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IS 16021 (2012): Good Manufacturing Practices (GMP) – Requirements for Organizations in the Food Processing Sector [FAD 15: Food Hygiene, Safety Management and Other Systems]



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“Knowledge is such a treasure which cannot be stolen”

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बेहतर उत्पादन की रीतियाँ (जी एम पी) — खाद्य प्रसंस्करण
क्षेत्र में संगठन की अपेक्षाएँ

Indian Standard

GOOD MANUFACTURING PRACTICES (GMP) —
REQUIREMENTS FOR ORGANIZATIONS IN THE FOOD
PROCESSING SECTOR

ICS 67.020

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Food Hygiene, Safety Management and Other Systems Sectional Committee had been approved by the Food and Agriculture Division Council.

Food processing sector includes the food processors, suppliers of equipment, raw materials, ingredients, packing materials, processing aids, pesticides, fertilizers and cleaning chemicals. However, it does not include primary production, transportation, storage and retail.

The good manufacturing practices (GMP) — Requirements for organization in the food processing sector, has been developed to assist organizations to implement and operate effective manufacturing practices, to produce and process products as per specifications and reduce the risk of contamination. The design, documentation and implementation of an organization's GMP system is influenced by the specific needs of the products provided and the processes employed. This standard does not aim to imply uniformity in structure of the GMP systems or uniformity in documentation.

The requirements specified in this standard are complimentary to the requirements of the product. Information marked 'NOTE' is not auditable and has been provided for providing guidance in understanding the associated requirement.

This standard may be treated as a generic pre requisite to IS 15000 : 1998 'Food hygiene — Hazard analysis and critical control point (HACCP) and guidelines for its application' and IS/ISO 22000 : 2005. It may be used by internal and external parties including certification bodies, to assess the organizations' ability to meet the requirements of good manufacturing practices as a part of a food safety and quality systems requirements.

Nothing in this Indian Standard shall affect the operation of the *Food Safety and Standards Act, 2006* and regulations framed thereunder; *Standards of Weights and Measures Act, 1977* or any other law for the time being in force and shall be subject to the restrictions imposed thereunder, wherever applicable.

In the formulation of this standard considerable assistance has derived from the following International Standards and documents:

| | |
|----------------------------|---|
| ISO 9001 : 2008 | Quality management systems — Requirements |
| ISO 10012 : 2003 | Measurement management systems — Requirements for measurement processes measuring equipment |
| ISO 14159 : 2002 | Safety of machinery — Hygiene requirements for the design of machinery |
| ISO 15161 : 2001 | Guidelines on the application of ISO 9001 : 2000 for the food and drink industry |
| ISO 19011 : 2002 | Guidelines for quality and/or environmental management systems auditing |
| IS/ISO 22000 : 2005 | Food safety management systems — Requirements for any organization in the food chain |
| IS/ISO/TS 22004 : 2005 | Food safety management systems — Guidelines on the application of ISO 22000 : 2005 |
| ISO 22005 : 2007 | Traceability in the feed and food chain — General principles and guidance for system design and development |
| ISO/IEC Guide 51 : 1999 | Safety aspects — Guidelines for their inclusion in standards |
| ISO/IEC Guide 17021 : 2006 | Conformity assessment — Requirements for bodies providing audit and certification of management systems |

Codex Alimentarius Food Hygiene Basic Texts, Food and Agricultural Organization of the United Nations, World Health Organization, Rome, 2001.

CAC/RCP 1 — 1969 Rev 4 — 2003 Recommended International Code of Practice, General Principles of Food Hygiene

Indian Standard

GOOD MANUFACTURING PRACTICES (GMP) — REQUIREMENTS FOR ORGANIZATIONS IN THE FOOD PROCESSING SECTOR

1 SCOPE

This standard specifies the requirements for good manufacturing practices, regardless of their size to implement systems that would consistently contribute to producing safe and quality products. All requirements of this standard are generic and intended to be applicable to organizations belonging to the food processing sector.

Food processing sector includes the food processors, suppliers of equipment, raw materials, ingredients, packing materials, processing aids, pesticides, fertilizers and cleaning chemicals. However, it does not include primary production, transportation, storage and retail.

This standard specifies requirements to enable an organization,

- a) to plan, implement, operate, maintain and update Good Manufacturing Practices, aimed at providing quality products that, according to their intended use are safe for the consumer;
- b) to demonstrate compliance with good hygiene practices and applicable statutory and regulatory requirements;
- c) to effectively communicate food safety and quality issues to suppliers, customers and relevant interested parties in the food chain;
- d) to facilitate the organization towards achievement of the stated food safety and quality policy and objectives;
- e) to demonstrate such conformity to relevant interested parties; and
- f) to seek certification or registration of its Good Manufacturing Practices by an external organization or make a self assessment of conformity to this Indian Standard.

NOTE — Examples of food safety management system are good agricultural practices, good aquaculture practices, good animal husbandry practices, good hygiene practices, good manufacturing practices, good retail practices, hazard analysis and critical control points and food safety management systems.

2 REFERENCES

The following standards contain provisions which through reference in this text, constitute provisions of

this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

| <i>IS No.</i> | <i>Title</i> |
|-----------------|--|
| 7688 | Code of practice for labelling of pre-packaged foods: |
| (Part 1) : 1975 | General guidelines |
| (Part 2) : 1976 | Guidelines on claims |
| (Part 3) : 1976 | Nutritional labelling |
| IS/ISO 9000 : | Quality management systems — |
| 2005 | Fundamentals and vocabulary |
| 10500 : 1991 | Drinking water — Specification (<i>first revision</i>) |
| IS/ISO 22000 : | Food safety management systems — |
| 2005 | Requirements for any organization in the food chain |

3 TERMS AND DEFINITIONS

For the purpose of this standard, the terms and definitions given in IS/ISO 9000, IS/ISO 22000 and the following shall apply.

