

Dairy Industries Pvt. Ltd.

QUALITY MANUAL

Issue No. : 01
Date of Issue :
Prepared by :
Approved by :
Copy No. :
Name of Copy Holder :
Revision No. : 00
Revision Date :

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/CS/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Content Sheet

Contents	Ref. No.	Page
Content Sheet	QMS/CS/00	2
List of Control Copy Holders	QSM/LOC/00	4
Scope of the manual	QSM/SCO/00	4
Amendment Procedure & Issue Control	QSM/AP/00	4
List of Abbreviations	QSM/ LOA /00	8
Industry Introduction	QSM/CI/00	9
List of Customer	QSM/CL/00	10
4.0 Quality Management System	QSM/04/00	11
4.1 General Requirements	QSM/04/00	11
4.2. Documentation Requirements	QSM/04/00	11
4.2.1 General	QSM/04/00	11
4.2.2 Document Introduction	QSM/04/00	11
4.2.3 Control of Documents	QSM /04/00	12
4.2.4 Control of Records	QSM /04/00	13
5.0 Management Responsibility	QSM /05/00	15
5.1 Management Commitment	QSM /05/00	15
5.2 Customer Focus	QSM /05/00	15
5.3 Quality Policy	QSM /05/00	15
5.4 Planning	QSM /05/00	16
5.4.1 Quality Objectives	QSM /05/00	16
5.4.2 Quality Management System Planning	QSM /05/00	17
5.5 Responsibility, Authority & Communication	QSM /05/00	17
5.5.1 Managing Director	QSM /05/00	17
5.5.2 Management Representative	QSM/05/00	20
5.5.3 Internal Communication	QMS/05/00	21
5.6 Management Review	QMS/05/00	21
6.0 Resource Management	QMS/06/00	23
6.1 Provision of Resource	QMS/06/00	23
6.2 Human Resource	QMS/06/00	23
6.2.1 General	QMS/06/00	23
6.2.2 Competency, Training & Awareness	QMS/06/00	23
6.3 Infrastructure	QMS/06/00	23
6.4 Work Environment	QMS/06/00	23

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/CS/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

7.0 Product Realization	QMS/07/00	25
7.1 Planning of Product Realization	QMS/07/00	25
7.2 Customer Related Process	QMS/07/00	25
7.2.1 Determination of Requirements related to the Product	QMS/07/00	25
7.2.2 Review of Requirements related to the Product	QMS/07/00	26
7.2.3 Customer Communication	QMS/07/00	26
7.3 Design and Development	QMS/07/00	26
7.4 Purchasing	QMS/07/00	27
7.4.1 Purchasing Process	QMS/07/00	27
7.4.2 Purchasing Information	QMS/07/00	27
7.4.3 Verification of Purchased Product	QMS/07/00	27
7.5 Production & Service Operation	QMS/07/00	28
7.5.1 Control of Production	QMS/07/00	28
7.5.2 Validation of Process for Production	QMS/07/00	29
7.5.3 Identification & Traceability	QMS/07/00	29
7.5.4 Customer Property	QMS/07/00	29
7.5.5 Preservation of Product	QMS/07/00	30
7.6 Control of Measuring Monitoring Equipments	QMS/07/00	30
8.0 Measurement, Analysis & Improvement	QMS /08/00	31
8.1 General	QMS /08/00	31
8.2 Monitoring & Measurement	QMS/08/00	31
8.2.1 Customer Satisfaction	QMS/08/00	31
8.2.2 Internal Audit	QMS/08/00	31
8.2.3 Measurement & Monitoring of Process	QMS/08/00	32
8.2.4 Measurement & Monitoring of Product	QMS/08/00	32
8.3 Control of non -confirming Product	QMS/08/00	32
8.4 Analysis of Data	QMS/08/00	33
8.5 Improvement	QMS/08/00	34
8.5.1 Continual Improvement	QMS/08/00	34
8.5.2 Corrective action	QMS/08/00	34
8.5.3 Preventive Action	QMS/08/00	34
Annex - A- List of Procedure		
Annex - B - Process Flow Chart		
Annex - C - Organization Chart		

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/LOC/00	XYZ	Issue No: 01
	Quality System Manual	Issue Date:

Scope of the Quality Management System

The scope of the Quality Management System of Dairy Industries Pvt. Ltd. is as follows:
“Manufacture and distribution of pasteurized milk

List of Control Copy Holders

This Manual shall be distributed as per the distribution list.

Copy No.

- 1.
- 2.
- 3.
- 4.

Holder

Managing Director
 General Manger
 Q.C. In charge
 Certification Body

Note:- Management Representative's copy shall be treated as the Master Copy.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/AP/00	XYZ	Issue No: 01
	Quality System Manual	Issue Date:

AMENDMENT –PROCEDURE

The purpose of amendments to this manual is to carry them out systematically so that all versions of the various sections are controlled i.e. properly approved, released and distributed in order to ensure that revised document is provided to the respective person in appropriate period.

Description

Any individual or group of individuals can make request for amendments to this manual. This is to be made in writing to the MR with a copy to the management review committee.

The MR, convenes, if necessary, a meeting of MRC and decides on approving /reflecting the proposed amendment.

The approved version is checked and the MR who also arranges for the required number of copies to be duly signed by the concerned authority accordingly updates Documentation Control System (DCS).

Amendment to any section of the manual is recorded in the list of amendment section. The MR distributes this list and the list of latest version along with the revised section.

ISSUE CONTROL

This quality manual has been prepared in accordance with ISO 9001:2008 standards. It outlines the quality system requirement of the industry to meet the requirement of the standards.

The management representative shall issue this manual. It shall be controlled as per the clause 4.2.3, of this manual. All authorized holders as per distribution list shall be responsible for implementation of the quality system in their respective area.

Individuals in possession of the controlled copies shall receive revision or amendments as and when issued.

Quality manual may be issued outside the organization (if required). It shall however not be controlled, shall not have copy no and shall be stamped ‘Uncontrolled’. No distribution record shall be maintained.

