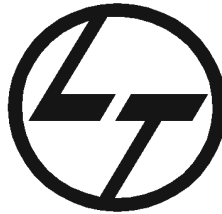


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## Technical Article on: "Design Guide lines for Process Plants"

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## **Design guidelines for Process Plants**

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### **Abstract:**

*This technical article highlights the basic concepts of legal system, standards and codes, safety requirements, safe practice while designing a process plant. Importance of GMP (Good Manufacturing Practices) and modular design concepts have been explained. Plant personnel and plant designers are required to know these basic plant design criteria/guide lines while designing a process plant.*

*Plant Design refers to the automation technologies, work practices and business rules supporting the design and engineering of process plants. Such plants can be built for CPG (Consumer Packaged Goods) industries such as Dairy, Food, Home & Personal Care (HPC), Pharmaceuticals, and chemical.*

***Key words:*** *Safety, Hygienic design, GMP (Good Manufacturing Practice), and Modular design.*

### **1.0 Safety requirements for process plant:**

Safety of personnel, products, and plant facilities play an important role in any process and plant design.

Plant safety is particularly important in the HPC (Home & Personal Care), chemical and petrochemical industry, where major accidents and emissions of hazardous chemicals can cause serious injuries, loss of lives, and destruction of facilities. Process safety regulations should be followed in the design and operation of any processing plant.

The following federal agencies regulate the safety of personnel and plant facilities in the USA; Occupational Safety and Health Administration, OSHA (Process Safety Management Standards, Hazardous Operations, HAZOP); Environmental Protection Agency (EPA); and National Fire Protection Agency (NFPA). In addition, the Centre of Chemical Process Safety (CCPS) of the American Institute of Chemical Engineers (AIChE) is concerned with process safety.

There are specific requirements, recommended by various organizations, for fire hazards, electric motors, dust explosions, etc. Dust explosions are particularly important in processing and storage of food powders. Moisture-proof electric motors must be used in damp environments, such as canning. Carbon monoxide (CO) analyzer, explosion-proof electric motors should be used for dusty environments, such as grain mills and powder conveyors.

Steam boilers should be located in a separate boiler house to confine any explosion hazard. Plant layout and construction should prevent accidents caused on the personnel, e.g., special floor coatings, and protective rails in silos.

The noise level in the processing areas should be not too high to avoid health problems to the operators. Maximum noise levels, according to Directive 86/188 of the European Union, should not exceed 90 dB in 8 hour work, and 93 dB for 4 hour work near the noisy equipment. In some processing areas, the noise level may be excessive, for example 90 – 110 dB in a bottling plant. In such cases, the operators must make protective measures, e.g., using earmuffs.

Noise can be reduced by proper selection of equipment, better foundations and seating of equipment with moving parts, gentle conveying, and isolation of noisy equipment in special rooms. On some unavoidable case, noise insulation may be required, for example, Centrifugal pumps, industrial fans, and roots blowers, etc.

In Food Processing, food safety (protection of the consumers' health) is of paramount importance, and it deserves special consideration over the general plant safety.

### **2.0 Hygienic Design:**

Hygienic or sanitary design of food process plant and equipment is based on proper selection of construction materials and fabrication techniques, which will facilitate food processing and thorough cleaning of the equipment.

Hygienic design of process equipment must be accompanied by a thorough hygienic design of the whole food process and processing plant. Engineering implications of hygienic process design should be considered from the outset of the design process, especially for new food processing systems.

An ideal food processing plant consists of elements from raw material conditioning through processing stages to a packed consumer acceptable product ready for human consumption.

Microbial product contamination may originate from raw materials, or the product may be contaminated with microorganisms during processing and packaging. For example, if equipment is of poor hygienic design, it will be difficult to clean and difficult to free from microorganisms, which may survive and multiply in product residues in crevices and dead areas. Hence, hygienic design assumes greater importance in case of food, dairy, HPC, and pharmaceutical machinery than many other factors. Hygienic design consists of four important areas of activity in the design and fabrication of these equipment. They are:

- Selection of raw material for processing/equipment
- Ideal design for optimum operation of plants and equipment
- Avoidance of hazards during fabrication/transport/packaging etc. of raw material and finished products.
- Surface finishes of equipment and geometry of plant connections, sanitary and discharge aspects of plant effluents.

Hygienic requirements should be taken into account at the initial design stage. The basic objective of the hygienic design is that the machine itself should not contribute to microbial or other types of contamination or spoilage of the product.

### **2.1. Hygienic Standards and Regulations:**

The design and operation of food processes and processing equipment should ensure the microbiological safety of the final food products. Design engineers, equipment manufacturers and food processors should follow strict hygienic standards and government regulations.

