

Integration of hygienic and aseptic systems

This article is an extended summary of the report prepared by the Integration of Hygienic and Aseptic Systems sub-group of The European Hygienic Engineering & Design Group (EHEDG). Originally published in March 2006, it is the 34th in the series of EHEDG summaries to be featured in TIFS. The full report prepared by R. Cocker (Chairman), S. Akesson, P.V. Bartels, A. Friis, H. Hoogland, G. Klimmeck, J. Oosterom, L.D. Steenstrup and J. Wilkinson is available from CCFRA at pubs@campden.co.uk. For information about EHEDG and to order papers please visit www.ehedg.org. The production of EHEDG guidelines is supported by the European Commission under the Quality of Life Programme; project HYFOMA (QLK1-CT-2000-01359).

Introduction

Experience has shown that despite the existence of design guidelines to support those who are building and implementing hygienic and aseptic systems, integration of hygienic systems remains an area where real expertise is scarce. The integration of traditional and novel hygienic systems is where things often go wrong. In addition, guidelines on procedures and training are still a significant challenge.

This guideline is about the safe integration of hygienic (including aseptic) systems, focusing on food production and is aimed at management teams, designers, builders and project team members.

Hygiene laws

Designers and users must comply with hygiene laws that apply where the equipment is sold and used. Selected European Legal Instruments relevant to Hygienic Integration (Regulations and Directives) are obtainable *gratis* at <http://europa.eu.int/eur-lex> and standards need to be ordered from national standards authorities and ISO agents (see <http://www.iso.org/iso>).

Definitions

Readers are referred to the EHEDG Glossary, which can be downloaded from www.ehedg.org.

Procedural systems

The application of ISO 9001 or an equivalent management system is recommended as a support for any integrated hygienic operation, including equipment design and manufacture.

The food industry already has Hazard Analysis and Critical Control Points (HACCP) as its best tool for analysing and managing the food safety risks of any design or design change. HACCP is often supported by the application of failure mode and effect analysis (FMEA). It is recommended that HACCP and its supporting risk management tools also be utilised to prevent those quality failures such as off-flavours, spoilage, non-hazardous foreign bodies and discolouration that are not incidentally prevented by HACCP.

Parts are integrated into modules, modules into units, which are in turn integrated into larger entities such as process lines, buildings, areas, factories, sites or enterprises (Fig. 1).

Parts and unassigned modules should be given a preliminary, or *prospective* HACCP according to the intended range of products and processes (e.g. “hygienic”, “aseptic”, “wet products”, “fresh meat”, “dry products”). In some cases, they may also be tested and certified according to EHEDG test procedures or other validated and defined procedures.

Thus, an unassigned item can be designed to be broadly suitable for use with, for example, dry goods, even if it would be unsuitable for use with wet products or fresh meat or has not been validated for use with these products.

It is recommended that an acceptable lifetime or duty be simulated before the EHEDG test procedures are performed (see EHEDG Doc. 16: “Hygienic Pipe Couplings”).

Hygienic systems may include unclassified or non-hygienic entities, as indicated by the continuous application of a HACCP risk assessment process. For this to be acceptable, these parts must have a non-hygienic requirement or be in an unclassified (non-hygienic) zone or have an acceptable level of hygiene risk. This application of risk analysis can often reduce cost and complexity or allow safe traditional