For the convenience of the uses of this standard, some of the definitions given in ISO 9000 are quoted with added notes that are applicable only to this special application.

NOTE — Terms are not defined where they retain their normal dictionary definition.

3.1 Cleaning — The removal of soil, food residue, dirt, grease or other objectionable matter.

3.2 Contaminant — Any biological, chemical agent (including allergens), foreign matter, or other substances not intentionally added to food, which may compromise food safety or suitability.

3.3 Contamination — The introduction or occurrence of a contaminant in food or food environment.

3.4 Control Measure — (Food safety) action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

3.5 Correction — Action to eliminate a detected non-conformity.

NOTES

1 For the purpose of this standard, a correction relates to the handling of potentially unsafe products and can therefore, be made in conjunction with a corrective action.

2 A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the non-conformity (such as disposal for other use of specific labelling).

3.6 Corrective Action — Action to eliminate the cause of a detected non-conformity or other undesirable situation.

NOTES

1 There can be more than one cause for a non-conformity.

2 Corrective action includes cause analysis and is taken to prevent recurrence.

3.7 Disinfection — The reduction by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

3.8 End Product — Product that will undergo no further processing or transformation by the organization.

3.9 Establishment — Any building or area in which food is handled and the surroundings, under the control of the same food business operation.

3.10 Flow Diagram — Schematic and systematic presentation of the sequence and interactions of steps.

3.11 Food Business Management/Owner — The person or persons responsible for ensuring that the requirements of this standard are met within the food business under his/their control.

3.12 Food Chain — Sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption.

NOTES

1 This includes the production of feed for food-producing animals and for animals intended for food production.

2 The food chain also includes the production of materials intended to come into contact with food or raw materials.

3.13 Food Handler — Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore, expected to comply with food hygiene requirements.

3.14 Food Hygiene — All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

3.15 Food Safety — Concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

NOTE — Food safety is related to the occurrence of food safety hazards and does not include other human health aspects related to for example, malnutrition.

3.16 Food Safety Hazard — Biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect.

NOTES

1 The term 'hazard' is not to be confused with the terms 'risk' which in the context of food safety, means a function of the probability of an adverse health effect (for example becoming diseased) and the severity of that effect (death, hospitalisation, absence from work, etc) when exposed to a specified hazard. Risk is the combination of the probability of occurrence of harm and the severity of that harm.

2 Food safety hazards include allergens.

3 In the context of feed and feed ingredients, relevant food safety hazards are those that may be present in and/or on feed and feed ingredients and that may subsequently be transferred to food through animal consumption of feed and may thus have the potential to cause an adverse human health effect. In the context of operations other than those directly handling feed and food (for example producers of packaging materials, cleaning agents, etc) relevant food safety hazards are those hazards that can be directly or indirectly transferred to food because of the intended use of the provided products and for services and thus can have the potential to cause an adverse human health effect.

3.17 Food Suitability — Assurance that food is acceptable for human consumption according to intended use.

3.18 Good Manufacturing Practices (GMP) — The Good Manufacturing Practices (GMP) are the procedures or universal steps which provide the basic environmental conditions and a management system structure necessary for the production of safe and wholesome foods.

3.19 GMP Policy — Overall intentions and direction of an organization related to good manufacturing practices towards food safety and quality as formally expressed by top management.

3.20 HACCP — A system which identifies, evaluates and controls hazards which are significant for food safety.

3.21 Monitoring — Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.

3.22 Primary Production — Those steps in the food chain up to and including, for example, harvesting, milking, fishing.

3.23 Product — A result of processes.

NOTE — A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.24 Quality — Degree to which a set of inherent characteristics fulfills requirements.

3.25 Quality Assurance — Part of quality

management focussed on providing confidence that quality requirements will be fulfilled.

3.26 Quality Management — Co-ordinated activities to direct and control an organization with regard to quality.

3.27 Updating — Immediate and/or planned activity to ensure application of the most recent information.

3.28 Verification — Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

4 GOOD MANUFACTURING PRACTICES

4.1 General Requirements

4.1.1 Obligations Upon Food Business

The top management of the food business shall ensure that requirements specified below which are applicable to the nature of food operations, are complied with in addition to the applicable statutory and regulatory requirements.

The organization shall,

- a) manage basic conditions and activities for the purpose of maintaining hygienic and suitable production, processing and/or handling environment;
- b) ensure quality assurance systems for the products and services;
- c) communicate appropriate information throughout the food processing sector and relevant interested parties (for example, statutory and regulatory authorities, customers and consumers) regarding food safety and quality issues related to the products;
- d) communicate information concerning development, implementation and updating of the good manufacturing practices system throughout the organization to the extent necessary to ensure practices for safe and quality products; and
- e) evaluate periodically and update as necessary, the GMP system to ensure that the system reflects the organizations activities and incorporates the most recent information on food safety hazards that is subject to control through good manufacturing practices.

Where the organization chooses to outsource any process that may affect end product conformity, the organization shall ensure control over such processes. Control over such outsourced processes shall be identified and documented within the GMP system.

NOTE — The GMP system design shall be appropriate to the organization's needs with respect to food safety and quality, the size and type of operation and is to be approved by the GMP team.

4.2 Documentation Requirements

4.2.1 General

The GMP system documentation shall include;

- a) documented statements of GMP policy and related objectives;
- b) the scope of the GMP system. The scope shall specify the products or product categories, processes and production sites that are addressed by the GMP system;
- c) documented procedures and records required by this standard; and
- d) documents needed by the organization to ensure the effectiveness, development, implementation and updating of the GMP system.

4.2.2 Control of Documents

Documents required by the GMP system shall be controlled. Records are a special type of document that shall be controlled according to the requirements given in **4.2.3**.

The controls shall ensure that all proposed changes are reviewed prior to implementation in order to determine their effects on food safety and their impact on the GMP system.

