

**TAMILNADU LIVESTOCK DEVELOPMENT AGENCY
FROZEN SEMEN PRODUCTION STATION
District Livestock Farm - Hosur
A Unit of Department of Animal Husbandry and Veterinary Services –
Tamilnadu**



**QUALITY SYSTEM MANUAL
DISTRICT LIVESTOCK FARM
FROZEN SEMEN PRODUCTION STATION,
HOSUR-635 110
TAMILNADU**

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AUTHORIZATION

I authorize this document as an official Quality Management System manual of M/s **DISTRICT LIVESTOCK FARM, HOSUR**. This manual is implemented to ensure continual improvement of the operations of the company through complying with the requirements of ISO 9001:2015, Quality Policy and Objectives. The management and all employees of the organization are committed to implement this manual at all levels of the organization. **This Quality manual was adopted on 05.07.2024**

**DEPUTY DIRECTOR (AH)
DISTRICT LIVESTOCK FARM
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Amendment Sheet

Date	Manual Clause No.	Page No.	Brief Description of amendment

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PROFILE

Livestock is a major source of supplementary income to the farming community in Tamil Nadu. Development of livestock production is, therefore, a critical pathway to rural prosperity apart from providing employment to rural youth. According to, 20th quinquennial Livestock Census, the total Cattle population is 95.19 lakh.

NATIONAL PROJECT FOR CATTLE AND BUFFALO BREEDING (NPCBB)

At the beginning of IX Five Year Plan, to strengthen the bovine breeding program, the Government of India, Ministry of Agriculture, Department of Animal Husbandry, Dairying & Fisheries, New Delhi initiated a newly centrally sponsored scheme “National Project for Cattle and Buffalo Breeding Program” (NPCBB) with the aims of the following

- Consolidating the gains of the previous projects
- Maximizing returns on investments by increasing productivity to optimum level.
- Ensuring the sustainability of the operations.
- Thorough restructuring and reorienting Cattle and Buffalo breeding.
- The minimum Standard Protocol for Semen Stations as approved by Government of India and Standard Operating Procedures for Semen Stations will be the reference Documents in this regard (current version 2022)

TAMIL NADU LIVESTOCK DEVELOPMENT AGENCY

“Tamil Nadu Livestock Development Agency” (TNLDA) was formed by the Government of Tamil Nadu as an autonomous body to function as the State Implementation Agency of the National project of Cattle and Buffalo breeding and to reinforce breeding activities in Cattle and Buffalo at the State level.

The agency was registered as a society on 11.02.2003 under the Registration of Societies Act 1975 and started functioning from 9-1-2003 with the Secretary to Government of Animal Husbandry, Dairying and Fisheries Department as its Chairman and a senior level technical officer, as its Chief Executive Officer

One of the Project components of TNLDA under NPCBB is Quality Control of goods and services at sperm stations, semen banks and training institutions, and this is to be achieved by appropriate strengthening of these institutions, laying down standards for bulls/semen and establishment of a computer network for close monitoring.

In keeping with the objectives of the project, Quality Management System has been established at the Frozen Semen Production Unit of DISTRICT LIVESTOCK FARM, HOSUR, KRISHNAGIRI during the year 2024.

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2. Definitions & Abbreviations

The organization	DISTRICT LIVESTOCK FARM (DLF)
AI	Artificial Insemination
BIS	Bureau of Indian Standards
CBFD	Cattle Breeding And Fodder Development
CMU	Central Monitoring Unit
Doc	Document
DD	Deputy Director
DLF	District Livestock Farm
FSS	Frozen Semen Straw
FSPS	Frozen Semen Production Station
HOD	Head of the Department
ISO	International Organization for Standardization
JD	Joint Director
Lab	Laboratory
MOM	Minutes of the Meeting
MRM	Management Review Meeting
NCR	Non conformity Report
QSM	Quality System Manual
QMS	Quality Management System
QP	Quality Plan
QSP	Quality System Procedure
Ref	Reference
Rev	Revision

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SOP	Standard Operating Procedure
T.M	Top Management
TNLDA	Tamil Nadu Livestock Development Agency
VAS	Veterinary Assistant surgeon
WI	Work Instructions

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3.Scope of the Manual

3.1 This manual describes the Quality Management System (QMS) and associated processes of DLF, Hosur dealing with the DLF. The description of the QMS is in alignment with the requirements of ISO 9001:2015.

3.2 The manual contains three introductory sections, numbered 1 to 3 and seven process sections numbered 4 to 10. These sections correspond to the ISO 9001:2015 Standard. Supporting documentation is identified and referenced within their corresponding section of this manual.

3.3 The distribution of the quality manual is given in **Section 0 of** the Manual.

3.4 Unless otherwise defined, the definitions of terms used within this manual are as described in the ISO 9001:2015 and ISO 9000:2015 apply.

3.5 By adopting the requirements referred to in ISO 9001:2015, the organization expects:

- a) To enhance customer satisfaction through the affective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements, and
- b) To demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

4 Context of the Organization

4.1 Context of the Organization

DLF, Hosur has determined Internal/External issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Quality Management system through PESTLE and SWOT analysis.

