the processes.

BAI establishes implements, maintains and continually improves the Quality Management System (QMS) including the processes needed and their interactions in accordance with the requirements of this Standard. Likewise, maintain and retain documented information.

BAI has adopted a process approach for its management system. By identifying the top-level processes within the bureau and then managing each of these discretely, this reduces the potential for nonconforming Products or Services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

The following top-level processes have been identified for BAI:

A. Management System Administration
   - Human Resource Training and Development Procedure
   - Physical Asset and Supplies Inventory procedure
   - Preventive Maintenance Procedure
   - Purchasing (Procurement) Procedure
   - Planning Procedure
   - Administrative Services Procedure
   - Performance Evaluation Procedure
   - Risk Registry Procedure

B. Production and Service Provision Procedure
   - Permits/Licenses Procedure
   - Regulatory Procedure
   - Production Procedure
   - Testing Procedure
   - Design and Development Procedure
   - Accreditation Procedure
   - Technical Services Procedure

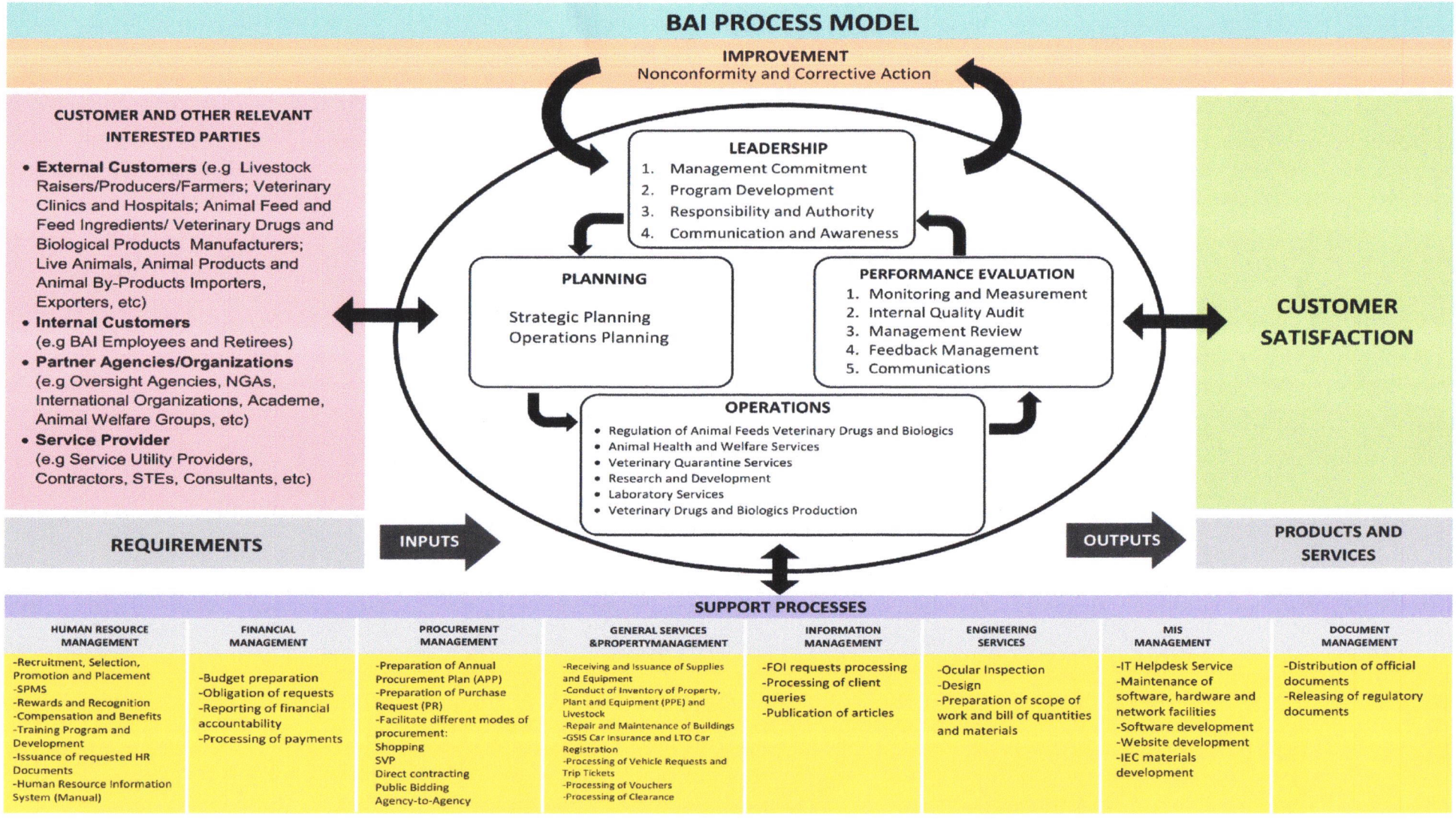
The macro business process map shows the role and how they interrelate with the organization's value creation stream management (see Figure 3). The processes supporting the organization at the same time include the development and management of human capital; construction and management of facilities, management of procurement processes in accordance with the regulatory requirements; management of financial resources, information technology, legal and ethical issues, environmental, health and safety and external relationships.