A documented procedure shall be established to define the controls needed,

- a) to approve documents for adequacy prior to issue;
- b) to review and update documents as necessary and re-approve documents;
- c) to ensure that changes and the current revision status of documents are identified;
- d) to ensure that relevant versions of applicable documents are available at points of use;
- e) to ensure that documents remain legible and readily identifiable;
- f) to ensure that relevant documents of external origin are identified and their distribution controlled; and
- g) to prevent the unintended use of obsolete documents and to ensure that they are suitably identified as such, if they are retained for any purpose.

4.2.3 Control of Records

Records shall be established and maintained to provide evidence of conformity to requirements and evidence of

the effective operation of the GMP system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the GMP system and to continually improving its effectiveness by,

- a) showing food safety and quality is supported by the business objectives of the organization;
- b) communicating to the organization the importance of meeting the requirements of this standard, *Food Safety and Standards Act, 2006* and regulations framed thereunder and any statutory and regulatory, as well as customer requirements relating to food safety and quality;
- c) establishing the GMP policy;
- d) conducting management reviews; and
- e) ensuring the availability of resources.

5.2 GMP Policy

Top management shall define, document and communicate its GMP policy with regard to food safety and quality.

Top management shall ensure that the GMP policy;

- a) is appropriate to the role of the organization in the food processing sector;
- b) conforms with both statutory and regulatory requirements and with mutually agreed food safety and quality requirements;
- c) is communicated, implemented and maintained at all levels of the organization;
- d) is reviewed for continued suitability;
- e) adequately addresses communication; and
- f) is supported by measurable food safety objectives.

5.3 GMP System Planning

Top management shall ensure that,

- a) planning of the GMP system is carried out to meet requirements given in GMP standard, in **4.1** as well as the objectives of the organization that support food safety and quality,
- b) the integrity of the GMP system is maintained

when changes to the GMP system are planned and implemented, and

- c) Planning is based on the following considerations:
 - 1) The likelihood of introducing food safety hazards to the products through the work environment;
 - 2) Biological, chemical and physical contamination of the product(s), including cross contamination between products; and
 - 3) Food safety hazard levels in the product processing environment.

5.4 Responsibility and Authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the GMP system.

All personnel having responsibility to report problems within the GMP system shall be identified. Designated personnel shall have defined responsibility and authority to initiate and record actions.

5.4.1 GMP Team Leader

Top management shall appoint a GMP competent team leader who, irrespective of other responsibilities, shall have the responsibility and authority,

- a) to manage a GMP team and organize its work relating to GMP system;
- b) to ensure relevant training and education of the GMP team members (*see 6.2.1*);
- c) to ensure that the GMP system is established, implemented, maintained and updated; and
- d) to report to the organization's top management on the effectiveness and suitability of the GMP system.

NOTE — The responsibility of the GMP team leader may include liaison with external parties on matters relating to the food safety management system.

5.4.2 GMP Team

A GMP team shall be appointed.

The GMP team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the GMP system. This includes, but need not be limited to the organization's products, processes, equipment and food safety hazards within the scope of the GMP system.

Records shall be maintained to demonstrate that the GMP team has the required knowledge and experience (*see 6.2.2*).

5.5 Communication

5.5.1 External Communication

To ensure that sufficient information on issues concerning food safety and quality is available throughout the food chain, the organization shall establish, implement and maintain effective arrangements for communicating with,

- a) suppliers and contractors;
- b) customers or consumers in relation to product information including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life, allergens wherever applicable, enquiries, contracts or order handling including amendments and customer feedback including customer complaints;
- c) statutory and regulatory authorities; and
- d) other organizations that have an impact on, or shall be affected by, the effectiveness or updating of the GMP system.

Such communication shall provide information on food safety and quality aspects of the organization's products and/or processes that may be relevant to other organizations in the food chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the food chain. Records of communications shall be maintained.

Food safety requirements from statutory and regulatory authorities and customers shall be available.

Designated personnel shall have defined responsibilities and authority to communicate externally any information concerning food safety. Information obtained through external communication shall be included as input to system updating (*see 9.1*) and management review (*see 5.7*).

5.5.2 Internal Communication

The organization shall establish, implement and maintain effective arrangements for communicating with personnel on following issues having an impact on food safety and quality:

- a) Products or new products;
- b) Raw materials, ingredients and services;
- c) Production systems and equipment;
- d) Production premises, location of equipment, surrounding environment;
- e) Cleaning and sanitation programmes;
- f) Packaging storage and distribution systems;
- g) Personnel qualification levels and/or allocation of responsibilities and authorizations;

- h) Statutory and regulatory requirements;
- j) Knowledge regarding food safety hazards and control;
- k) Customer, sector and other requirements that the organization feels is necessary;
- m) Relevant enquiries from external interested parties;
- n) Complaints indicating food safety hazards associated with the product; and
- p) Other conditions that have an impact on food safety and quality.

The GMP team shall ensure that this information is included in the updating of the good manufacturing practices system (*see 9.1*). Top management shall ensure that relevant information is used as input to management review (*see 5.7.2*).

5.6 Emergency Preparedness and Response

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain.

NOTE — Emergency situations may include, for example, fire, flooding, food contamination, poisoning, bio-terrorism, sabotage, energy failure, vehicle accidents and contamination of the environment.

Such situations may be suitably categorized as 'A', 'B' or 'C' depending on the severity and/or extent of the situation.

5.7 Management Review

5.7.1 General

Top management shall review the organization's GMP system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the GMP system, including the GMP policy. Records of management reviews shall be maintained (*see 4.2.3*).