The output of the functioning of the various process of the unit is, quality frozen semen straws (doses) of various breeds of cattle consistent with the bovine breeding policy of the State for Artificial Insemination conforming to the applicable regulatory requirements and customer satisfaction.

The Quality Management System structure and documents have been prepared based on the specific objectives, needs, process followed, product real^{ised}, environment size and structure of the Organisation and the guidelines provided by the International Standards.

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The QMS requirements specified in these internal standards are correlated to the requirements of the product (s) offered by this organization.

The Quality Manual documented based on the international standard, is used by internal and external agencies including certifying bodies to assess organization's ability to meet statutory & regulatory requirements applicable to product and the organizations own requirements.

Internal/External issues have been considered for the Analysis and they are monitored and reviewed under the following classification:

External Context	Internal Context
Legal	Organization Values
Technological	Culture
Competitive Market	Knowledge
Cultural	Performance of the organization
Social and Economic Environment	

4.2 Understanding the needs and expectations of interested parties

DLF, Hosur has determined the interested parties that are of relevance to its activities and who in turn affect its activities and its QMS. The requirements of these interested parties affect or potentially affect its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

Interested parties that are relevant to the QMS of DLF, Hosur are:

- Customers and consumers
- Statutory and regulatory authorities
- Employees
- Management
- Bank/Finance/Insurance
- Suppliers and service providers
- Local residents

DLF, Hosur monitors and reviews information about these interested parties and their requirements.

Legal, regulatory and other requirements relevant to this QMS are duly taken care off.

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4.3 Scope of the Quality Management System

The scope of the QMS has been determined after considering the context of the organization, the needs and expectations of the interested parties and the products and services provided by DLF, Hosur

Scope of QMS: To produce and supply superior quality frozen semen straws for Artificial Insemination in Cows.

All requirements of ISO 9001:2015 are applicable except:

CI 8.3 Design and development of products and services is not applicable.

Since DLF, Hosur is producing frozen semen straws for Artificial Insemination through technologies developed by National and International procedures and practices.

4.4 Quality management system and its processes

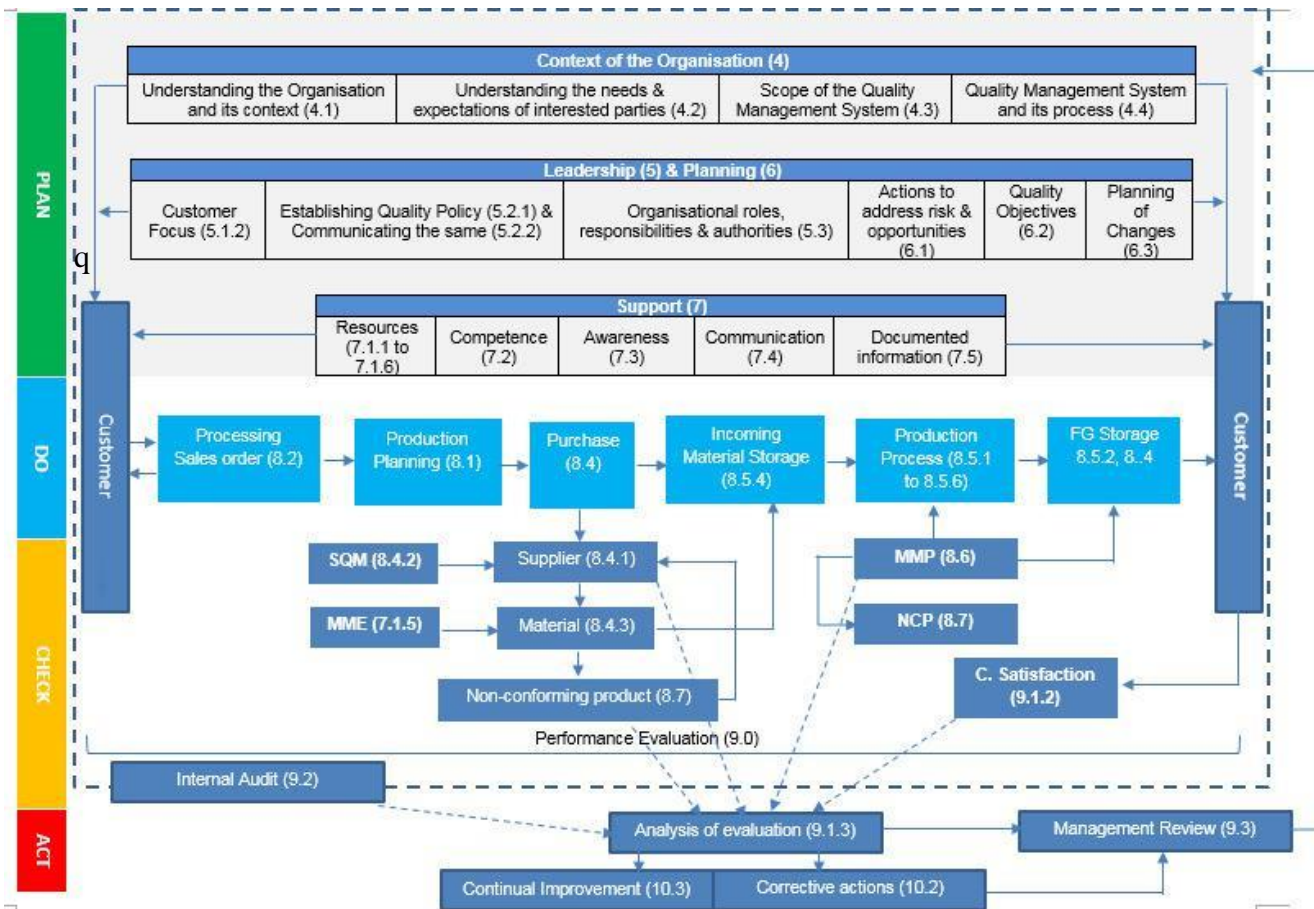
DLF, Hosur has established, implemented, maintains and continually improves its quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.