During the internal quality audit the concerned clauses shall be reviewed to ensure the current practice and effectiveness of the documents.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

--	--	--	--	--

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/ LOA/ 00	XYZ	Issue No: 01
	Quality System Manual	Issue Date: /03/2003

LIST OF ABBREVIATON

- CS - Content Sheet
- CEO - Chief Executive Officer
- HACCP - Hazard Analysis Critical Control Point
- ISO - International organization for standardization
- MD - Managing Director
- MR - Management Representative
- NS - Nepal Standard
- QSM - Quality System Manual
- QSP - Quality System Procedure
- SOP - Standard Operating Procedure
- GMP - Good Manufacturing Practice.
- WI - Work Instructions
- XYZ - Dairy Industries Pvt. Ltd.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/CI/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Introduction

A Quality Management System is the way an organization directs and controls those business activities which are associated with quality. Broadly, it consists of an organizational structure together with the planning, processes, resources and documentation that are used to achieve quality objectives, to provide improvement of the products and services and to meet customers' requirements. ISO 9001: 2008 is a structural framework of a business system specifies, in very board terms, the necessary components of a quality management system.

Bhaktapur Dairy Pvt. Ltd and Kathmandu Dairy Industries Pvt. Ltd. have been striving to improve the quality of life of urban milk producers by developing and organizing the milk collection and distribution system. These Industries have been contributing to distribute the milk and other dairy products within the Kathmandu Valley since from two decades of year. It has been supporting to provide the urban dairy diets and support to achieve the governmental objectives to improve and supply of dairy products for urban population. Now, it is excellent news that Bhaktapur Dairy Pvt. Ltd and Kathmandu Dairy Industries Pvt. Ltd. have been going to implement the Quality Management System for the Supply of Quality and Hygienic milk and other dairy products to Nepalese people.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/CI/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

List of Customers

Being daily consumable goods, there are no any specific customers. All general public are its customers. There is no any dealer or retailers. Milk is distributed to general public of Kathmandu valley through milk boots and grocery shops located in different places of Kathmandu Valley.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/04/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirement:

XYZ shall establish, document, implement and maintain continually to improve the Quality Management System in accordance with the requirements of ISO 9001-2008.

- 4.1.1. The organization has identified the process for the Quality Management System and their application. The system can be implemented throughout the organization without any exclusion except clause 7.3, 7.5.2 and 7.5.4 i.e. Design and development, validation process for production, service provision and customer property. The detailed reason for exclusion is given in the preface.
- 4.1.2. The identified sequence and interaction of the processes are given in the respective clause of the quality manual.
- 4.1.3. The Industry shall ensure the availability of resources & information necessary for the process, and measure, monitors and analyze these processes and implement action necessary to achieve planned result and continual improvement. These shall be made available in clause 6.0 and clause 8.0 of manual.
- 4.1.4. The organization does not out-source any process. Hence this part of the standard is not applicable.

4.2 DOCUMENTATION REQUIREMENTS:

4.2.1 General

The organization has developed and documented its quality system to ensure that product conforms to the specified requirement. That quality system covers the organizational structure, responsibilities, procedure, process and resource for implementing effective quality management system.

The Reference of quality system procedure and work instructions shall be made available at appropriate section of this manual whereas the reference of records and specification shall be made available at appropriate sections of quality procedures. The reference of the forms/formats are given in the respective Quality System Procedure

The Quality Policy and Quality Objectives are given in Section 5.3 and 5.4.1. A separate manual has been prepared for quality system procedures.

**4.2.2. Document Introduction
Quality Manual**

Primary document, which defines the scope of the QMS, policy and objectives of the organization addressing the requirements of ISO-9001: 2008. It also includes the Reference of documented procedures, description of the sequence and interaction of

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/04/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

processes included in the QSM. The manual does not have the details of 7.3, 7.5.2 and 7.5.4 because these are excluded and not applicable. This Quality Manual shall be numbered as QSM/XX/ZZ where

QSM- Quality System Manual

XX- ISO-9001 (2008) clause No.

ZZ- Revision No.

Quality System Procedures

These procedures describe how activities related to various elements of ISO-9001:2008 standards are carried out in the industry. They also include work to be performed and responsibility of that activity. This shall be numbered as QSP.

Standard operating procedure (SOP)

These are the procedure not included in the 'Quality System Procedure'. They include process standards for the various components of each process of ISO-9001: 2008, Standard flowchart, work-instruction' etc.

Specifications/standards:

These are related to raw milk, polythene packing material, and skimmed milk powder and contain precise requirement against which conformity can be evaluated.

Master List

These are informative Reference document containing updated listing of classified information's (e.g. supplier list, document list, instrument list etc.)

Forms/Registers/Records:

These are used for recording the results of action taken.

The Quality system document shall be controlled as per the 'quality manual' section 4.2.3. The major quality system procedures established in XYZ industries shall contain the following sections.

Purpose

Scope

Responsibility

Description/Procedure

Records

4.2.3. Control of Documents

Since quality documents are source of industry know-how, it is necessary to establish and operate the procedure for control, release, retention, retrieval and disposition of these documents in order to ensure that the precise, accurate, reliable and valid data are available at the place of use at the required time as well as obsolete documents are promptly removed from the work place.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/04/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Description of Document and Data Control

- I) MR shall ensure that relevant documents are available with respective departments to demonstrate the “Quality Management System” in the Industry.
- II) Head of each division shall ensure that pertinent documents are available at the place of use.
- III) Registry of each division shall be maintained by each department.
- IV) Head of each division shall ensure that obsolete documents are promptly removed from the work place and should be marked with “OBSOLETE DOCUMENT” or NOT APPLICABLE”. If retention is required those shall be retained at a separate place maintaining separate register.
- V) MR shall ensure the proper identification, distribution, maintenance and retrieval of all document and data.
- VI) A set of document as “MASTER DOCUMENT” shall be under MR.

Reference:

Procedure for “**Document and Data Control**”

- XYZ /QSP/01/00

4.2.4. Control of Records:

The purpose of this clause is to establish and maintain procedure for identification, indexing, filing and maintenance of “Quality-Records” in order to demonstrate that quality system is being operated in the industry with all the proof for quality assurance.

The departmental heads are responsible for the control of record in their respective area i.e. all quality records shall be filled and stored by the respective department for a period mentioned in retention period.