5.7.2 Review Input

The input to management review shall include, but is not limited to, information on,

- a) follow-up actions from previous management reviews;
- b) analysis of results of verification activities;
- c) changing circumstances that can affect food safety and quality (*see 5.3*);
- d) changes required in infrastructure, work environment, product and end product characteristics, intended use, operational

- control and others to ensure food safety and quality;
- e) emergency situations, accidents (*see 5.6*) and withdrawals (*see 8.4*);
- f) reviewing results of system-updating activities (*see 9.1*);
- g) review of communication activities, including customer feedback [*see 5.5.1 (b)*]; and
- h) external audits or inspections.

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the system.

NOTE — The term 'withdrawal' includes recall.

5.7.3 Review Output

The output from the management review shall include decisions and actions related,

- a) assurance of food safety and quality (*see 4.1*);
- b) improvement of the effectiveness of the GMP system (*see 9*);
- c) resource needs (*see 6*); and
- d) revisions of the organization's GMP policy and objectives.

6 RESOURCES

6.1 General

The organization shall determine and provide resources needed to implement and maintain the GMP system and continually improve its effectiveness.

6.2 Human Resources

6.2.1 General

The GMP team and the other personnel carrying out activities having an impact on food safety and quality shall be competent and shall have appropriate education, training, skills and experience

Where the assistance of external experts is required for the development, implementation, operation or assessment of the GMP system, records of agreement or contract defining the responsibility and authority of external experts shall be available.

Those engaged in food operation and who come directly or indirectly into contact with food shall be trained, and/or instructed in food hygiene and quality to a level appropriate to the operation they perform.

6.2.2 Competence, Awareness and Training

The organization shall,

- a) identify the necessary competencies for personnel whose activities have an impact on food safety and quality;

- b) provide training or take other action to ensure personnel have the necessary competencies;
- c) training should be given from time-to-time to food handlers to maintain GMP;
- d) ensure that personnel responsible for monitoring, corrections and corrective actions of the GMP system are trained;
- e) periodic assessments of the effectiveness of training and instruction programmes shall be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively;
- f) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to GMP system. All personnel shall be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers shall have the necessary knowledge and skills to enable them to handle food hygienically;
- g) instruct those who handle strong cleaning chemical or other potentially hazardous chemical, in safe handling techniques;
- h) managers and supervisors of food processes shall have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to rectify deficiencies;
- j) ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety and quality;
- k) training programmes shall be routinely reviewed and updated where necessary; systems shall be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food; and
- m) maintain appropriate records of training and actions related to 6.2.2 (a) and 6.2.2 (b).

NOTE — Factors to take into account in assessing the level of training required shall include,

- a) the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage;
- b) micro-organisms: the manner in which the food is handled and packed, including the probability of contamination;
- c) the extent and nature of processing or further preparation before final consumption;
- d) the conditions under which the food will be stored; and
- e) the expected length of time before consumption.

6.3 Infrastructure

6.3.1 General

The organization shall provide the resources for the establishment and maintenance of the infrastructure

needed to implement the requirements of this standard. Depending on the nature of the operations and the risks associated with them, premises, equipment and facilities shall be located, designed and constructed to ensure that,

- a) contamination is minimized;
- b) design and layout permit appropriate maintenance and prevents cross contamination by keeping unidirectional flow of process and materials, cross-contamination from workers and product and location of wash room to minimize contamination, cleaning and disinfections and minimize airborne contamination;
- c) surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;
- d) where appropriate, suitable facilities are available for light, temperature, humidity and other controls; and
- e) there is effective protection against pest access and harbourage; and
- f) it has identified place for keeping waste suitably located away from processes or plant building such that it prevent any possibility of contamination.

6.3.2 Location

6.3.2.1 Establishments location

Potential sources of contamination shall be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food from contamination. Effective measure shall be taken to prevent contamination from neighbouring surroundings.

NOTE — In particular, establishments should normally be located away from:

- a) environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- b) areas prone to infestations of pests; and
- c) areas where wastes, either solid or liquid, cannot be removed effectively.

6.3.2.2 Equipment location

Equipment shall be located so that it,

- a) permits adequate maintenance and cleaning and prevent cross-contamination;
- b) functions in accordance with its intended use; and
- c) facilitates good hygiene practices, including monitoring.

6.3.3 Premises and Rooms

6.3.3.1 Design and layout

Where appropriate, the internal design and layout of food establishments shall permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

NOTE — Ensure smooth flow of material during production to prevent cross-contamination between products.

6.3.3.2 Internal structures and fittings

Structures within food establishments shall be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected.

NOTE — In particular the following specific conditions should be satisfied, where necessary, to protect the safety and suitability of food:

- a) Surfaces of walls, partitions and floors should be made of impervious materials with non-toxic effect in intended use;
- b) Walls and partitions should have a smooth surface up to a height appropriate to the operation;
- c) Floors should be constructed to allow adequate drainage and cleaning;
- d) Ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles;
- e) Windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;
- f) Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- g) Doors between external environment and the production areas should be provided with air curtains or suitable means to prevent entry of air from the external environment into the production area; and
- h) Working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

6.3.4 Temporary/Mobile Premises and Vending Machines

Premises and structures covered here include market stalls, mobile stalls and street vending vehicles, temporary premises in which food is handled such as tents.

Such premises and structures shall be sited, designed and constructed to prevent contamination of food and harbouring pests.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities shall be adequately controlled to ensure the safety and suitability of food.

Potable water (*see* IS 10500) and effective waste disposal system shall be provided.

6.3.5 *Equipment Design*

6.3.5.1 *General*

Equipment and containers (other than once—only use containers and packaging) coming into contact with food, shall be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers shall be made of materials with no toxic effect in intended use. Where necessary, equipment shall be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

6.3.5.2 *Food control and monitoring equipment*

In addition to the general requirements given in 6.3.5.1, equipment used to cook, heat treat, cool, store or freeze food shall be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment shall also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment shall have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety, quality or suitability of food.