DLF, Hosur has:

- Determined the processes needed for its quality management system, evaluated these processes and implemented any changes needed their application throughout the organization to ensure that these processes achieve their intended results.
- Determined the inputs required and the outputs expected from each process
- Determined the sequence and interaction of the processes and their interaction is given below in the process mapping:
- Determined and applies the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the affective operation and control of these processes in documented information of each process.
- Determined the resources needed for these processes and ensures their availability
- Assigned the roles, responsibilities and authorities for each person
- Address risks and opportunities as determined in accordance with the requirements of 6.1; Improve the processes and the quality management system through implementation of the requirements of ISO 9001:2015.

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Major Processes/functions within DLF, Hosur are:

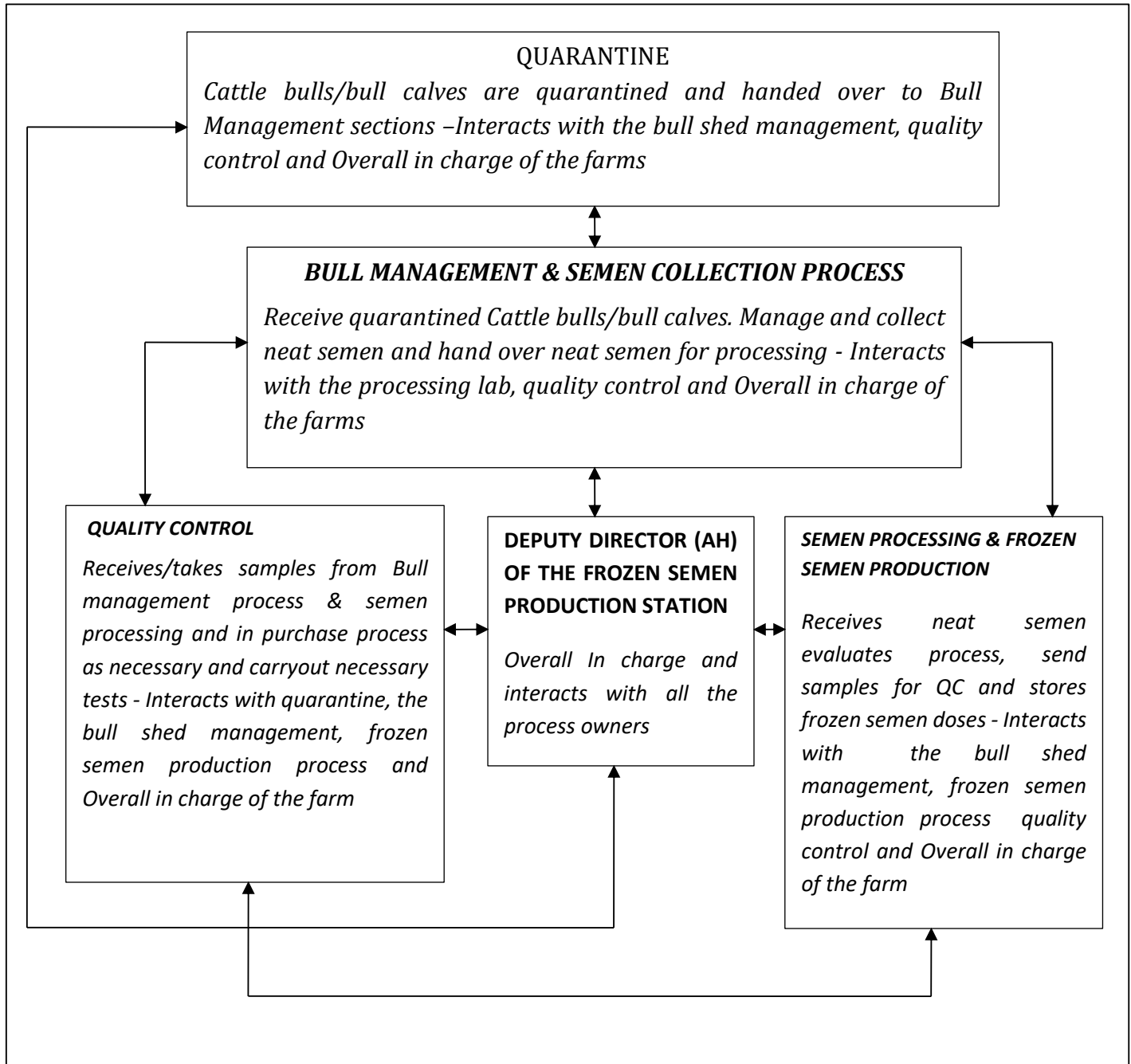
1. Top Management & Management Representative
2. Bull Shed Management
3. Semen Processing, Storage and Distribution
4. Quality Control
5. Purchase and Stores