- Files are numbered for easy and quick retrieval.
- All departments maintain a master list of records.
- A procedure has been established for “control of quality” records.

The control includes:

- a) The identifiability of all formats, tags and register to bear unique title and document number.
- b) All files and register to be numbered.
- c) All records to be properly indexed.
- d) Safe and secure storage facilities and condition.
- e) The records mostly to be controlled are
 - Minutes of management review, Internal and external audit report, customer order, contract reviews, customer-survey reports.
 - Non-conformance records (service failure, reports, warranty claims, customer complains) corrective action records.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/04/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

- Supplier record (evaluation of supplier)
- Inspection and testing reports, training records.
- Records of goods received and delivered.
- IMT equipments record (calibration)
- Purchasing record, inventory record, dispatch record i.e. all records of each department related with the element of ISO-9001, which are essential to meet the requirements of quality management system.

Reference:

Procedure for “**Control of Records**”

- XYZ/QSP /04/02/00

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management commitment:

XYZ shall provide the evidence of its commitment to Quality Management System in the organization by

- ❑ Communicating to the organization the importance of meeting customers as well as statutory & regulatory requirements through appropriate methods (like training, open discussions and various formal meetings).
- ❑ Establishing quality policy and quality objectives.
- ❑ Conducting management review meeting.
- ❑ Ensuring the availability of resource to achieve stated policy and objectives.

5.2 Customer Focus:

The top management ensures that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving customer satisfaction.

Reference:

Procedure for “**Customer Related Process**” - XYZ/QSP/05/00

5.3 Quality Policy:

Top management shall ensure that the quality policy is

- a. Appropriate to the purpose of the organization
- b. Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.
- c. Provides a framework for establishing and reviewing quality objectives.
- d. Communicated and understood within the organization.
- e. Reviewed for continuing suitability.

Quality Policy

This is the policy and firm determination of **XYZ** to provide packaged drinking milk conforming to relevant specification and other requirements as specified in Nepal Food Law, to provide at competitive price to meet the requirements and satisfaction of our valued customers, which shall be achieved through continual improvement in quality of work, enhancing employee participation at all levels and by using best available resources.

Approved by:
Managing Director

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date: /03/2003

-In achieving the Quality Policy following shall be ensured

- The quality policy is known to all employees of the organization
- The intent of the policy is understood by everyone in the organization
- The quality-system as laid-down in this manual is implemented and followed.
- Efforts are given for the continual improvement of the system as well as the quality of the product.

5.4 **PLANNING**

5.4.1 **Quality Objectives**

Department	Quality Objectives	Units of Measurement
Sales & Marketing	Increasing of sales volume Increasing customer satisfaction index Deliver packaged milk within specified time	%
Quality Assurance	Minimizing the rejection level - Incoming - In-process - Final	%
Production	Increasing Productivity	Liters
Maintenance	Minimizing the breakdown hrs	Hrs
Purchase	Conduct the awareness program to farmers to improve raw milk quality. Monitoring the supplier rating	Nos. %
Stores	Reducing the stock variation for consumable items Maintaining the required stock of processed milk as per demand only	. Liters
Dispatch	Reducing the non-conformances due to leakage and other physical damage.	Liters
MR	Reducing the no. of non-conformances due to audit	Nos.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

5.4.2 Quality management system planning:

The organization shall ensures that

- All the facilities and manpower are being provided accordingly.
- The production process is well established based on the experience gained by the organization.
- The standards of acceptability have been well defined in the form of “Quality Assurance plan” for all stages of verification.
- All changes in the organization are planned in a manner that the working of the quality management system is not affected during these changes.
- All the planning and programs is monitored through the management review meeting at defined interval.

5.5 Responsibility, Authority & Communication

5.5.1 Job Description & Responsibility

Designation: Managing Director (MD)

Responsibilities

- Over all supervision, decision, implementation authorization.
- Shall appoint Management Representative (MR)
- Organize board meetings and annual general board meeting as per statutory requirements in appraise the board on the industry’s performance and approval for any major decisions
- Overall responsible for the entire business operation at XYZ.
- Ensure that quality system is being implemented in each and every division and shall review its effectiveness periodically.
- Shall define policy and objective and make aware of the same to the employees.
-

Responsibilities

- Responsible for all production activities.
- Supervision of the assistant & supervisor.
- Conduct the training for mechanical/ production aspects.
- Reporting the mechanical defaults.
- Supervision of all machines conditions and evaluate the machine performance.
- Reporting to high authority and take decision for corrective action.

<p>.....</p> <p>Prepared & Issued by Sign & date</p>	<p>.....</p> <p>Approved by Sign & date</p>	
--	---	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Designation: Marketing Manager

Responsibilities

- Formulation of marketing policy.
- Decision making for proper marketing & sales.
- Approach & dealing with customer.
- Entertain the customer complaints.
- Inform the quality Control Department regarding quality aspects
- Attention to customer demands.

Designation: Quality Control In charge

Responsibilities

- Supervision of all quality control activities.
- Process control, production, supervision, and personnel hygiene.
- Reporting to high authority and take decision for exact corrective action.
- Report to production department incase of any non-conformance observed.
- Inspection and testing of incoming raw milk, in process and finished product (milk).
- QC documentation.
- Directly dealing with Managing Director and Marketing Manager to overcome the customer complaint
- Responsible for the calibration of the lab. Equipments.
- Arrange the testing of plastic pouch for overall migration trace metal analysis of water in the frequency as mentioned in the QP.
- Test report approval.
-

Designation: QC Officer/ QC Supervisor

Responsibilities

- Analysis of sample.
- Laboratory equipment performance check.
- Tanker supervision.
- QC documentation
- Dealing about laboratory problems.

Designation: Administrative Manger

Responsibilities

- Shall be responsible for day-to-day administrative activities like labor handling, leaves & dealing with various organizations.
- Shall delegate authority to his assistant (Officer)

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Designation: Chilling Center In charge

Responsibilities

- Responsible for supervision of chilling center and testing of collected milk as per Quality Plan.
- Supervision of chilling center (CC) status.
- Aware the top management about CC defaults.
- Supervise overall chilling process.
- Maintain all the records about activities in chilling center.