NOTE — These requirements are intended to ensure that,

- a) harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled; and
- b) temperature and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

6.3.6 *Containers for Waste and Inedible Substances*

Containers for waste, by-products and inedible or hazardous substances, shall be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

Containers used to hold dangerous substances shall be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

6.3.7 *Facilities*

6.3.7.1 *Water supply*

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, shall be available whenever necessary to ensure the safety and suitability of food.

Potable water shall be as specified in IS 10500 or water of a higher standard or as specified by applicable statutory or regulatory requirement. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system.

Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems. Ice and steam used in direct contact with food shall be made from potable water.

6.3.7.2 *Drainage and waste disposal*

Adequate drainage and waste disposal systems and facilities shall be provided. They shall be designed and constructed so that the risk of pest ingress contaminating food processing area or the potable water supply is avoided. Waste storage shall be covered and kept away from food handling, food storage and other working area so as to avoid the contamination in food processing, storage and environment. The proper disposal of sewage and effluent (solid, liquid and gas) shall be provided in such a manner so as to eliminate the risk of contamination.

6.3.7.3 *Cleaning*

Adequate facilities, suitably designated, shall be provided for cleaning food, utensils and equipment. Such facilities shall have an adequate supply of hot and cold potable water where appropriate. Records for cleaning and sanitation of equipments and whole plant should be maintained on daily basis.

6.3.7.4 *Air quality and ventilation*

Adequate means of natural or mechanical ventilation shall be provided.

Ventilation systems shall be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

NOTE — Ventilation should be provided in particular to,

- a) minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- b) control ambient temperatures;
- c) control odours which might affect the suitability of food; and
- d) control humidity, where necessary, to ensure the safety and suitability of food.

6.3.7.5 *Lighting*

Adequate natural or artificial lighting shall be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting shall not be such that the resulting colour is misleading. The intensity shall be adequate to the nature of the operation. Lighting fixtures shall, where appropriate, be protected to ensure that food is not contaminated by breakages.

NOTE — The minimum illumination requirements are, approximately, as follows:

- a) Utility sections, loading area and near equipment like pasteurizer, separator, can washer and other general equipment: 215-3 245 lux;

- b) Near control panels, gauges, scales, 540-755 lux; and thermometers, etc:
- c) Laboratory: 1 080 lux

6.4 Work Environment

6.4.1 General

The organization shall provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of this standard.

6.4.2 Maintenance, Cleaning and Sanitation

6.4.2.1 General

Organization shall establish effective systems to,

- a) ensure adequate and appropriate maintenance and cleaning;
- b) control pests (*see* 6.4.3);
- c) manage waste; and
- d) monitor effectiveness of maintenance and sanitation procedures.

6.4.2.2 Maintenance and cleaning

6.4.2.2.1 General

Establishments and equipment shall be kept in an appropriate state of repair and condition to,

- a) facilitate all sanitation procedures;
- b) function as intended, particularly at critical steps; and
- c) prevent contamination of food, for example, from metal fragments, flaking plaster, paint, debris and chemicals.

Cleaning shall remove food residues and dirt, which may be a source of contamination. The necessary cleaning methods and materials shall depend on the nature of the food business. Disinfection may be necessary after cleaning.

Cleaning chemicals shall be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

6.4.2.3 Cleaning procedures and methods

Cleaning shall be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water and chemical methods using detergents, alkalis or acids. Containers used for the raw material or chemicals or cleaning chemicals shall be identified and where appropriate, be lockable to prevent accidental contamination of food and shall be of non-toxic material.

NOTES

1 Cleaning procedures should involve, where appropriate:

- a) removing gross debris from surfaces;
- b) applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- c) rinsing with water (*see* 6.3.7.1), to remove loosened soil and residues of detergent;
- d) dry cleaning or other appropriate methods for removing and collecting residues and debris;
- e) where necessary, disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required; and
- f) hygienic storage and handling of cleaned portable equipment and utensils.

2 Some processes are dry wherein entry of water can cause spoilage/infections and therefore need dry methods of cleaning such as flushing with sugar or salt, after brushing down or vacuum cleaning to remove carry over flavours. Disinfection can be by use of alcohol based non-toxic microstatics/microcidals.

6.4.2.4 Cleaning programmes

Cleaning and disinfection programmes shall ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of cleaning equipment.

Cleaning and disinfection programmes shall be continually and effectively monitored for their suitability and effectiveness and documented.

NOTES — Where written cleaning programmes are used, they should specify,

- a) areas, items of equipment and utensils to be cleaned;
- b) responsibility for particular tasks;
- c) method and frequency of cleaning; and
- d) monitoring arrangements.

Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

6.4.3 Pest Control Systems

6.4.3.1 General

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices shall be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring shall be implemented to minimize the likelihood of infestation and thereby limit the need for pesticides. Records for pesticide used for control of pest infection in the plant shall be maintained on daily basis.

6.4.3.2 Preventing access

Buildings shall be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access shall be kept sealed. Animals shall, wherever possible, be excluded from the grounds of factories and food processing plants.

NOTE — Guard openings like windows, exhaust fans with fly-proof mesh and provide double doors or fix strip curtains or air curtains on entrance.

6.4.3.3 *Harbourage and infestation*

The availability of food and water encourages pest harbourage and infestation. Potential food sources shall be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises shall be kept clean. Where appropriate, refuse shall be stored in covered, pest-proof containers.

6.4.3.4 *Monitoring and detection*

Establishments and surrounding areas shall be regularly examined for evidence of infestation.

6.4.3.5 *Eradication*

Pest infestations shall be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents suitable for use in food and beverage industry shall be carried out without posing a threat to the safety or suitability of food.

All chemicals used for pest control or cleaning/sanitation shall be supported by 'Material Safety Data Sheets (MSDS)'.

6.4.4 *Waste Management*

Suitable provision shall be made for the removal and storage of waste. Waste shall not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

Waste stores shall be kept appropriately isolated and clean and regularly inspected. Waste bins used should be self closing with foot-operated lids.