DLF, Hosur also maintains documented information in the form of operating procedures/work instructions to support the operation of its processes wherever necessary and retains documented information in the form of records to have confidence that the processes are being carried out as planned.

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INTERACTION OF PROCESSES OF THE FROZEN SEMEN PRODUCTION STATION



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5. Leadership

5.1 Leadership and commitment

5.1.1 General

Top management of DLF, Hosur demonstrates its leadership and commitment with respect to the quality management system through the following actions:

- a) taking accountability for the effectiveness of the quality management system;
- b) 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;
- c) ensuring the integration of the quality management system requirements into the organization’s business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of affective quality management and of conforming to the quality management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

Top management of DLF, Hosur demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

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5.2 Policy

5.2.1 Establishing the quality policy

Top management of DLF, Hosur has established, implemented and maintains a quality policy (given below) that:

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

QUALITY POLICY

DISTRICT LIVESTOCK FARM, HOSUR, FSPS IS COMMITTED TO PRODUCE SUPERIOR QUALITY FROZEN SEMEN STRAWS (DOSES), FROM SEMEN DONATED BY GOOD QUALITY AND HEALTHY BULLS FOR ARTIFICIAL INSEMINATION AND SUSTAIN PRODUCTION WITH CONTINUOUS IMPROVEMENT IN QUALITY FOR ARTIFICIAL INSEMINATION IN CATTLE AND BENEFIT THE FARMING COMMUNITY INCLUDING INSTITUTIONAL CUSTOMERS WITH DISTRICT LIVESTOCK FARM MEETING THEIR REQUIREMENTS AND STATUTORY & REGULATORY REQUIREMENTS, ENSURING CONTINUAL IMPROVEMENT IN ITS PROCESSES TO ENSURE SUSTAINABLE DEVELOPMENT.

DEPUTY DIRECTOR (AH)
05-07-2024

5.2.2 Communicating the quality policy

We ensure that the quality policy is:

- a) available and maintained as documented information;
- b) communicated, understood and applied within the organization;
- c) available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

The organization chart is available and kept separately.

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Top management of DLF, Hosur ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management assigned the Veterinary Assistant Surgeon (Bull shed) as Management Representative (MR). DLF, Hosur has assigned the roles, responsibilities and authorities for personnel at different levels. The roles, responsibilities and authority are documented and kept separately. The responsibilities are for

- a) ensuring that the quality management system conforms to the requirements of ISO 9001:2015
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, DLF, Hosur has considered the issues (internal/external) and the requirements of the interested parties and determined the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable affects;
- c) prevent, or reduce, undesired affects;
- d) achieve improvement.

6.1.2 DLF, Hosur has also planned:

- a) actions to address these risks and opportunities;
- b) actions to:
 - 1) integrate and implement the actions into its quality management system processes
 - 2) evaluate the effectiveness of these actions.

Actions taken by DLF, Hosur to address risks and opportunities are proportionate to the potential impact on the conformity of products and services it provides. The list of various activities, issues of internal and external nature, interested parties involved and their needs and expectations, risks and opportunities associated therein, the scores of different risks and finally the control action available to address the risks are compiled and tabulated in a Risk Matrix.

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These risk matrices are compiled department wise and are reviewed for their suitability in regular intervals. Risk matrix is documented and kept separately.

6.2 Quality objectives and planning to achieve them

6.2.1 The company has established quality objectives at relevant functions, levels and processes needed for the quality management system.

DLF, Hosur maintains documented information on the quality objectives for the individual departments in their respective places. Quality objectives are kept separately department wise.

6.2.2 For achieving the objectives, DLF, Hosur has an action plan which specifies

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.3 Planning of changes

Whenever we determine the need for changes to the quality management system, the changes shall be carried out in a planned manner considering the following:

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

7 Support

7.1 Resources

7.1.1 General

DLF, Hosur has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

While providing the resources the following are considered:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

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7.1.2 People

DLF, Hosur has determined and provided persons necessary for the affective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

DLF, Hosur has determined, provided and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

Infrastructure includes the following:

- a) buildings and associated utilities;
- b) machinery, equipment, tools, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the operation of processes

DLF, Hosur has determined, provided and maintain an environment necessary for the operation of its processes and to achieve conformity of products and services. Adequate employee facilities, including proper lighting, physically and ergonomically comfortable facilities are provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

DLF, Hosur has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. These include adequate processing and test equipment as specified by CMU requirements and identified by us.