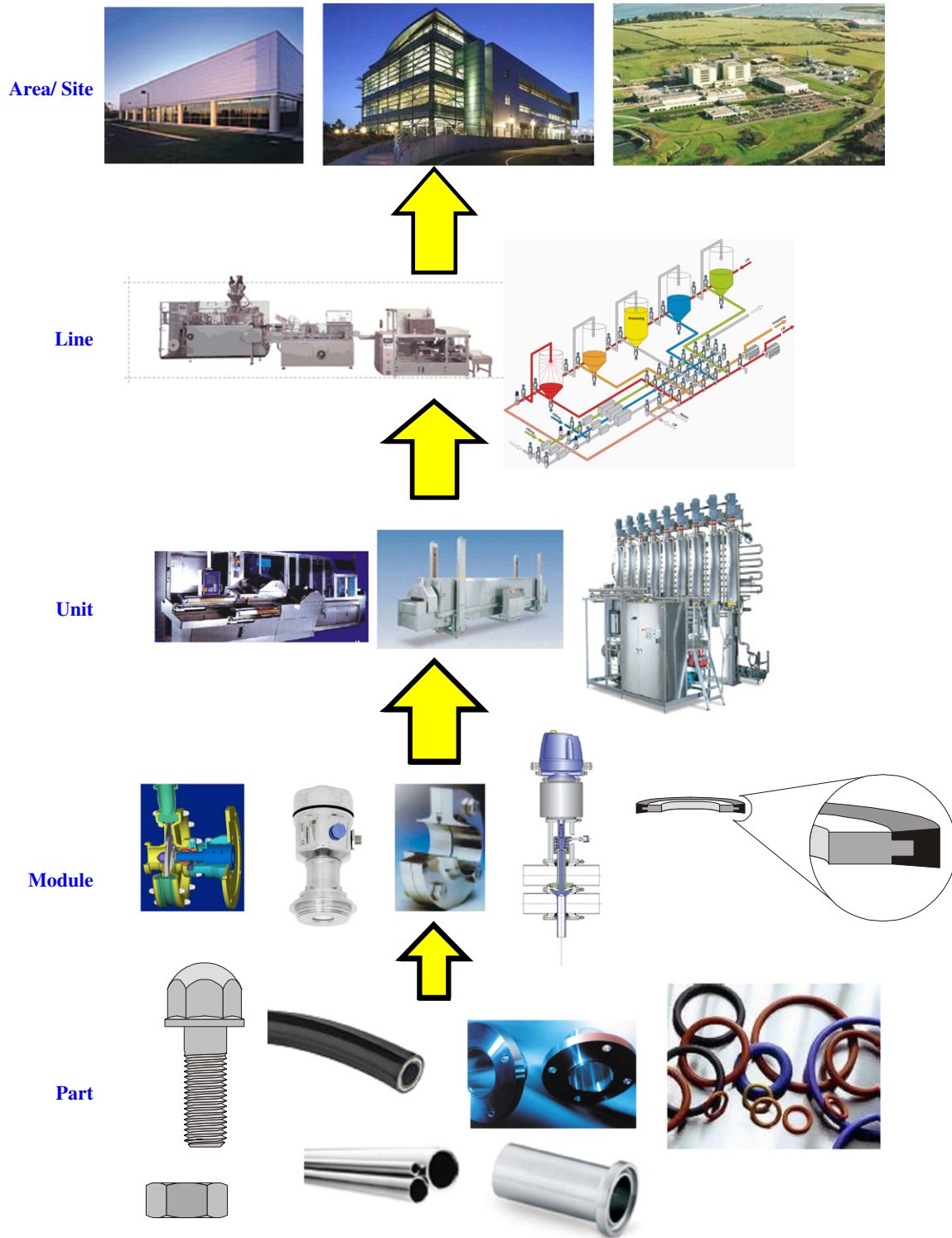


Fig. 1. Schematic representation of modular integration levels.

production. Additional examples of such acceptable designs include:

- An unsealed metal-to-metal joint in a permanently dry system.
- Sharp corners, porosities, crevices and unsealed joints in single-use items.
- Wooden barrels used to mature wine or spirits.
- The reduced hygiene classification of a zone around a closed aseptic process line.

- Processes such as dry meat curing and cheese making, where the production or storage takes place in zones or equipment with an essential resident microbiological flora.
- Lower hygiene classifications for products with low water activity, such as flour and vegetable oil; high-acidity products such as vinegar and citrus juices; high alcohol content, such as whisky or beer; high temperature, etc.

It is important to clone functional entities as part of a standardised, modular approach; for example, an HVAC filter or a steam block-and-bleed barrier should become standardised pre-validated modules. This is to minimise risk and cost and to facilitate design, training, maintenance and troubleshooting. Where possible, prefabrication of such standard pre-validated entities should take place under controlled factory conditions. This is to maximise control over fabrication and fabrication hygiene and to ensure minimum duration and cost of on-site work.

Flowchart

The flowchart based on the ISO/IEC 15288:2000 *System life cycle processes* structure is used to describe and define the procedures to organise entities into hygienic systems. The appendices provide detailed information about how to apply this process to building, system and module design.

Training

The integration of people, procedures and equipment into hygienic systems cannot be properly carried out unless attention is paid to proper training.

General training

Knowledge and expertise such as electrical engineering, probability theory, physics, particle and fluid dynamics, rheology, thermodynamics, food processing, microbiology and cleaning, etc may need to be available within design or operational teams but not necessarily via more than one member. It is however necessary for the members of the hygienic design team to be aware of when these skills must be applied, if necessary by obtaining specialist advice.

Training in hygienic design

It is strongly recommended that users of this guideline should have received training in hygienic design.