Designation: Store In -charge

Responsibilities

- Responsible for all store activities
- Maintain the records of issued In coming materials
- Aware the necessity material for industry to his officer and make reliable when needed.
- Maintain all the records
- Responsible for store audits.
- Maintain minimum and maximum inventory level by using bin card system where applicable.

Designation: Maintenance In-Charge

Responsibilities

- Responsible for maintenance of all machinery's of industry.
- Arrange the required expert for machinery.
- Arrange the required Spare- parts & tools for maintenance.
- Keep the records of all the maintenance activities
- Always forward the records to authorized person.
- Supervision of all machineries condition and evaluate the machine performance.

Designation: Marketing Supervisor

Responsibilities

- Responsible for product marketing supervision.
- Check the product's delivery on right booth on right time.
- Entertain the any complaints from customer (Booth) to authorized department.
- Supervise the salesman.
- Maintain the records.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Designation: Operators

Responsibilities

- Responsible for machine operation.
- Aware & informed the status of his own machineries.
- Keep the machinery in working conditions.
- Responsible for able to machine small defaults
- Maintain the records and approved from authorized to their seniors.

Internal Auditor

Responsibility and Duties

- Be prepared to be deputized for the management representative
- Provide assistance and input to the preparation of formal audit programs.
- Prepare details for conducting audits in line with the overall audits program.
- Prepare details for conducting audits in line with the overall audits program.
- Remain impartial and independent in the conduct of audits
- Conduct audit in strict according to procedure of internal audits.
- Report internal audits all non-conformities found as a result of audits major or minor Significance without prejudice as bias.
- Establish with personnel being audited the proposed corrective action and time period for completion of agreed actions.

5.5.2 Management Representative

The MD has appointed Mr. ABC as MR. The major responsibility and duties of MR are as follows: -

- Shall ensure development and compliance of quality management system based on ISO-9001: 2008.
- Shall organize and conduct training at all the levels in the industry as per requirement.
- Shall co-ordinate with the international quality auditors for carrying out internal quality audit as per plan.
- Also co-ordinate with external auditor.
- Shall ensure continuous suitability and effectiveness of the organization quality management system through audit and management reviews and maintain the records.
- Develop and implement efficient management information system regarding quality management system on going status.
- Prepare and maintains a formal documents distribution
- Arrange distribution of completed procedure and quality manual in accordance with the 'Distribution Matrix' and the program.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

5.5.3 Internal Communication

The internal Communication regarding to the process of 'Quality Management System' between both the units and various department is affected through the various documents for examples the work instruction, quality assurance plan etc. and through internal contact meeting & formal letter. The effectiveness of quality management system is reviewed during management review meeting and minutes thereof.

5.6 Management Review

5.6.1 General

The purpose of management review is for providing guidelines for reviewing of the quality system at appropriate time to ensure suitability and effectiveness of the quality management system continuously in the organization. The management review meeting shall be conducted at liaison office, once in every four months. The minutes of Management Review Meeting shall be recorded by the MR. The management review committee shall be comprised of Managing Director and General Manger.

5.6.2 Review Input

The inputs of management review shall include information on:

- Results of audit
- Customer feedback

QSM/05/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

- Process performances and product conformity/ continual improvement
- Status of preventive and corrective action.
- Follow-up action from previous management system
- Change that could affect the quality management system and Agenda is prepared by MR and recorded in Minutes of Management Review Meeting.
- Recommendations for improvement
- Resource requirement
- Any other agenda raised by members

5.6.3 Review Output

Review output from the management review shall include any decisions actions related to

- Improvement of the effectiveness of the quality management system and its processes.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

- ❑ Improvement of production related to customer requirement
- ❑ Resources needs
- ❑ The agenda shall be prepared and circulated by MR.
- ❑ The minutes of the meeting shall be recorded and circulated to all the concerned member of the management review meeting.
- ❑ The minutes of the meeting shall include action plan for corrective measure, responsibility and target date for completion, implementation of corrective measures shall be monitored by the MR.

Reference

Procedure for “**Management Review Meeting**”

- XYZ/QSP/03/00

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/06/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

6.0 Resource Management

6.1 Provisions of Resources:

The management ensures that the adequate resources are provided to

- i. Implement and improve the process of quality management system
- ii. Address customer satisfaction

6.2 Human Resources

6.2.1 General

The organization has defined system of recruitment based on the job recruitment and promotions after requisite 'Quality Awareness Tests' and examination. The availability of skilled manpower with appropriate education, training, skills and experience is therefore assured for the special process.

6.2.2 Competence, training and Awareness: -

The organization has well defined system of:

- Identifying the Competency needs for personnel performing activities Affecting Quality.
- Providing training needed to satisfy these needs.
- Evaluating the effectiveness of training provided
- Ensuring that the employees are aware of the relevance of their activities and how they contribute to the achievement of the Quality Objectives.
- Maintain appropriate records of education, experience, training and qualification.

6.3. Infrastructure:

6.3.1 The industry has adequate and well-ventilated building with sound construction designed to facilitate hygienic operation and is maintained in good conditions.

6.3.2 Adequate working space is provided to allow for satisfactory performance of all operations.

6.3.3 The production plant consists of machineries from renowned manufactures.
Raw milk transported through the tanker is immediately fed for processing after preliminary visual inspection

6.3.4. The cold storage facility is available for the packaged milk. Similarly, a capacious store is available for consumable goods.

6.4. Work Environment

6.4.1 General Manager shall identify the human and physical factors of the work environment needed to achieve conformity of the product.

6.4.2 The same function shall be reviewed once in a year.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/06/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

- 6.4.3 The production operator shall be facilitate for proper hygienic condition i.e. dress code (Cap, Shoe, Mask Glove & Apron), personnel hygiene.
- 6.4.4 The movement of working personnel within production area shall be minimize to avoid cross contamination.
- 6.4.5 The visitors shall be not allowed to production area.
- 6.4.6 Those visitors whom can't be avoided shall be provide proper dress code for entrance.

Reference:

Procedure for “Competency, Training and Awareness” - XYZ/QSP/04/00

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date: /03/2003

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization:

The planning of the process to meet the requirement of the customer is achieved through the work instructions and quality assurance plan.