6.4.5 *Monitoring Effectiveness*

Sanitation systems shall be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

6.4.6 *Personal Hygiene*

6.4.6.1 *General*

Organization shall ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by,

- a) maintaining an appropriate degree of personal cleanliness; and

- b) behaving and operating in an appropriate manner (see 6.4.6.5).

6.4.6.2 *Health status*

Annual medical check up of food handlers is to be carried out and records maintained.

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, shall not be allowed to enter any food handling area, if there is a likelihood of their contaminating food. Any person so affected shall immediately report illness or symptoms of illness to the management.

6.4.6.3 *Illness and injuries*

Conditions which shall be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include,

- a) jaundice;
- b) diaorrhoea;
- c) vomiting;
- d) fever;
- e) sore throat with fever;
- f) visibly infected skin lesions (boils, cuts, etc); and
- g) discharges from the ear, eye or nose.

Medical examination of a food handler shall be carried out and if clinically or epidemiologically indicated and records maintained.

NOTE — Periodic vaccinations are recommended as a good practice for the food handlers.

6.4.6.4 *Personal cleanliness*

Food handlers shall maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, shall be covered by suitable waterproof dressings.

Personnel shall always wash and disinfect their hands when personal cleanliness may affect food safety.

NOTE — For example:

- a) At the start of food handling activities;
- b) Immediately after using the toilet; and
- c) After handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

6.4.6.5 *Personal behaviour*

People engaged in food handling activities shall refrain from behaviour which could result in contamination

of food, for example:

- a) Smoking;
- b) Spitting;
- c) Chewing or eating; and
- d) Sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins, flowers or other items shall not be worn or brought into food handling areas, if they pose a threat to the safety and suitability of food.

6.4.6.6 Visitors

Visitors to food manufacturing, processing or handling areas shall, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

6.4.6.7 Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food.

Such facilities shall be suitably located and designated.

NOTE — Where appropriate, facilities should include,

- a) adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water; and
- b) lavatories of appropriate hygienic design; and adequate changing facilities for personnel.

7 PLANNING AND REALIZATION OF PRODUCTS

The organization shall plan and develop the processes needed to manufacture products. The organization shall implement, operate and ensure the effectiveness of the planned activities and any changes to these activities.

7.1 Customer Processes

7.1.1 Determination of Requirements Related to the Product

The organization shall determine,

- 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 specified or intended use, where known;
- c) statutory and regulatory requirements related to the product; and
- d) any additional requirements determined by the organization.

7.1.2 Review of Requirements Related to the Product

The organization shall review the requirements

related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (for example submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that,

- a) product requirements are defined;
- b) contract or order requirements differing from those previously expressed are resolved; and
- c) organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE — In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.1.3 Customer Communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to customer feedback, including customer complaints.

7.2 Design and Development

7.2.1 Design and Development Planning

The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine,

- a) design and development stages;
- b) review, verification and validation that are appropriate to each design and development stage; and
- c) responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.2.2 Design and Development Inputs

Inputs related to product requirements shall be

determined and records maintained (*see 4.2.3*). These inputs shall include,

- a) functional and performance requirements;
- b) applicable statutory and regulatory requirements;
- c) where applicable, information derived from previous similar designs; and
- d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.2.3 Design and Development Outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall,

- a) meet the input requirements for design and development;
- b) provide appropriate information for purchasing, production and for service provision;
- c) contain or reference product acceptance criteria; and
- d) specify the characteristics of the product that are essential for its safe and proper use.

7.2.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (*see 7.3.1*),

- a) to evaluate the ability of the results of design and development to meet requirements; and
- b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (*see 4.2.3*).

7.2.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements (*see 7.3.1*) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (*see 4.2.3*).

7.2.6 Design and Development Validation

Design and development validation shall be performed

in accordance with planned arrangements (*see 7.3.1*) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever applicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (*see 4.2.3*).

7.2.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (*see 4.2.3*).

7.3 Purchasing

7.3.1 General

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate the select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (*see 4.2.3*).

7.3.2 Purchased Product Characteristics

Purchasing information shall describe the product to be purchased. All raw material, ingredients and product-contact materials shall be described in documents as appropriate. Such information includes,

- a) biological, chemical and physical characteristics;
- b) composition of formulated ingredients, including additives and processing aids;
- c) origin (for example animal, plant, etc);
- d) method of production;
- e) packaging and delivery methods;
- f) storage conditions and shelf life;
- g) preparation and/or handling before use or processing; and
- h) food safety and quality related acceptance

criteria or specification of purchased materials and ingredients appropriate to their intended uses.

The organization shall identify statutory and regulatory food safety and quality requirements related to the above.

As per specifications of incoming material, those known to contain parasites, undesirable micro-organisms, pesticides or other toxic, decomposed, extraneous matter, which would not be reduced to acceptable levels through sorting and or processing, shall not be accepted. As required, incoming material shall be inspected and sorted before processing. Where necessary, laboratory tests shall be made to establish fitness for use. Stocks shall be subject to effective stock rotation.

The descriptions shall be kept up-to-date including when required in accordance with 9.1.

Responsibility and authority for inspection, testing and release and rejection to be defined. Records shall be maintained (*see* 4.2.3). Rejected material to be identified and if required, stored away from accepted material.

7.3.3 Storage of Incoming Material

Raw material shall be used in first-in/first-out (FIFO) basis according to plant specified product rotation/inventory control schedule. Raw material shall be stored at temperatures that maintain product condition. Frozen material to be kept frozen, if required. The package pallet integrity must be maintained throughout storage period to maintain condition of material. Product identity in storage should allow for in plant tracking system.

7.4 Planning and Control of Operations for Product Realization

7.4.1 Intended Use and Product Information

The intended use, the reasonably expected coding of the end product and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents.