Government regulations of food processing equipment are essential for the manufacture of safe and wholesome foods and the protection of Public health. In USA, the following Government Agencies and Private Organizations have published sanitary standards for food processing equipment.

1. US Dept. of Agriculture (USDA), Washington, DC.
2. US Dept. of Interior, Washington, DC
3. US Public Health Service, Washington, DC: FDA (Food and Drug Administration), GMPs.
4. International Association of Milk, Food, and Environmental Sanitarians, Inc. (IAMFES), Ames, Iowa: committee on Sanitary Procedures “3-A Sanitary Standards”.
5. ASME (American Society of Mechanical Engineers), New York: ANSI-ASME F2-1: “Food, Drug and Beverage Equipment”.
6. BISSC (Baking Industry Sanitation Standards Committee), New York: BISSC Sanitation Standards.
7. AFDOUS (Association of Food and Drug Officials of the United States), Littleton: “AFDOUS Frozen Food Code”.
8. National Sanitation Foundation, Ann Arbor, MI: a). Food Service Equipment Standards.; b). Food preparation and Service Equipment.

The 3-A sanitary standards were developed originally for the milk industry, but they have been extended to other food products in the USA and other countries. They resulted from the collaboration of equipment manufacturers, the users of food equipment, the International Association of Milk, Food, and Environmental Sanitations, the Dairy and Food Industries Suppliers Association (DFISA), the poultry and Egg Institute of America, and representatives of the USPH/FDA and USDA. The 3-A standards refer mainly to milk processing equipment, including storage tanks, heat exchangers, pasteurizers, freezers, evaporators, drying equipment, and various fittings.

In addition to the 3-A standards, the following two rules/regulations should be considered in the USA: The pasteurized Milk Ordinance, and the Good Manufacturing Practices (GMPs) of the FDA.

Equipment used in USDA – inspected food plants must previously be approved and listed in the “Compendium of USDA Approved Equipment”. In addition to the US federal regulations, the departments of Health of some states have specific requirements for dairy processing equipment. Special caution is needed, when equipment used in a less regulated industry is applied to strictly regulated food industries, such as meat and poultry.

The design of modern food processing equipment should be based on data bases of hygienic requirements and regulatory standards. Special attention should be given to the sealing spots of moving parts, e.g., rotating and reciprocating shafts, where microbial contamination is possible.

The EU “Machinery Directives” (e.g., 89/392 and 91/368) specify that food processing machinery must be designed and constructed as to avoid any risk of infection and sickness. EU documents, such as CEN/TC 153 (CEN = European Standardization Committee, TC = technical Committee) specify machinery, safety, and hygienic requirements for various food industries. The standard CEN 1672 - 2 is concerned about food machinery, safety, and hygienic requirements. The European food industry has, in general, adopted the US 3-A standards within the framework of the standards being developed by the EHEDG.

Other specifications used in the food industry are the International Standardization Organization (ISO), the German Standardization Authority (DIN) requirements for fittings, the bulletins of the International Dairy Foundation (IDF), and the British Standards BS 5750. The symbols “CE” (Conformite Europeenne) on equipment are used as evidence of compliance.

A number of guidelines have been published by EHEDG, which are voluntary and complementary to the corresponding national and international hygienic standards. The EHEDG guidelines include the following:

1. Microbiologically safe continuous pasteurization of liquid foods.
2. A method for assessing the in-place cleanability of food processing equipment.
3. Microbiologically safe aseptic packing of food products.
4. A method for the assessment of in-line pasteurization of food processing equipment.

### **3.0 Good Manufacturing Practice (GMP):**

A good plant design should compliance to GMP guidelines to manufacture the product for safe human consumption.

GMP guidelines gives the information on a minimum requirement for various facility and utility components (i.e. floor finishes, HVAC, etc.) or spaces, and various systems dealing with piping, processing, and packing.

GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act (See Chapter IV for food, and Chapter V, Subchapters A, B, C, D, and E for drugs and devices.) These regulations, which have the force of law, require that manufacturers, processors, and packagers of product, take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. This in turn, protects the consumer from purchasing a product which is not effective or even dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

In the US, the phrase "current good manufacturing practice" appears in 501(B) of the 1938 Food, Drug, and Cosmetic Act (21USC351). US courts may theoretically hold that a drug product is adulterated even if there is no specific regulatory requirement that was violated as long as the process was not performed according to industry standards.

GMP regulations address issues including recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

Regulatory agencies (including the FDA in the US and regulatory agencies in many European nations) are authorized to conduct unannounced inspections. FDA routine domestic inspections are usually unannounced, but must be conducted according to 704(A) of the FD&C Act (21USC374), which requires that they are performed at a "reasonable time."