Each process may be supported by other activities; such as tasks or sub-processes. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process is in the Procedures Manual document which defines:
- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process

The sequence of interaction of these processes is illustrated in (see Figure 3).

FIGURE 3. BAI BUSINESS PROCESS MODEL



4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it's impact on Products or Services, and associated risks.

Note: Whereas ISO 9001 discusses process measurements and "quality objectives" as separate concepts, BAI combines them; i.e., quality objectives are used to control the processes. Additional objectives for Products or Services may be assigned, but these will also be used to measure process effectiveness.

Throughout the year, metrics data is measured and gathered by process owners or other assigned project managers, in order to present the data to the Division Chiefs/Top Management. The data is then analyzed by the Planning Officer in order that the Division Chiefs/Top Management may set goals and make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable QM 6.2 Quality Objectives.

Metrics, along with current standings and goals for each objective, are recorded in Monthly Accomplishment Reports (GF BAI-57) and in records of the management review (R-BAI-93 Minutes of the Management Review).

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

4.4.3 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in GP BAI-07 Purchasing Process.

We also recognize the significant role that suppliers play in achieving desired results and recognize that we must ensure proper control over outsourced QMS processes.

Our outsourced processes include calibration of monitoring and measuring equipment, delivery of finished products, procurement of supplies and materials, security personnel and training and development of employees which necessitates external resources are managed and controlled according to the procedures indicated for each concern.

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the purchasing contract requirements.

4.4.4 Documented Information

The QMS include documented information on:

a. External and internal issues (monitoring and review)

b. Criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure effective operation and control of processes;

c. Quality objectives (monitoring)

d. External providers (selection, monitoring of performance, evaluation, and re-evaluation based on their ability to provide services in accordance with their requirements and communication regarding their performance)

e. Service provision (monitoring and measurement activities)

f. Customer's perception (obtaining, monitoring and reviewing)

Documentation structure in BAI's QMS

Level 1: Quality (QM) Manual – The highest level of Quality System documentation. It contains the quality policy, organizational structure, resource management, and specific policies for business process, quality control and improvement.

Level 2: General Procedures Manual (GP) – Operational guide on what the company does and how it achieves stated policies. It also provides guidance on how to communicate and perform various activities. It includes operational instructions that describe the detailed series of steps in performing routine activities in the administrative processes like the procurement of goods/raw materials and infrastructure and inspection of goods/services.

Level 3: Thekey processes in our laboratories are what we call **Technical Procedures (TP) and Regulatory Procedures** for the regulatory activities, which are in place to meet the specific needs of our external customers, which directly relate to requirements contained in Clause 8 of ISO 9001:20015, Operation processes.