DLF, Hosur ensures that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

DLF, Hosur retains appropriate documented information (records) as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

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When measurement traceability is a requirement, or is considered by DLF, Hosur to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

At any time, the validity of previous measurement results is found to be adversely affected due to measuring equipment being found to be unfit for its intended purpose, DLF, Hosur shall take appropriate action as necessary to ensure the validity of such measurements.

7.1.6 Organizational knowledge

DLF, Hosur has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and is made available to the extent necessary, mostly through documented information.

When addressing changing needs and trends, we consider current knowledge and will determine how to acquire or access any necessary additional knowledge and required updates.

The organizational knowledge of DLF, Hosur is based on internal sources like knowledge gained from experience, training, technology transfer, etc and external sources like standards, customers, statutory regulations and suppliers.

7.2 Competence

DLF, Hosur has:

- a) determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensured that these persons are competent on the basis of appropriate education, training, or experience; qualification, experience, skill and training details are kept in records maintained by the establish department in the Deputy Director’s office.
- c) where applicable, taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) Retained appropriate documented information as evidence of competence.

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7.3 Awareness

DLF, Hosur ensures that persons doing work under its control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.

7.4 Communication

DLF, Hosur has determined the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

7.5 Documented information

7.5.1 General

DLF, Hosur’s quality management system includes:

- a) documented information required by ISO 9001:2015
- b) documented information determined by the company as being necessary for the effectiveness of the quality management system, like technical details, standards, procedures and work instructions, plans, etc

7.5.2 Creating and updating

When creating and updating documented information, DLF, Hosur ensures appropriate:

- a) identification and description (title and/or number, date, issue/revision number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

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7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 is controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, DLF, Hosur addresses the following activities, as applicable:

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

Documented information of external origin determined by DLF, Hosur to be necessary for the planning and operation of the quality management system are identified as appropriate, and are controlled (Indian Standards, Statutory regulations, etc).

Documented information retained as evidence of conformity are protected from unintended alterations. Procedure for control of documents: QMSPS/1 and Procedure for control of records: QMSPS/2

8 Operation

8.1 Operational planning and control

DLF, Hosur plans, implements and controls processes needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
 - 1) the processes;
 - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and 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 products and services to their requirements.

The output of this planning, viz. Quality Plan is suitable for its operations.

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DLF, Hosur controls planned changes and review the consequences of unintended changes, acting to mitigate any adverse affects, as necessary (through corrections and corrective actions).

DLF, Hosur ensures that outsourced processes, as applicable to its operations, are controlled.

8.2 Requirements for products and services

8.2.1 Customer communication

DLF, Hosur’s communication with customers includes:

- a) providing information relating to products and 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 (where applicable);
- e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, DLF, Hosur ensures that:

- a) the requirements for the products and services are defined, including:
 - 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by us;
- b) we can meet the claims for the products and services offered.

8.2.3 Review of the requirements for products and services

8.2.3.1 DLF, Hosur ensures that it has the ability to meet the requirements for products and services to be offered to customers. DLF, Hosur conducts a review before committing to supply products and services to a customer, to include:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the organization;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

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DLF, Hosur also ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by DLF, Hosur before acceptance, when the customer does not provide a documented statement of their requirements, which is the situation in its case.

8.2.3.2 DLF, Hosur retains documented information (records), as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

DLF, Hosur ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

This requirement is not applicable for the reasons mentioned in the scope under **CI 4.3**.

8.4.1 General

DLF, Hosur ensures that externally provided processes, products and services conform to requirements.

For DLF, Hosur the following services are outsourced from external agencies

- Purchase of Animal Feed; Mineral Mixture; Office & Lab equipment; Chemical consumables; Lab Equipment & instruments through enlisted vendors;
- Calibration of equipment and
- AMC for equipment.

DLF, Hosur has determined the controls to be applied to externally provided services when:

- a) services from external providers are intended for incorporation into or used in the its own services;
- b) services are provided directly to the customer(s) by external providers on behalf of the organization; this however, is not applicable to its operations

DLF, Hosur determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. DLF, Hosur retains documented information of these activities and any necessary actions arising from the evaluations.

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8.4.2 Type and extent of control

DLF, Hosur ensures that externally provided services do not adversely affect its ability to consistently deliver conforming products and services to its customers as follows:

- a) ensures that externally provided processes remain within the control of its quality management system;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) takes into consideration:
 - 1) the potential impact of the externally provided processes, products and services on its ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;
- d) determines 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

DLF, Hosur ensures the adequacy of requirements prior to their communication to the external provider.

DLF, Hosur communicates to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products 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 company;
- f) verification or validation activities that the company, 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

DLF, Hosur implements production and service provision under controlled conditions.

Controlled conditions as applied by DLF, Hosur in its activities and processes include, as applicable the following:

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- a) the availability of documented information (procedures) that defines:
 - 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2) the results to be achieved;
- 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

DLF, Hosur uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

DLF, Hosur identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

DLF, Hosur controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

DLF, Hosur exercises care with property belonging to customers or external providers while it is under the company's control or being used by the company.