Critical control points (CCP) training

All personnel, contractors and (where there is a risk of inadvertent interference) visitors to the process line (factory) should be made appropriately aware of the importance, location, operation and need for protection of the equipment, products and procedures associated with each CCP.

Specific operational training

Those operating or maintaining hygienic entities should be appropriately qualified. In addition to the provision of

instructions, equipment suppliers may find it necessary to provide training to assure hygienic performance.

Training to assure continuity of hygiene knowledge

Periodic catastrophic losses of hygiene control can occur in food production systems as the reason for hygiene procedures and equipment is forgotten and false economies made. Best practice is that continuity of relevant knowledge is assured by documented procedures and training.

An important corollary to this is the establishment and maintenance of detailed and accessible records of the design criteria, the design decisions taken, their reasons, and the entities used in the integrated system, as shown in the flowcharts. This information can be critical for the choice of maintenance procedures and to support risk assessment prior to design change or reassessment.

Appendix 1. Building design example

This design example is generic and could be appropriate for the design of buildings, enclosures and/or environments (*facilities*) for many different food processes.

1. Define stakeholder requirements

The stakeholders will identify their needs and constraints with respect to the intended process.

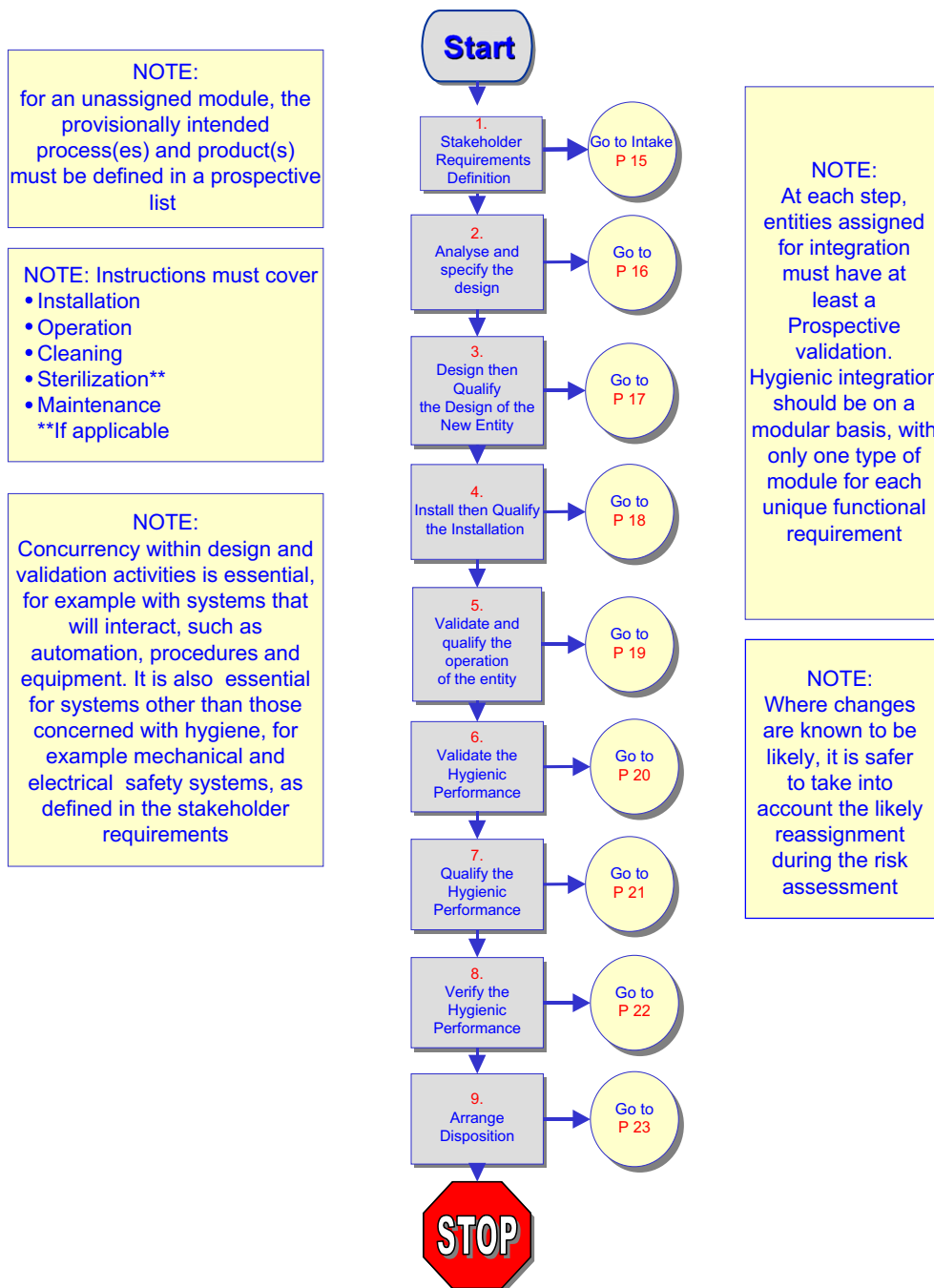
The following need to be defined:

- The raw materials to be stored
- The products to be manufactured and stored
- Process equipment loadings, dimensions and requirements
- Process production flow rates
- Environmental conditions for raw and completed goods
- Environmental conditions for processes
- Utilities requirements
- Numbers and sexes of operatives (for changing and washroom requirements)
- Raw and finished goods transport loading/unloading
- Logistics
- Wastes and effluent from the process
- Maintenance/cleaning regimes – wet/dry
- Design life
- Hygiene and food safety
- Security

It is usual that the location of the production facility will have already been defined, and in tandem with the above, the basic constraints resulting from this will be considered by the stakeholders and recorded:

- Site location
- Weather conditions/prevaling wind direction
- Topography and vegetation
- Ground conditions/contamination
- Utilities supplies

Design Process for a **single** Integration Step (Master Process Flowchart)



- Drainage and effluent systems/capacities/discharge approvals
- Access – pedestrian and vehicular
- Construction details of existing buildings and infrastructure
- Environmental factors

The outcome is a ‘Stakeholder Requirement Specification’ (SRS), sometimes known as a Design Brief. This document requires input from the designers as well as the stakeholders and will list and quantify the performance requirements of the facility in order to satisfy the

needs of the process and all associated raw materials and products.

When completed, the document will be reviewed by the stakeholders and errors corrected before the document is issued.

2. Analyse and specify the design

Based on the information in the Stakeholder Requirement Specification the designers, stakeholders and Users will analyse and organise the requirements and constraints to formulate a conceptual strategic design.

This will take into account and incorporate such factors as:

- Process flows including diagrams
- Dimensions, areas, and heights of functional spaces – circulation, storage, process, food safety, plant, amenity, maintenance
- Critical functional and special relationships

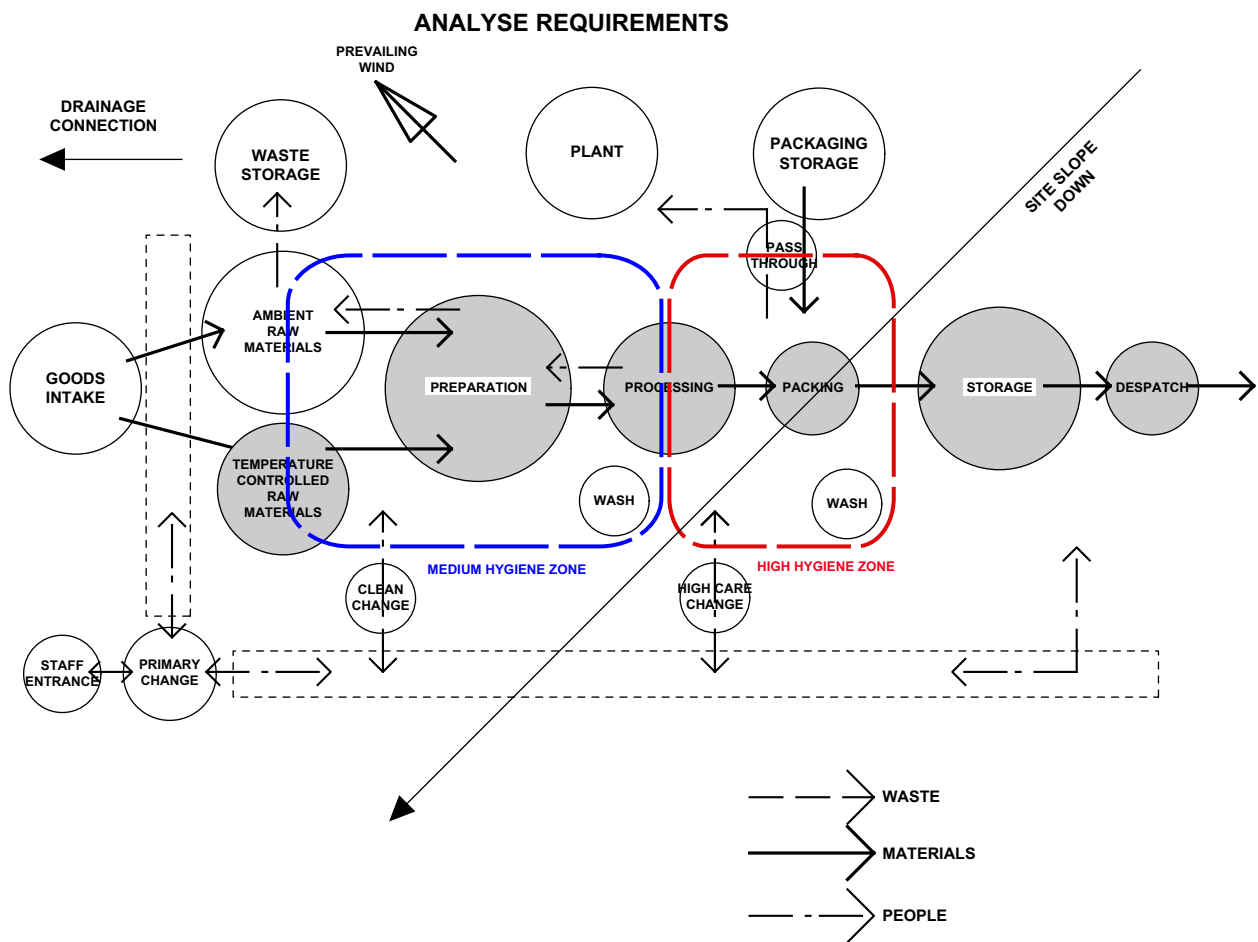
- Environmental conditions/zoning
- HACCP, hygiene risk/care classification, demarcation and zoning
- Flexibility
- Security
- Construction materials and components