7.1.1 These work instruction, quality procedures of quality plan shall describe.

- Sequence of operations and sub-operations required realizing the product.
- In process and final inspection requirements, acceptance criteria for the measuring equipment needed.

7.1.2 The work instructions, quality procedures and quality plan shall be formulated keeping in view.

- a. 1. Quality objectives
2. Need to establish the procedures, documents, resources and facilities.
- b. Verification and validation (if required) monitoring, inspection and test activities and criteria for acceptability
- c. List of Work Instruction

Reference:

Procedure for “Production & Operation control”	- XYZ/QSP/07/00
Incoming Material Quality Plan	- XYZ/QP/01/00
In Process Quality Plan	- XYZ/QP/02/00
Finish Product Quality plan	- XYZ/QP/03/00

7.2 Customer Related Process

7.2.1 Determination of Requirements related to the product:

- Statutory and regulatory requirements related to the product shall be followed.
- The industry products distribute to local market.
- Since, milk is daily consumable items. Regarding the characteristics of product requirements of the customer are mentioned in relevant standard e.g. Central food research & QC department.
- If there are certain requirements, which are not stated by the customer but necessary for specified or intended use, the same shall be asked from the customer or identified internally.

Regulatory Requirements

Statutory Requirements

- | | |
|---------------------|--|
| 1. Sales Tax/VAT | Standards/Specifications of packaged milk of Nepal where it is to be marketed. |
| 2. DOI registration | |
| 3. Factory Act | |
| 4. Labor Act | |
| 5. Food Act | |
- The specific requirement of the product/process which the organization has identified shall be applied during the manufacture.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

7.2.2 Review of Requirement Related to the Product

- The marketing activities of the organization shall be monitored and supervised by the Marketing Manger.
- Being daily consumable product milk is marketed on the basis of targeted sales based on past data.
 - Documented product specification/References to any standard e.g. Nepal Standard; Food Act IS 15000:98 etc.
- The milk is dispatch to the market. The leakage and quality non-compliance milk should be collected back at the same day paying attention to the customer attitude.

7.2.3 Customer Communication

- a) The organization shall communicate the customer about the details of the product including the delivery condition as soon as the order is received.
- b) In order to handle the customer complaints a register/form shall be maintained by the marketing manager. Any customer complaints shall be recorded and discussed by the Heads of Marketing, Production and Management Representative. The feedback of the action taken on the complaint shall be intimated to the customer.

Reference:

Procedure for “Customer Related Process” - XYZ/QSP/05/00

7.3. Design and Development

Since the manufacturing of packaged milk is mostly done as per the specification laid down specification may be as per National, Industry standards. Hence at present we are not practicing the design and development activities. So, design and development activities are excluded from this ‘Quality Management System.’

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

7.4 Purchasing

7.4.1 Purchasing process:

The purpose of purchasing is to establish and maintain documented procedures for purchase and procurement activities in order to ensure that procured material conforms to specified requirements as per industry’s policy with respect to cost, quality, and quantity and delivery period. The purchasing process includes the following:

- (a) Suppliers shall be identified, evaluated and approved for skimmed milk powder, packaging material consumable items and service providers.
- (b) All the suppliers of skim milk powder; packaging material is re-evaluated at the frequency of ‘one year’.
- (c) Raw milk shall be accepted as per condition mentioned in procedure for purchasing
- (d) Supplier shall be selected on the basis of “procedure for selection of supplier”. (Except raw milk)
- (e) All new suppliers shall be selected on the basis of material quality, price and a trail order by following the procedure as mentioned in (C) above.
- (f) All the service providers shall be selected on the basis of market reputation and feedback from other customer.
- (g) The calibration agency shall be selected on the basis of
 - (1) Traceability to National standard
 - (2) Better accuracy of master equipment used.
- (h) The record of the results of evaluation and necessary action arising from the evaluation shall be maintained.

7.4.2 Purchasing Information:

- (a) Production Manager prepares for all types of consumable items and skimmed milk powder purchase requisition containing all relevant information.
- (b) Prior to release purchase order are reviewed and approved by Director (Liaison Office) against the description of goods, specification, quality, delivery schedule, quantity etc.
- (c) Irrespective of whether the order is written or verbal the record shall be maintained so that it will be easier to confirm that the industry has products, service as stated in order.

7.4.3 Verification of Purchased Product:

- (a) Wherever necessary the organization shall appoint a person to inspect the material at the supplier’s end for skimmed milk powder, consumable items & machinery.
- (b) Purchase materials are inward in the plant only after receiving inspection.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

- (i) Specified Consumables
 - a) If possible specification of consumable shall be maintained
 - b) The list of approved suppliers shall be maintained.
 - c) Purchase orders are placed as per the procedure described, thus ensuring that all the relevant data is made available to the suppliers.
- (ii) Specified production equipment shall be purchased from the reputed supplier by fixing certain required criteria.

Reference:

Procedure for “**Purchasing, Evaluation and Selection of Supplier**”- XYZ/QSP/06/00

7.5 Production and Service Provision

7.5.1 Control of Production

- The manufacturing process of the industry is given in flowchart.
- For packaged milk to be supplied as per order, first of all a quality assurance plan shall be developed in which all the details such as from Raw material receipt, intermediate process inspection to final production and testing shall be clearly stated.

A production planning, based on the last year data, shall be prepared and production shall be carried out as per planning. Some major points of production and service provision are enumerated below

- (a) Documented quality procedure or operating instruction shall be used when absence of such procedures/instructions would adversely affect quality.
- (b) Machinery used for pasteurization of milk and processing of milk shall be maintained at desired level through the use of preventive maintenance.
- (c) Manufacturing/Processing instructions shall be adhered strictly during manufacturing/processing sequence.
- (d) Any non-conforming processed milk found during production shall be identified, segregated & disposed to stream. Necessary corrective action shall be initiated in order to prevent such non-conformities.
- (e) The milk shall be inspected against the requirements given in quality plan. The milk shall be released for the next operation only when it gives the satisfactory result at the previous stage.
- (f) All personnel and equipment shall be upgrade wherever applicable.
- (g) Preventive and breakdown maintenance of all machines shall be done as per the list of machine/equipment for maintenance and recorded in preventive maintenance register.
- (h) The characteristics of the process and products (packaged milk) shall be monitored and controlled during production to ensure compliance with product specification.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

- (i) All new equipment and processes are approved prior being placed for production. The approval is based on achieving the desired process capability for key quality parameters and has defined process control and preventive maintenance plan.
- (j) Once the milk is ready and final inspection is performed the conforming product shall be delivered as per delivery schedule.
- (k) The servicing and maintenance and repair of plant and equipment shall be carried out according to the procedure for “Preventive Maintenance”.