DLF, Hosur identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, DLF, Hosur reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

DLF, Hosur preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

DLF, Hosur meets requirements for post-delivery activities associated with the products and services, as stipulated by the customers in their order.

In determining the extent of post-delivery activities that are required, DLF, Hosur considers:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

DLF, Hosur reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

DLF, Hosur retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

DLF, Hosur implements 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.

DLF, Hosur retains documented information on the release of products and services. The documented information includes:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

The planned arrangements to verify that the product requirements have been met are stipulated in the Quality Plan.

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8.7 Control of nonconforming outputs

8.7.1 DLF, Hosur ensures that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

DLF, Hosur takes appropriate action based on the nature of the nonconformity and its affect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

DLF, Hosur deals with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

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

8.7.2 DLF, Hosur retains 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.

Procedure for control of non-conforming product: QMSPS/3

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9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

DLF, Hosur determines:

- 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 analyzed and evaluated.

The details regarding monitoring and measurement as related to the product are available in the Quality Plan.

The company evaluates the performance and the effectiveness of the quality management system through internal audits and management reviews.

The company retains appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

DLF, Hosur monitors customers’ perception of the degree to which their needs and expectations have been fulfilled. The organization determines the methods for obtaining, monitoring and reviewing this information.

Monitoring customer perceptions includes customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and repeat orders.

9.1.3 Analysis and evaluation

DLF, Hosur analyses and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented affectively;
- e) the effectiveness of actions taken to address risks and opportunities;

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- f) the performance of external providers;
- g) the need for improvements to the quality management system.

9.2 Internal audit

9.2.1 DLF, Hosur conducts internal audits at planned intervals to provide information on whether the quality management system:

- a) conforms to:
 - 1) the organization’s own requirements for its quality management system;
 - 2) the requirements of ISO 9001:2015
- b) is effectively implemented and maintained.
- c) Procedure for Internal Audit: QMSPS/4

9.2.2 The organization

- a) plans, establishes, implements and maintains an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) defines the audit criteria and scope for each audit;
- c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensures that the results of the audits are reported to relevant management;
- e) takes appropriate correction and corrective actions without undue delay;
- f) retains documented information as evidence of the implementation of the audit programme and the audit results.

9.3 Management review

9.3.1 General

Top management of DLF, Hosur reviews the company’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management reviews are planned and carried out taking into consideration:

- 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:

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- 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 of the management review include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

DLF, Hosur retains documented information as evidence of the results of management reviews.

Procedure for Management review meeting: QMSPS/6

10 Improvement

10.1 General

DLF, Hosur determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired affects;
- c) improving the performance and effectiveness of the quality management system.

Opportunities for improvement include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization and actions arising out of customer feedback.

10.2 Nonconformity and corrective action

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10.2.1 When a non-conformity occurs, including any arising from complaints, DLF, Hosur:

- a) reacts to the nonconformity and, as applicable:
 - 1) take action to control and correct it;
 - 2) deals with the consequences;
- b) evaluates 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) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the quality management system, if necessary.

Corrective actions taken are appropriate to the affects of the nonconformities encountered.

Procedure for corrective action: QMSPS/5

10.2.2 DLF, Hosur retains 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

DLF, Hosur continually improves the suitability, adequacy and effectiveness of the quality management system.