The outcome could be a conceptual diagram, for example:

The conceptual design must be checked by the stakeholders to ensure that it conforms to the Stakeholder Requirements Specification document before proceeding.

3. Design, then qualify the design of the new hygienic entity, including its instructions and documentation

Using the verified conceptual design and the relevant statutory codes, building and hygienic standards as a basis,



This type of diagram may be used to organise the functional requirements into logical sequences incorporating as many factors as possible.

The sizes of enclosure 'bubbles' to the various functions/processes can represent the sizes of the relative spaces/areas required.

The thicknesses of link and flow arrows can be varied to represent the relative strengths of relationships or quantity of product flow.

Colours can be used to represent space temperatures/air system demarkations.

the synthesis of the user requirements within the limitations of the site conditions can take place.

This process can be tempered by other factors such as cost and aesthetics, within the legal, hygienic and other fixed constraints. Hygiene risk assessment coupled with zoning can be a very important way to reduce not only food safety risks, but also costs.

A series of basic layout versions may be prepared, each of greater complexity and accuracy as more and more factors are considered and refined. The design will consider and incorporate external site layouts as required, together with three-dimensional aspects as well as the plan layouts. Processes may be contained within an existing modified facility, a newly built facility, or a combination of both.

Detailed drawings of the site, services, buildings and components will be prepared, along with specifications of the materials, components and required workmanship standards.

At relevant stages in the design process, the design will be reviewed and examined to verify that it satisfies the Stakeholder Requirements Specification, before finally qualifying the design.

4. Install, then qualify the installation

Installation is meant in this context to be the construction of the site/building enclosure including services.