Reference

Procedure for “**Production & Operation Control**” - XYZ/QSP/07/00

7.5.2 Validation of Process

The organization has no processes where the resulting output cannot be verified by subsequent measurement or monitoring. As when need arises this system will be addressed.

7.5.3 Identification and Traceability

The organization has established and maintained a procedure for identification of products at production, storage, handling, dispatch and delivery to ensure that required materials are easily available at the time of need and also there is no misuse of the material by confused and missed identity. The following steps shall be followed.

- (i) Department heads shall ensure that materials at different stages like receiving, inspection, processing quality, assurance, storage, dispatch and delivery are clearly identified.
- ii) Non-conforming milk shall be disposed immediately.
- iii) There is a clear-cut procedure for store management, including coding, storage and issuance of consumables & packaged milk.
- iv) Accountability of misuse due to wrong or non-identify goes to the production manager.
- v) For processed milk traceability is locatable up to the service point.

7.5.4 Customer Property

The organization do not use any customer-supplied product, therefore this clause is not applicable.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/07/00	XYZ	Issue No.: 01 Issue Date:
	Quality System Manual	

7.5.5 Preservation of Product

The industry shall preserve conformity of product as per standard during internal processing, preserve in cold store and delivery to the intended destination. The above activity shall include: -

- Identification
- Handling
- Packaging
- Cold Storage and
- Delivery

Reference:

Procedure for “**Handling, Storage & Preservation of Product**”- XYZ/QSP/08/00

7.6 Control of Measuring and Monitoring Equipments

The organization has established and maintained documented procedures to control calibrate and maintain inspection, measuring and test equipment to ensure that all inspection, measuring and test equipment are controlled, calibrated and maintained to demonstrate the conformance of product to the specified requirements. The steps followed are presented below.

- a) The measurement to be made and accuracy required shall be determined and the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision will be selected.
- b) All inspection, measuring and test equipment that can affect milk quality shall be identified, calibrated and shall be adjusted at prescribed intervals or prior to use against certified equipment having a known valid relationship to nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented.
- c) Requirements for the calibration of instruments are documented and include:
 - Identification of the instrument type.
 - Unique identification (usually a code number) for each code number.
 - Location of each instrument.
 - Frequency of calibration checks.
 - Acceptance criteria for the calibration checks.
 - Action to be taken when the results of calibration checks are unsatisfactory.
- d) The calibration status of instruments is verified by means of documented calibration records.
- e) The validity of previous inspection and test result is assessed and the outcome is documented when equipment is found to be out of calibration.

Reference:

Procedure for “**Monitoring and Measurement of product**” - XYZ/QSP/10/00

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/08/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

8.0 Measurement, Analysis & Improvements

8.1 General

- (A) The measurement and monitoring activities needed to assure conformity in the operations performed in the organization.
The process improvement is ongoing activities and may sometimes need additional measurement and monitoring activities. The measurements are also planned and implemented while executing these improvements.
- (B) In order to obtain the scope of improvement and hence continuous improvement, problem-solving tools shall be used.
- (C) Using the variable control charts or any other suitable statistical tools shall ensure the continuous improvement and its effectiveness.

8.2 Monitoring & Measurement

8.2.1 Customer satisfaction

There will be two inputs for the measurement of customer satisfaction

- (a) The customer Complaints
- (b) The customer Feedback obtained from the customer in the prescribed format

In case of customer complaints the alarm will be raised to all concerned departments and a manager meeting will be called within forty-eight hours. The action will be started immediately to find out the root cause and hence corrective and preventive action shall be taken. The customer will also be intimated on the action taken and results of the same.

The customers will be requested to fill-up the feedback form at least once in '3' months. The feedback obtained from various customers will be analyzed and action taken on areas of improvement.

Reference:

Procedure for “**Customer Related Process**” - XYZ/QSP/05/00

8.2.2 Internal Audit

- Internal quality audit shall be carried out to monitor continuous effectiveness of the quality management system.
- Internal quality audit shall be co-ordinate by the MR and the minimum frequency for audits shall be three times per year shall be ensured for all the departments.
- The personnel trained for this purpose that shall have no direct responsibilities for the departments being audited shall carry out the audits.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/08/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

- Prior to carrying out audits, audit plan and audit schedule shall be drawn by MR.
- The auditor shall record the audit findings. The auditor shall countersign audit finding. The findings shall be registered in Audit finding report.
- Respective department in-charge shall spell out corrective action and time frame for correcting the non-conformance.
- Follow-up audit shall be carried out by concerned auditor/MR to verify effective implementation of corrective action.

MR shall maintain and analyze audit records.

Reference:

Procedure for “**Internal Audit**”

- XYZ/QSP/09/00

8.2.3 Measurement & Monitoring of Process

The organization shall apply suitable methods for measurement and monitoring of realization processes necessary to meet customer requirements. The methods shall confirm the continuing ability of each process to satisfy the internal purpose.

8.2.4 Monitoring and Measurement of Product

The processed milk characteristics shall be verified against the criteria defined in the Quality Assurance Plan. The inspection and test records of the product shall be maintained. The product shall not be realized for the next operation unless it qualifies the requirement of the previous operation. The final product shall not be allowed for dispatch unless planned arrangement has been satisfactorily implemented.