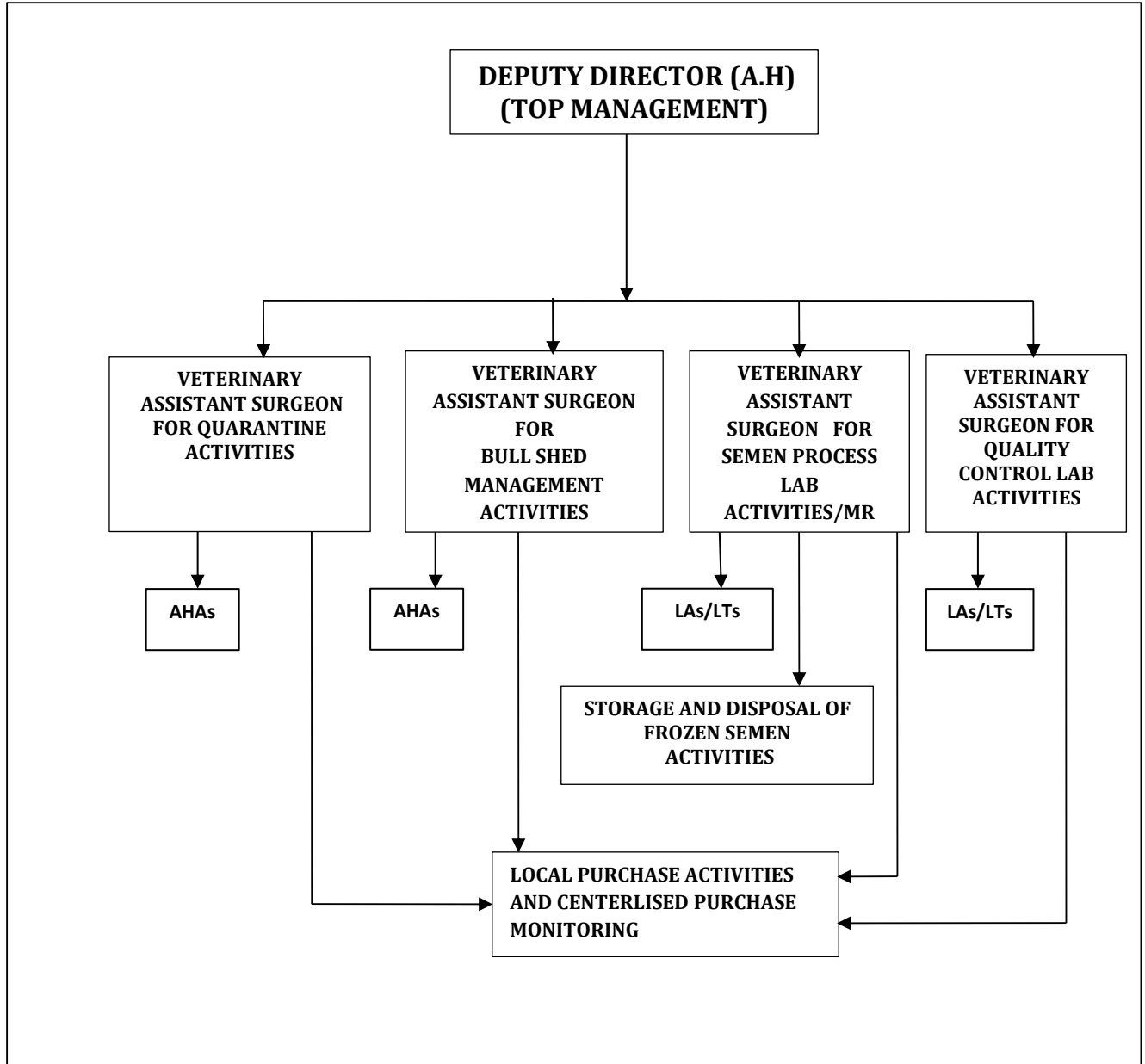
DLF, Hosur considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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Annex - 1

ORGANIZATION CHART OF FROZEN SEMEN PRODUCTION STATION



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Annex -II

Roles, Responsibilities & Authority

A-2.1 : Chief Executive Officer (DD)

Role:

1. Overall management of the unit.

Responsibilities:

1. Provide finance & give guidelines to financial planning.
2. Observe the overall performance.
3. Monitor the statutory and taxation compliances and give the guidelines.
4. Feedback to Joint Director/Director.

Authority:

1. Finalization of financial requirements and commitments.
2. Finalization of statutory requirements.
3. To stop production in the case of any valid reason.
4. To take disciplinary action on any staff due to lack of responsibilities.

A-2.2 VAS – QUARANTINE SHED

Role:

1. Manage the overall quarantine shed Maintenance under the instructions of DD.

Responsibilities:

- a. Veterinary care for bulls (Including scheduled vaccinations, deworming and disease screening)
- b. Training of supporting staff for effective bull management
- c. Data collections and review related to bull management and other duties assigned from time to time by the top management
- d. Records, documents and registers maintenance

Authority:

- a. Reject the feed & fodder for non quality.

A-2.3 VAS - BULL SHED

Role:

2. Manage the overall Bull Shed Maintenance under the instructions of DD.

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Responsibilities:

- a) Total Management of bulls for quality neat semen output
- b) Preparation of bulls for semen collection
- c) Management of bulls during semen collection process
- d) Planning corrective and preventive actions on bulls with poor performances
- e) Veterinary care for bulls (Including scheduled vaccinations, deworming and disease screening)
- f) Training of supporting staff for effective bull management
- g) Data collections and review related to bull management and other duties assigned from time to time by the top management
- h) Records, documents and registers maintenance

Authority:

1. Reject the feed & fodder for non quality.

A-2.4 VAS – SEMEN PROCESSING LAB

Role: Manage the overall production & Process under the instructions of DD.

Responsibility:

- a) Responsible for all the Tests related to FSS production
- b) Preparation for the tests to be done
- c) FSS production and accounting the straws
- d) Monitoring the lab activities
- e) Training the lab workers
- f) Maintaining the records, documents and registers
- g) Maintenance of calibration records
- h) Maintenance of AMC for the instruments and equipments
- i) Indenting the requirements and consumables for the FSS production
- j) Interpretation of results of various observations on neat semen
- k) Data processing, analysis and reviewing of bulls against production status
- l) Other works assigned by top management
- m) Ascertaining the availability of chemicals
- n) Storage and distribution of straws, silo maintenance, availability of In2 in silo and jumbo
- o) Proper training to handling the containers

Authority

1. Reject the raw material for non quality.
2. Reject the finished goods from despatch due to not meeting the quality.
3. Maintenance of machineries and Lab equipment.