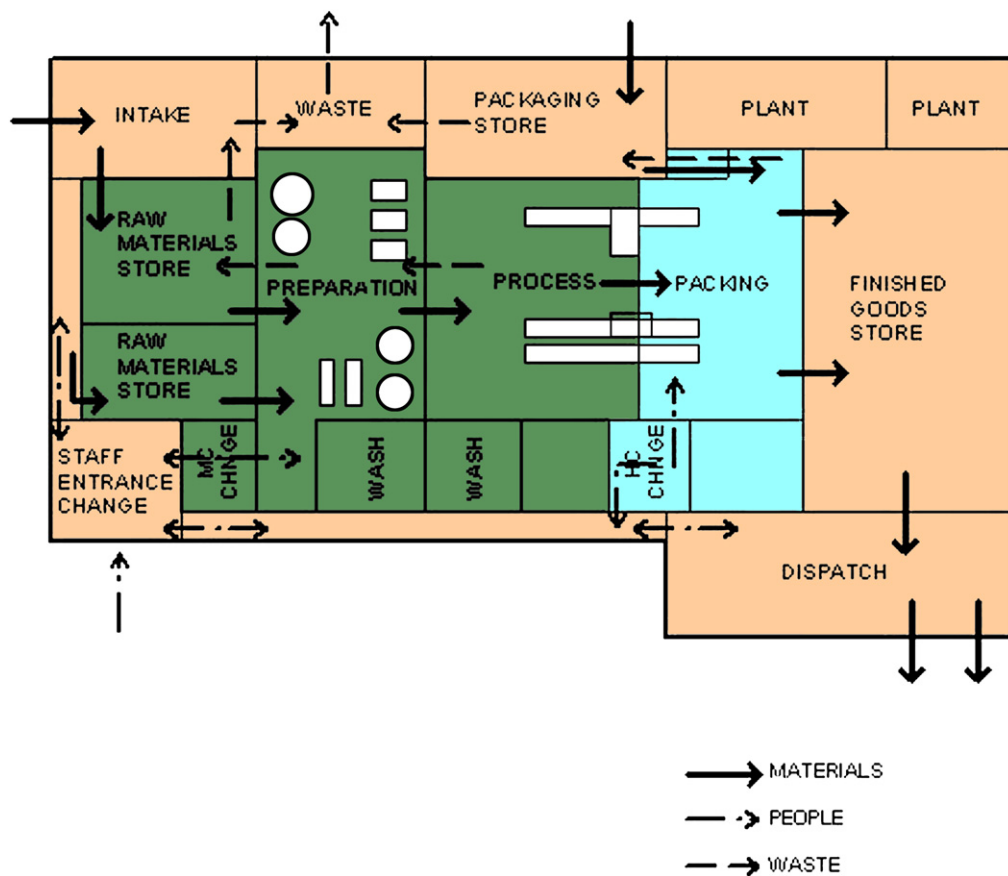
Materials, components and services will be procured and the structures/enclosures/elements must be constructed in accordance with the validated drawings and specifications.

Formal, checking, inspection and recording of the received components, installation and construction will be required, generally in accordance with ISO EN 9001 or similar norms, to ensure conformance to the specifications and the standards of workmanship, which should include clean and tidy working.

If during the course of the construction there is a re-assignment of the design or of the specifications, then it is essential that these changes are recorded and validated.

5. Validate and qualify the operation

Before engaging in the potentially expensive work of testing with real products and processes, it is wise to validate that the building and site systems can operate as specified (flow rates, capacities, temperatures, pressures, directions, etc.). In the context of a site or building enclosure this takes place during the commissioning procedures. Commissioning is defined as the process of bringing into a state of readiness the building/enclosure, its infrastructure, or its services systems for operation and occupation. These will be validated to operate in accordance with the design specifications and parameters.



However, the design of the facility and the process systems is usually interdependent and interlinked. There are many instances where the enclosure finishes or services systems cannot be fully tested and proven to function to specification until the process systems are in operation and are interacting with services e.g. steam supplies, process drainage systems, cooling, CIP infrastructure systems.

To make correct and best use of the facility in accordance with the SRS, the users and maintenance personnel should be formally acquainted with, and trained in, its intended operation, maintenance procedures requirements and limitations by the designers. In the best practice, representatives of these functions will have been identified as stakeholders and will have had intimate knowledge and input throughout the project. These representatives can assist in communication and training to their colleagues.

6. Validate the hygienic performance

The nature and physical design of the buildings, enclosures and surroundings must be considered as an integral part of the overall hygienic system. This is because they strongly affect the efficiency and effectiveness of the design, installation, operation and maintenance of hygienic production processes.

The validation procedures and hygienic risk assessments should therefore include consideration of such matters as cleanability/sterilisation of surfaces, air systems, drains, people and materials/product flows and ease of process equipment access and maintenance.

The building design, or elements of it, may have to be reconsidered in the light of the findings of the validation procedures. If the design changes, for example substitution of sterile filtration for thermal sterilisation or a reassignment takes place, for example an extra product type with different hazards is added, then revalidation will have to take place.

In addition to the process equipment, the facility and its services require to be hygienically challenged, both themselves and in conjunction with the operation of the process in use. The facility may have been designed, procured and installed perfectly correctly in accordance with the design drawings, specifications but initial assumptions, parameters, manufacturers' and performance claims on which they were based may be incorrect. Challenge testing is one way to expose this.

For example:

- Do the drainage systems, wall, floor and ceiling surfaces perform satisfactorily?
- Does cleaning according to the designed methods clean them to the specified standards?
- Do the air supply and extract systems perform at the correct filtration/hygienic designed parameters? Can these systems be cleaned in accordance with the designed methods to the specified standards?
- Do the air paths behave according to the CFD analyses?