Reference:

Procedure for “**Monitoring & Measurement of Product**” - XYZ /QSP/10/00

8.3 Control of Non-conforming Product

The purpose of this clause is to establish and maintain documented procedure for control of non-conforming product to ensure that product that do not conform to specified requirements is prevented from further processing and packaging. To fulfill these following steps shall be followed: -

- All concerning departments shall establish and maintain procedures to ensure that product that do not conform to specified requirements is prevented from inadvertent use, control is provided for identification, documentation, evaluation, segregation and the disposition of non-conforming product.
- Responsible personnel of each department shall devise suitable format to record non-conformities and subsequent corrective action shall be taken.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/08/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

Non-conforming product shall be reviewed in accordance with documented procedures. It may be

- a) Rejected
- b) Regarded for alternative applications or
- MR reviews department wise number of non-conformance
- Occurrences of non-conformance are periodically summarized and reviewed for trends to be presented for corrective and preventive action.
- The causes for non-conformity are investigated and probable causes recorded for taking corrective and preventive action. In near future statistical tools like control chart, histogram, fish-bone diagram shall be used whenever possible and essential for analysis of the reflection of the problem.
- **System non-conformance:** At regular intervals audit shall be conducted of the entire department and non-conformity shall be recorded.
- Appropriate corrective action on the same shall be taken and the verification of the effectiveness shall be done by the concerned auditor/MR

Reference:

Procedure for “Control of Non-Conforming Product” - XYZ/QSP/11/00

8.4 Analysis of data: -

The organization shall collect and analyze the identified data to determine the suitability and effectiveness of ‘Quality Management System’ and to identify improvement that can be made. Data shall include measuring and monitoring activities and other identified sources.

The organization has identified the data analysis, which shall be

- * Customer satisfaction and / or dissatisfaction
- * Conformance to requirement
- * Characteristics of process, product and their trend
- * Supplier
- * Market shared & sales volume representation

The various techniques for data analysis shall be

- (a) Pareto analysis
- (b) Control Charts
- (c) Fish bone diagram etc.

..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

QSM/08/00	XYZ	Issue No.: 01
	Quality System Manual	Issue Date:

8.5 Improvement:

8.5.1 Continual Improvement

Planning for continual improvement: The organization shall plan and manage the process necessary for the continual improvements of “Quality Management System” The organization shall continual improve the effectiveness of the "QMS" through the use of the following:

- Quality Policy
- Quality Objective
- Corrective and preventive action
- Audit results
- Analysis of data
- Management review

8.5.2 Corrective Action

- (a) The organization shall take action to eliminate the cause of non-conformance in order to prevent the recurrence of the problem.
- (b) The input for analysis of the problem to take appropriate corrective action shall be as follows: -
 - i) The product and process and quality system non-conformity shall be analyzed to find out the root cause of the problem.
 - ii) Customer complaints shall be taken in the review points
 - iii) Joint decision shall be taken to identify the action required in order to prevent the non-conformities
 - iv) Prioritizing the corrective action and implementation.
 - v) The result of the action taken shall be recorded and reviewed for the further improvement.

8.5.3 Preventive Action:

- (a) The organization shall determine action to eliminate the cause of potential non-conformities in order to prevent their occurrence.
- (b) The control chart shall be used to identify the occurrence of the problem.
- (c) The root cause of the problem shall be identified.
- (d) The sequence of implementation of action needed shall be determined. Records of this effect shall be maintained.

Reference:

Procedure for “**Corrective and Preventive Action**”

- XYZ/QSP/12/00

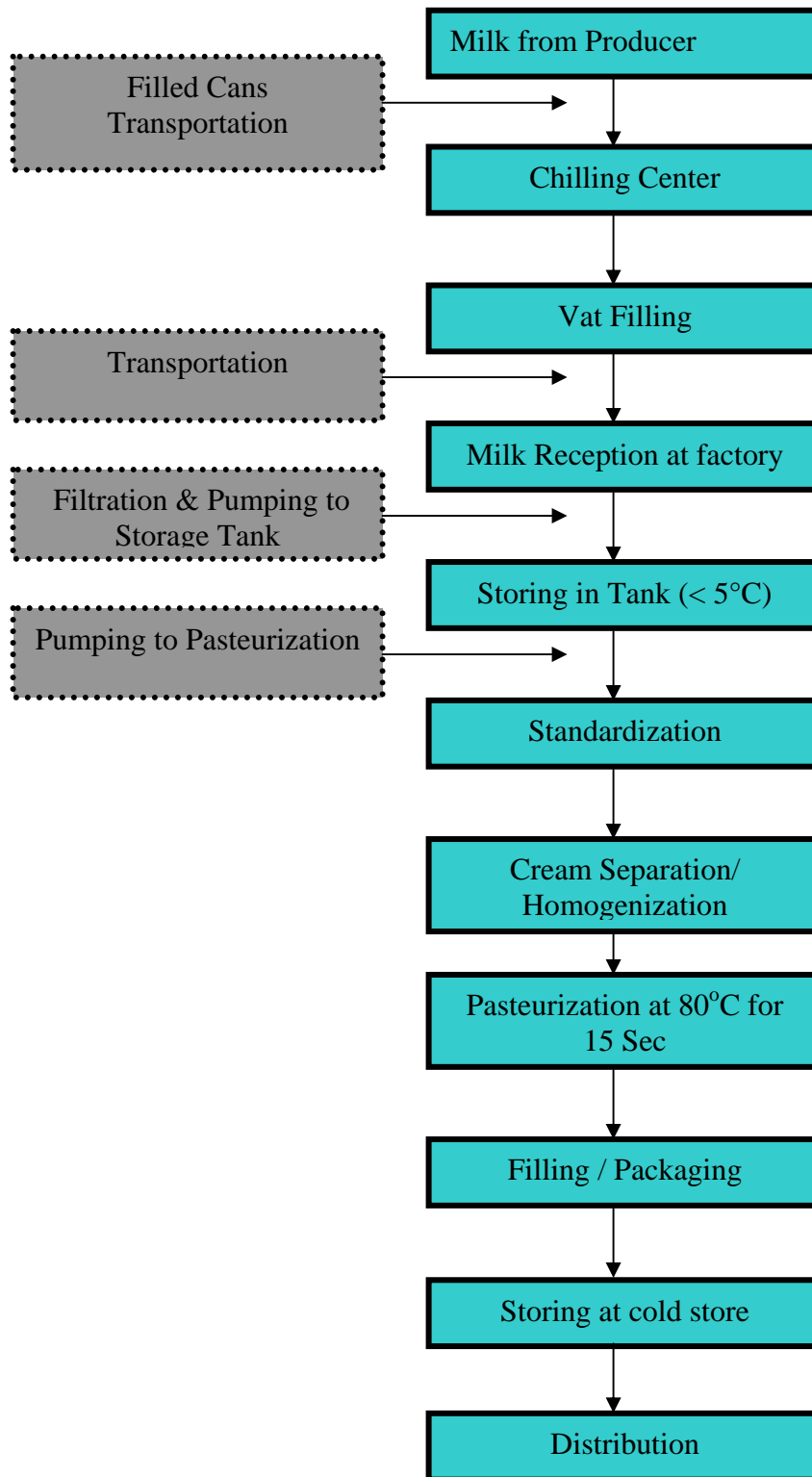
..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