GMP calls for the following steps:

- First, set standards of performance. These include GMP regulations and other standards which are necessary for your company. Then, train to those standards.
- The next step in the GMP is to reinforce what was learned in training. This falls on the managers and supervisors in a plant. Therefore, it is important that managers and supervisors be involved in training, so that they can support it through reinforcement. The same four job categories are listed as being the most critical in promoting and receiving reinforcement.
- The third stage is to audit to ensure that your efforts have provided adequate controls by auditing. Audits fall in the following three categories: personal, whereby every individual does a self-check to make sure that he/she is complying with all appropriate standards; internal audit, which should be performed by the quality assurance department as required by GMP, and external audits, which can consist of an FDA audit, a consultant checking your compliance status, or you performing a supplier audit.

- Finally, the results of audits will help you to know if you need to modify your standards of performance. Of course, no procedures should be changed without appropriate change control and approval from quality assurance. The glue that sticks the whole process together is commitment. Commitment to GMP and quality is critical at all levels of the organization, starting with top management.

#### **4.0 Modular design: Alternative to conventional construction**

Purpose of modularization is to minimize the installation and plant shut-down time at plant site. Interconnection at plant site shall be limited to bolted and/or quick coupling joints as far as possible. Modular construction involves the offsite fabrication, assembly, integration and debugging of manufacturing lines. After the equipment is debugged and shown to be operational, the line is shipped as “self-contained” modules that are then re-assembled at the plant in a minimal amount of time.

This technique is used to accomplish a number of objectives:

- It is imperative that all equipment is assembled and tested **to reduce the overall time** required to get a new line up and running to ensure that everything fits, works and goes together as intended.
- Develop packing material specifications early in the project and optimize interaction with equipment. Early definition of packing materials and testing on equipment at the integrator is essential for **a smooth start up and for staying on schedule**.

Construction can occur in areas where specialized trades or capabilities are available, rather than bringing all these capabilities to the plant.

#### **4.1 Module sizing**

Module sizes should be based on:

- Equipment layout considerations – whenever possible, make clean breaks between pieces of equipment rather than have one piece of equipment straddle two modules.
- Transportation restrictions – make sure module size meets the dimensions required by transportation regulations and physical limitations of the selected mode of transportation (i.e. land, sea, air). For overseas shipment, make sure that the modules are smaller than the inside dimensions of the container.
- It is important to verify dimensions of shipping containers and other shipping restrictions before determining module sizes.
- Verify that the modules can fit through plant doorways, aisles and past existing equipment at both the integrator facility and at the final installation location. Alternatively, the overall module sizing and configuration may be simplified if the plant will allow temporary doors or access through the roof, when existing aisles, doors and equipment are very restrictive and dictate many, small modules.
- Modules must be self-supporting (no racking or twisting). Each module must be capable of supporting the equipment mounted to it during shipping and installation.

- Concept of and envelope – keep everything within the envelope, avoid overhang edges of module. Shipping is more difficult with equipment hanging over the edges and damage is more likely.
- Maximum size of Module for fitting into a container is considered to be 40ft.X 10ft. X 10ft.

#### **4.2 Skid mounted modules**

Skid mounting floor level equipment facilitates shipping, speeds final assembly, and minimizes alignment issues. Static and dynamic testing can be minimized using this approach and therefore this approach should be considered for projects on tight time lines. This approach is usually more expensive to fabricate but has reduced final assembly costs.



***Fig.1: Process skid***

#### **Conclusions**

An attempt has been made to highlight the current safety guide lines, hygienic design guidelines, GMP guide lines, and modular design concepts for a good process plant design.

Readers are welcome to contact the authors for further details and information.

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**Plant Engineering Department, Larsen & Toubro Limited**

L&T's sound expertise and technical strength in plant engineering coupled with proven onsite-offshore engineering services model for delivery enables its clients effectively cut down the design and engineering time.

Setting up of process plants is a complex activity that necessitates perfect synchronization between various engineering functions viz. Process, Civil, Mechanical, Piping, Electrical, Instrumentation & Automation, and Project Management. With the use of collaborative technologies and state of art communication facilities, L&T provides plant engineering services that help its client optimize capital expenditures and improve operational efficiencies.

Plant Engineering offers the following services:

- Detailed Engineering & Procurement support services
- Project Management services
- GMP audits
- Energy audits
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  - MS Project for Project management.
  - Smart Plant PID, and INTools for P&ID
  - EXTEND, FLEXISM, and CFD for process simulation
  - PV Elite (for Vessel & Tank design)
  - E-Tap for lighting design
  - Wonderware, and RS Logix for proces automation
  - Power Tool Window (PTW) for load flow analysis, arc flash analysis, and short circuit analysis
  - STADD PRO for structural design and analysis

Plant Engineering at L&T offers solutions and services for the following industry verticals:

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- Home & Personal Care
- Pharmaceuticals, and Chemical industries