If not, then a redesign or modification of the particular system, component, composite or element will be necessary and revalidation must be accomplished.

7. Qualify the hygienic performance

On successful validation of the buildings, an authorised person or persons should qualify the validations. This is typically by the joint signature by supplier and customer representatives, of handover documents. This will form a key record in any subsequent HACCP study or studies.

8. Arrange disposition

Typically, the building is transferred to the user on signature of handover documents. It is essential to keep detailed and accessible records of the design criteria, calculations, the design decisions taken, their reasons, details of the drawings and specifications, components and materials used in the construction. This is usually bound together physically or electronically in the form of a 'Design File'. The information contained in these records can be critical for the future choice of maintenance and repair procedures, and if any part of the plant is subsequently reassigned to a new or modified process, it will be needed to support a new or upgraded risk assessment.

If this building is subsequently transferred as a part of a food production system to new management or ownership, then the documentation, instructions and training must be adequate to maintain hygienic safety.

Appendix 2. Module design example

This hypothetical case history is modelled on parts of EHEDG Document No. 16, Hygienic Pipe Couplings (1995).

The objective was to design a screw pipe coupling using an O-ring seal, which was suitable for general hygienic use.

1. Stakeholder requirements specification

The stakeholders were identified as a user, a manufacturer of couplings, and a manufacturer of seals. The stakeholders identified that the coupling design must:

- Be suitable for both hygienic and aseptic duties
- Be suitable for general food application
- Use an O-ring seal
- Be as easy and economical as possible to manufacture
- Be as easy as possible to assemble and operate reliably
- Be very robust and resistant to lateral loadings and abuse
- Conform in its design to EHEDG Document No. 8 Hygienic Equipment Design Criteria, Second Edition 2004
- Have a service interval equivalent to 200 sterilisations with steam at 140 °C, cooling to 35 °C each time

- Pass the EHEDG tests for cleanability, bacteria tightness and sterilisability *after* being subjected to a simulated service life of at least 200 sterilisation cycles

2. Analyse and specify the design

The Stakeholder Requirements Specification was then used to develop an appropriate design, for example:

- Elastomer gaskets 70 degree Shore A
- Metal faces $\leq 0.8 \mu\text{m} R_a$
- Elastomer faces as smooth as possible
- Contact pressure between 1.5 and 2.5 N/mm²
- Non-porous metal parts
- Elastomers with no pores $>1 \mu\text{m}$
- Friction at elastomer faces caused by sliding is minimised
- Room for expansion/deformation of the gasket
- Recess or protrusion of gasket not greater than 0.2 mm
- Tensile stress minimised
- Compression between 20% and 25%
- Sealing faces protected against damage
- Lead-ins on coupling to assist assembly
- Minimal tolerance between male components in its liner to assure a smooth bore line
- The O-ring is precision moulded
- The O-ring material chosen is a specific formulation of food-grade EPDM that is resistant to high temperatures

3. Design then qualify the design, including instructions and documentation

- A design was produced that cups the O-ring in a close-fitting curved recess.
- The sealing faces were designed to compress the O-ring so that it formed a narrow, nearly flush, seal at the product contact side.
- The O-ring was sized so that it helped to protect the sharp sealing face on the male part.
- The elastomer formulation was specified as food-grade high-temperature EPDM.
- The coupling material was specified as 316L stainless steel.
- The design was subjected to challenge testing by finite element analysis and practical confirmation of this result after simulated operation. It failed at this stage because the flat sealing surface on the female part of the coupling caused excessive stress where the O-ring was pinched to form the bore-line seal.
- A redesign was made following the adverse results of the first validation by finite element analysis.
- The new design was subjected to simulated operation by passing it through 200 sterilisation cycles.
- The coupling is re-tested to ensure that the coupling is easy to assemble according to the instructions and that the O-ring provides a flush seal and does not leak or shear under the specified conditions of use.
- The operation of the design is qualified.

4. Install, then qualify the installation

- A prototype of the coupling was manufactured and assembled according to the instructions by a qualified operator or installer.
- It was installed into a test piece suitable for use in the EHEDG test rig.
- The assembly was then checked for cleanliness and absence of problems such as gasket protrusion.

5. Validate and qualify the operation

- The coupling was subjected to a simulated use cycle of 200 steam sterilisations.
- It was checked for mechanical and engineering operation.
- The integrity of the O-ring was confirmed.
- The operation of the coupling was qualified.