Annex - A
List of Procedures

S. N.	Content	Clause Ref. of ISO 9001: 2000	Document No.	Page
1	Content Sheet	-	XYZ/QSP/CS/00	
2	Control Policy	-	XYZ/QSP/CP/00	
3	Amendment Record sheet	-	XYZ/QSP/ARC/00	
4	Procedure for Document and Data control	4.2	XYZ/QSP/01/00	
5	Procedure for control of Quality Records	4.2	XYZ/QSP/02/00	
7	Procedure for Management Review Meeting	5.6	XYZ/QSP/03/00	
8	Procedure for Competency, Training and Awareness	6.2	XYZ/QSP/04/00	
13	Procedure for Customer Related Process	7.2	XYZ/QSP/05/00	
14	Procedure for Purchasing Evaluation and Selection of Supplier	7.3	XYZ/QSP/06/00	
16	Procedure for Production & Operation Control	7.5	XYZ/QSP/07/00	
18	Procedure for Handling, Storage and Preservation of Product	7.5	XYZ/QSP/08/00	
22	Procedure for Internal audit	8.2	XYZ/QSP/09/00	
23	Procedure for Monitoring & Measuring of Processes & Products	8.2	XYZ/QSP/10/00	
24	Procedure for Control of non-conforming Product	8.3	XYZ/QSP/11/00	
27	Procedure for Corrective & Preventive Action	8.5	XYZ/QSP/12/00	

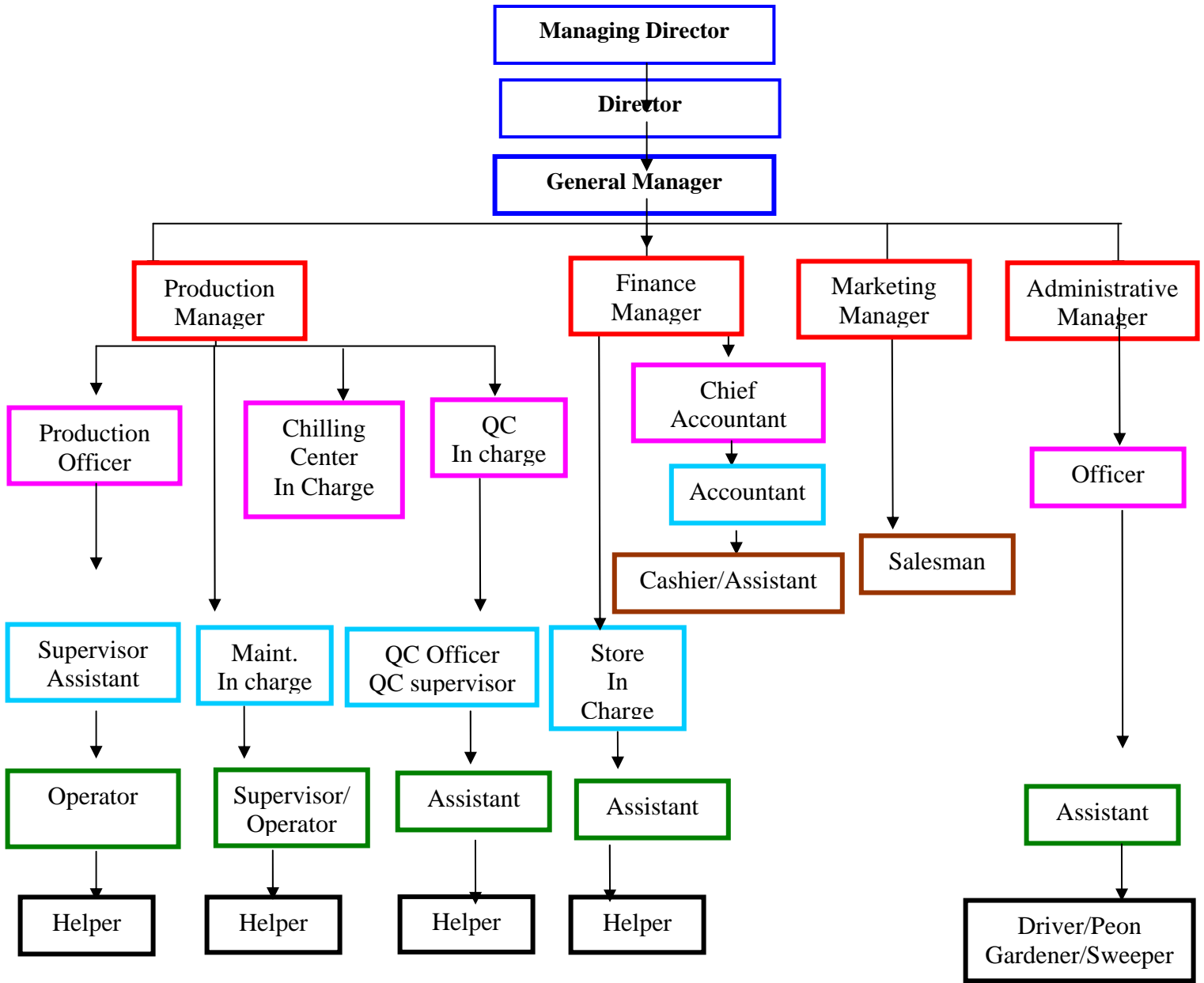
..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

Annex - B
Process Flow Chart of XYZ



..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--

Annex -C
ORGANIZATION CHART of XYZ Sample only



..... Prepared & Issued by Sign & date Approved by Sign & date	
--	-------------------------------------	--