Groups of users and where appropriate groups of consumers shall be identified for each product and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered.

The descriptions shall be kept up-to-date.

All food products shall be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store, prepare and use the product safely and correctly.

7.4.1.1 Flow diagrams

Flow diagrams shall be prepared for the products or process categories covered by the GMP system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate include the following:

- a) Sequence and interaction of all steps in the operation;
- b) Any outsourced processes and subcontracted work;
- c) Where raw materials, ingredients and intermediate products enter the flow;
- d) Where reworking and recycling take place by products;
- e) Where end products, intermediate products, and waste are released or removed; and
- f) pH and water activity during processing of food.

7.4.1.2 Control of operations

Food business operators shall produce food as per its specification and reduce the risk of unsafe food by ensuring control of operations,

- a) through an understanding of relevant food safety hazards like biological, chemical and physical contamination of product(s), including cross contamination between products; and
- b) by controlling the likelihood of introducing food safety hazards to the product through product processing environment.

When establishing operational controls, the organization shall consider and utilize appropriate information (that is statutory and regulatory requirement's, customer requirements, recognized guidelines and Codes of practices, national standards, etc) along with the following as appropriate:

- a) Construction and layout of buildings and associated utilities (*see* 6.3);
- b) Layout of premises, including workspace and employee facilities (*see* 6.3);
- c) Supply of air, water other utilities (*see* 6.3); and
- d) *Temperature control* — depending on the nature of food operations undertaken adequate facilities shall be available for heating, cooling, refrigeration and freezing food, for storing refrigerated or frozen foods,

monitoring food temperatures and when necessary, controlling ambient temperatures to ensure safety and suitability of food. Temperature control systems shall specify tolerance limits for time and temperature variations. Temperature recording devices shall be calibrated at stipulated intervals (*see 7.5*).

NOTES

- 1 Temperature control systems should take into account,
 - a) the nature of food, for example its water activity, pH and likely initial level and types of microorganism;
 - b) the intended shelf life of the product;
 - c) the method of packaging and processing;
 - d) how the product is intended to be used, for example further cooking/processing or ready to eat; and
 - e) specific process steps which contribute to food hygiene and quality shall be appropriately controlled through defined and documented process parameters within their specified tolerances.
- 2 Specific process steps which may contribute to food hygiene are:
 - a) chilling;
 - b) thermal processing;
 - c) irradiation;
 - d) drying;
 - e) chemical preservation; and
 - f) vacuum or modified atmosphere packaging.
- 3 Micro-biological and other specifications, where micro-biological, chemical or physical specifications are used in any food control systems, such specifications should be based on sound, scientific principles and state where appropriate, monitoring procedures, analytical methods and action limits.
- 4 Prevention of microbiological cross contamination
Raw unprocessed food shall be effectively separated either physically or by time, from ready to eat foods, with effective intermediate cleaning and where appropriate disinfection. Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to such processing area shall be made through a changing facility. Personnel may need to put on protective clothing including footwear and wash their hands before entering.
Surfaces, utensils, equipment, fixtures a fitting as applicable, shall be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry has been handled or processed.
- 5 Physical and chemical contamination
Systems shall be in place to prevent contamination of foods by foreign bodies such as glass or metal shreds from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection and screening devices shall be used as necessary.
- 6 The operational controls shall be documented and shall include the following information for the relevant programmes:
 - a) control measure(s) to ensure food safety and quality;
 - b) monitoring procedures that demonstrate that the operational controls are implemented;
 - c) corrections and corrective actions taken if monitoring shows that the operations are not in control;
 - d) responsibilities and authorities; and
 - e) record(s) of monitoring.
- 7 Refer to sector specific GMP Standards.

7.4.1.3 Characteristics of end products

The characteristics of end products shall be described in documents to the extent needed to ensure safe and quality food including information on the following as appropriate:

- a) Product name or similar identification;
- b) Composition;
- c) Biological, chemical and physical hazard specification and allergens relevant for food safety;
- d) Intended shelf life and storage conditions;
- e) Packaging: packaging design and materials shall provide adequate protection for products to minimize contamination, prevent damage and accommodate appropriate labelling. The material shall be non-toxic so as not to pose a threat to safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging shall be suitably durable and easy to clean and disinfect where necessary;
- f) Labelling relating to food safety and/or instructions for handling, preparation and usage; and
- g) Method(s) of distribution.

7.4.2 Validation of Processes for Production

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

The organization shall establish following arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes;
- b) Approval of equipment and qualification of personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records (*see 4.2.4*); and
- e) Revalidation requirements.

7.4.3 Traceability

7.4.3.1 Lot identification and traceability system

The food business shall ensure that effective traceability procedures are in place from raw material to finished products and to the consumer as appropriate, so as to deal with any food safety hazard and enable the complete, rapid recall of any implicated lot of product from market.

The organization shall identify product status with respect to inspection and testing.

Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.

7.4.3.2 Labelling

The packaging material shall be non-toxic and safe for packing the food products to prevent contamination, damage and shall accommodate proper labelling. Appropriate lot of food shall be permanently marked to identify the producer and the lot pre-packaged food shall be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely.

NOTE — See IS 7688 (Parts 1 to 3).

7.4.4 Customer Property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

NOTE — Customer property can include intellectual property.

7.4.5 Storage, Handling and Transportation

7.4.5.1 Preservation and storage of food

There shall be proper and separate storage for raw and finished products. The food products at any stage during its manufacture should be stored under appropriate conditions to maintain its safety and suitability.

Adequate facilities for the storage of food, ingredients, and non-food chemicals (for example cleaning materials, lubricants, fuels) shall be provided. Where necessary, separate, secure storage facility for cleaning materials and hazardous for substances shall be provided.

Where appropriate, food storage facilities shall be designed and constructed to,

- a) avoid pest access and harbourage;
- b) enable food to be effectively protected from contamination during storage; and
- c) provide an environment which minimizes the deterioration of food (for example by temperature and humidity control).