Level 4: Quality Records – These include records providing evidence of conformity to the established procedures and operational instructions, as well as the BAI's QMS.

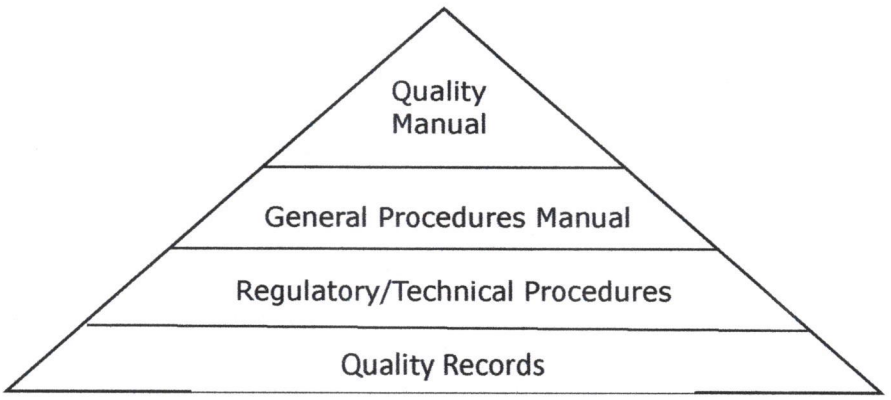


FIGURE 5. LEVELS OF DOCUMENTATION

Support documents which contain the Forms, Plans and Master List Manuals which contain the Quality Plans and other relevant Master Lists required by the ISO 9001:2015 and the BAI.

When creating and updating documented information, we ensure appropriate identification according to GP BAI-03 Coding of Controlled Documents. A template for the procedures and work instructions shall be provided to process owners (GF BAI-33 and GF BAI-34). Review and approval for suitability and adequacy shall be based on the Responsibility Matrix stated in QM 0.3 Updating and Distribution of the Manuals and Documents.

RELATED DOCUMENTED INFORMATION:

Document Code	Document Title
GP BAI-01	Control of Document
GP BAI-05	Control of Records

4.4.4.1 Control of Documents

The Document Control Officer (DCO) has the overall responsibility for ensuring that all QMS documents, including forms used to create quality records are controlled per procedure detailed in GP BAI-01 Control of Documents and are summarized below:

1. Approves documents for adequacy prior to issue.
2. Reviews updates as necessary and re-approve documents.
3. Identify the current revision status of documents.
4. Ensure that relevant versions of applicable documents are available at points of use.
5. Ensure that documents remain legible, readily identifiable and retrievable.
6. Ensure that documents of external origin are identified and their distribution controlled.

7. Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Requirements for the establishment and maintenance of Master Lists of Controlled Documents (PL BAI-15) and External Documents-General (PL BAI-16) are defined in GP BAI-01 Control of Documents.

4.4.4.2 Control of Records

The Document Control Officer and concerned Division/Section/Unit Document Custodians has overall responsibility for ensuring that all records required for the QMS (including customer-specified records) are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records are retained for a period defined by the customer, applicable regulatory requirements and/or BAI management, as applicable, and then disposed of in accordance with applicable requirements, PL BAI-17 Master List of Records-General. Records may be in the form of hard copy or electronic media. GP BAI-05 Control of Records details procedures necessary to control QMS records that, as a minimum, are prepared to document:

a) Results of processes performed, including identification of the individual performing the activity.

b) Product/process evaluation/acceptance criteria.

c) Procedures, drawings or instructions used to perform an activity, including revision or date of document.

d) Identification of material, parts, or equipment used in the making of the product.

e) Personnel, material or equipment qualifications.

f) Pertinent technical records from sub-contractors.

g) Customer feedback or survey results

h) Actions taken by Top Management for continual improvement purposes.

i) Supplier evaluations

j) Auditors' qualification matrix