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A-2.5 VAS – QUALITY CONTROL LAB

Role:

Manage the overall Quality control activities under the instructions of DD.

Responsibilities:

- a) Responsible for all the Quality control Tests related to FSS production
- b) Preparation for the tests to be done
- c) Preparation of Smear for AIT as sample received from Semen Processing Lab for regular bulls as well as young bulls
- d) Preparation smear for Live and Dead sperms for young bulls
- e) Preparation of smear for Sperm morphology in young bulls as well as in regular bulls
- f) Incubation Test
- g) Hypo Osmotic Swelling Test
- h) Preparation of Smear for PIA
- i) Inoculation of semen samples for microbial load
- j) Sperm Concentration Test in Frozen semen
- k) Post Thaw Motility tests
- l) Interpretation of stained smears for AIT, PIA, Live and Dead sperms and Sperm morphology
- m) Photometer validation for once in six months
- n) Every Saturday the media plates will be prepared and incubated for using in the Laboratory environment for counting colonies present in the working environment
- o) Every Monday the AV- washings and Empty straw washings will be collected for the absence colonies
- p) Split sample tests will be done as new batch of chemicals arrived for diluents preparation
- q) Interpretation of results of various tests
- r) Data processing, analysis and reviewing of bulls against quality control tests
- s) Other works assigned by top management

Authority:

1. Authorized to reject straws not meeting the quality as per norms.
2. Authorized to reject raw material meeting the quality as per norms.
3. Authorized to reject the manpower for non-skilled category.

A-2.6 Purchase & Store Assistant

Role:

1. Indent and procurement of raw material, consumables and tools for production.

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Responsibilities:

- a) Maintain stock register.
- b) Submission of stock detail to administrative officer.
- c) Indenting material requirement on minimum level.
- d) Issue of raw material, consumables and tools for production floor.
- e) Control on operational items.

Authority:

1. Control on any raw material, consumables & spares consumption.
2. Keep minimum inventory at store.

A-2.7 AHA – Bull Shed

Roles and Responsibilities

- a) Animal management-restraining and training the bulls
- b) Feeding
- c) Watering
- d) Grooming
- e) Exercising
- f) Shed cleaning
- g) Bull washing
- h) Veterinary assistance
- i) Hair shaving in hot weather in MBF
- j) Hair clipping (Prepuce)
- k) Hoof trimming
- l) Vaccination
- m) Deworming
- n) Semen collection
- o) Record maintenance
- p) Assisting the VAS-Bull shed

Authority - House keeping and Bull washing

A-2.8 AHA – Semen Processing Lab

Roles and Responsibilities

- a) Cleaning and wiping of work platform with disinfectants, care of instruments
- b) UV light operation for sterilization of rooms and lab premises
- c) Operating the vertical and horizontal autoclaves
- d) Extender preparation for the extension of semen samples
- e) Handling of LN₂ container and FSS

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- f) Assisting SPL - VAS for testing of semen samples
- g) Washing, cleaning, drying and sterilization of glass wares and pipette tips
- h) Lab maintenance activities
- i) Disposal of wastage
- j) Other works assigned by SPL-VAS
- k) And any other duties assigned to him from time to time
- l) Writing the records and record keeping

Authority – House keeping

A-2.9 AHA – Quality Control Lab

Roles and Responsibilities

- a) Cleaning and wiping of work platform with disinfectants, care of instruments
- b) UV light operation for sterilization of rooms and lab premises
- c) Operating the vertical and horizontal autoclaves
- d) Media preparation for the inoculation of semen samples
- e) Sterilization of media and glass wares and pipette tips
- f) Sterilization of Bacteriological Incubator and Hot air oven
- g) Handling of LN₂ container and FSS
- h) Assisting QC - VAS for testing of semen samples
- i) Washing, cleaning, drying and sterilization of glass wares and pipette tips
- j) Lab maintenance activities
- k) Disposal of wastage
- l) Other works assigned by management representative
- m) And any other duties assigned to him from time to time

Authority - House keeping

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Annex III

LIST OF PROCEDURES

PART I - SYSTEM PROCEDURES

Serial Number	PROCEDURE TITLES	Reference	Total Pages
1.	Procedure For Control Of Documents	DLF/HOS/QMSP/01	2
2.	Procedure For Control Of Records	DLF/HOS/QMSP/02	2
3.	Procedure For Control Of Non-Conforming Product	DLF/HOS/QMSP/03	2
4.	Procedure For Internal Audit	DLF/HOS/QMSP/04	2
5	Procedure For Management Review	DLF/HOS/QMSP/05	2
6	Procedure For Corrective Action	DLF/HOS/QMSP/06	2

PART II: - STANDARD OPERATING PROCEDURESS

Serial Number	PROCEDURE TITLES	Reference	Total Pages
1.	QUARANTINE SHED	DLF/HOS/QM/SOP/01	3
2.	BULL SHED MANAGEMENT	DLF/HOS/QM/SOP/02	11
3	SEMEN PROCESSING LAB	DLF/HOS/QM/SOP/03	10
4	QUALITY CONTROL LAB	DLF/HOS/QM/SOP/04	25

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