7.4.5.2 Handling and transportation

Products shall be adequately protected during transport. The type of conveyances or containers required depends on the nature of food and conditions under which it is to be transported.

Where necessary, conveyances and bulk containers shall be designed and constructed so that they,

- a) do not contaminate foods or packaging;
- b) can be effectively cleaned and where necessary disinfected;
- c) permit effective separation of different food or food from non-food items during transport;
- d) provide effective protection from contamination including dust and dirt;
- e) can effectively maintain temperature, humidity and other conditions necessary to protect food from harmful or undesirable micro-organism and deterioration likely to render it unsuitable for consumption;
- f) allow any necessary temperature, humidity and other conditions to be checked; and
- g) conveyances and containers for transportation of food shall be maintained at an appropriate state of cleanliness repair and condition. Where the same conveyance is used for different food or non-food items, effective cleaning and where necessary, disinfection shall be in place between loadings.

Where appropriate, these should be designated and marked for food use only and be used for that purpose only.

7.5 Control of Monitoring and Measuring Equipments

The organization shall provide evidence that the specified monitoring and measuring equipment are adequate to ensure the performance of the monitoring and measuring equipments.

Where necessary, to ensure valid results, the measuring equipment and methods used,

- a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) shall be adjusted or re-adjusted as necessary;
- c) shall be identified to enable the calibration status to be determined;
- d) shall be safeguarded from adjustments that would invalidate the measurement results; and

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- e) shall be protected from damage and deterioration.

Records of the results of calibration and verification shall be maintained.

In addition, the organization shall assess the validity of the previous, measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is non-conforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting actions shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be reconfirmed as necessary.

7.6 GMP System Verification

The organization shall conduct internal audits at planned intervals to determine whether the GMP system,

- a) confirms to the planned arrangements and to the requirements of this Indian Standard; and
- b) is effectively implemented and updated.

An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits (*see 9.1 and 5.7.2*). The audit criteria, scope, frequency and methods, shall be defined. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work and shall be trained.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

7.7 Control and Non-conformity

7.7.1 Corrections

The organization shall ensure that when there is a loss of control of the GMP system, the process and products affected are identified and controlled with regard to their corrections, use and release, as necessary. Responsibilities for handling non-conformities shall be defined.

A documented procedure shall be established and maintained defining,

- a) the identification and assessment of affected process and end products to determine their status; and
- b) a review of the corrections carried out.

Products manufactured under conditions where operational controls have not been conformed shall be evaluated with respect to the cause(s) of the non-conformity and the consequences in terms of food safety and quality and shall, where necessary, be handled in accordance with **8.3**. The evaluation shall be recorded.

7.7.2 Corrective Action

The organization shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-conformities encountered.

A documented procedure shall be established to define requirements for,

- a) reviewing non-conformities (including customer complaints);
- b) determining the causes of non-conformities;
- c) evaluating the need for action to ensure that non-conformities do not recur;
- d) determining and implementing action needed;
- e) records of the results of action taken; and
- f) reviewing corrective action taken.

8 HANDLING OF POTENTIALLY UNSAFE PRODUCTS

8.1 General

The organization shall handle non-conforming products by taking action(s) to prevent the non-conforming product from entering the food chain, unless it is possible to ensure that,

- a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels;
- b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain; or
- c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the non-conformity.

All lot of product that may have been affected by a non-conformity situation shall be held under control. If necessary the organization shall notify relevant interested parties and initiate a withdrawal (*see 8.4*).

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

8.2 Evaluation for Release

Each lot of product affected by the non-conformity shall only be released as safe when any of the following conditions apply:

- a) Evidence that demonstrate that the control measures have been effective;
- b) Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended; and
- c) Results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

8.3 Disposition of Non-conforming Products

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

- a) Reprocessing of further processing within or outside the organization to ensure that the food safety hazard or parameters not within specified limit, is eliminated or reduced to acceptable levels, and
- b) Destruction and/or disposal as waste. Inadvertent use of such material shall be prevented.

NOTE — The following categories may be used to distinguish between the types of reprocessing, activities that may occur during the manufacturing process:

- a) *Re-cooking* — For those which do not meet production specifications, treatment or cooling conditions;
- b) Re-packaging; and
- c) *Returned and reinspected product* — A returned product should not be repackaged or redistributed until the establishment can evaluate and record the safety of the product handling since it left the facility and that product integrity has been maintained.

8.4 Withdrawals

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe,

- a) the top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal; and

- b) the organization shall establish and maintain a documented procedure for,
 - 1) notification to relevant interested parties (for example statutory and regulatory authorities, customers and/or consumers);
 - 2) handling of withdrawn products as well as affected lots of the products still in stock; and
 - 3) the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use or reprocessed in a manner to ensure they become safe. Other products which are produced under similar conditions and which may present a similar hazard to public health should be evaluated for safety and may need to be withdrawn. The need for public warnings may need to be considered.

NOTE — Withdrawn products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

9 CONTINUAL IMPROVEMENT

Top management shall ensure that the organization continually improves the effectiveness of the GMP system through the use of communication (*see 5.5*), management review (*see 5.7*), internal audit (*see 7.6*), corrective actions (*see 7.7.2*) and GMP system updating (*see 9.1*).

9.1 Updating the GMP System

Top management shall ensure that the GMP system is continually updated.

In order to achieve this, the GMP team shall evaluate the GMP system at planned intervals.

The evaluation and updating activities shall be based on,

- a) input from communication, external as well as internal, as stated in 5.5;
- b) input from other information concerning the suitability, adequacy and effectiveness of the GMP system; and
- c) output from management review (*see 5.7.3*).

System updating activities shall be recorded and reported, in an appropriate manner, as input to the management review (*see 5.7.2*).

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