6. Validate the hygienic performance

- After the simulated operation performed for the operational qualification, the coupling was subjected to a battery of EHEDG tests by an EHEDG-accredited laboratory.
- This new prototype passed all the tests.
- The test laboratory documented the full challenge- and testing-protocols.
- The instructions and documentation were implicitly validated as part of the EHEDG challenge tests.

7. Qualify the hygienic performance

The manufacturer applies for EHEDG certification and the successful prototype is type certified by the EHEDG-accredited laboratory that tested and validated it for cleanability, bacteria tightness and sterilisability.

Alternatively, the manufacturers and the user certify it for their exclusive use.

8. Verify the hygienic performance

As the coupling is not yet assigned, instruction must provide that measures to monitor and test the hygienic performance of the coupling must be implemented as appropriate. (For example, leakage integrity testing, inspection of seals and sealing faces on removal).

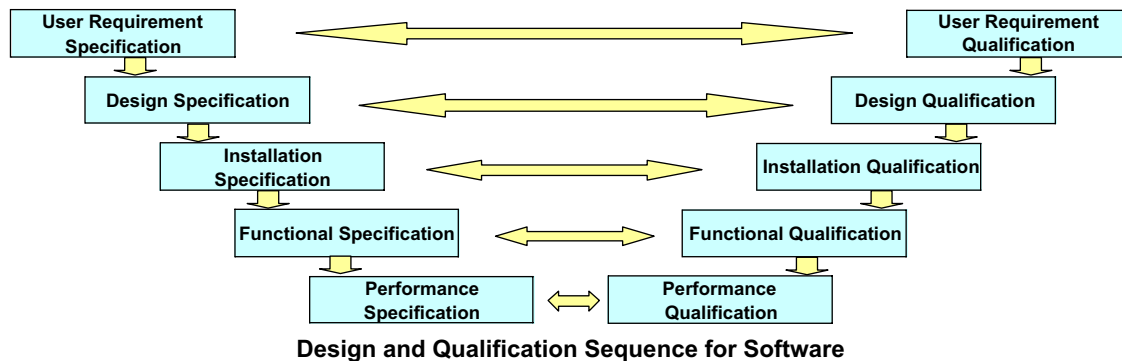
9. Arrange disposition

The certified design is made available for sale and added to the list of approved products.

Appendix 3. System design example

The control system should allow the identification/traceability of the businesses from which, and to which, the

Control systems follow a similar pattern to the generic process already described. However, the language used is more often as here:



materials or articles (and where appropriate, substances or products used in their manufacture) have been supplied. That information shall be made available to the competent authorities on demand.

Introduction

It is recommended that the overall system be partitioned into subsystems and subsystems into modules, etc. There are many automation systems on the market that are highly versatile and could probably be adapted to any production system. One of the most important demands on such a system is the possibility to extend the system when required. It should be possible to build a system of any size, step by step, by adding standard components/program units. A small controller installed to operate a unit can later be expanded to control a line by adding new control equipment from the same system. At the same time, management routines can be inserted into the existing processors or into a special management computer. In the expansion process it is very important that all system components between the operator and the process, from the remote sensor to the operator user interface, are part of the same system. It is important that the control system supports HACCP activities.

Engineers must also decide whether to make or buy the subsystems. If nothing satisfies all the requirements, then modification of an existing subsystem should be considered. If this proves unsatisfactory, then some subsystems will have to be designed in-house. Engineers designing one subsystem must understand the other subsystems with which their system will interact.

Interface between main and subsystems

Interfaces between subsystems and interfaces between the main system and the external environment must be designed. Subsystems should be defined along natural boundaries and to minimise the amount of information required to be exchanged between them. Well-designed subsystems send finished products to other subsystems. Feedback loops around individual subsystems are easier

to manage than feedback loops around interconnected subsystems. All this is analogous to the modular approach proposed for equipment, buildings and other systems.

Total integrated plant control

The next step is to configure a totally integrated plant control system. In this type of automation system, the site consists of more than one area for example, in a dairy plant; butter, cheese and liquid milk production. Each area has a configuration of several process controllers and will often have operator stations of its own, receiving products from one area and delivering products to another.

Within each area a network for communication is connected to the different units. The same network is then interconnected with all the other areas, so that data, commands, interlocks, etc. can be communicated between them. When all controllers in the plant are connected to the same network, it is possible to connect a central maintenance terminal to the system. This can then be used to provide input for re-programming, fault tracing, trimming and tuning.

It is essential to keep track of production parameters and batch production data in a plant. The process controllers contain a substantial amount of information and data from the process all the time, day and night, week and month. The process controllers themselves can provide a lot of data and reports, but the type of management information handling where the data must be further processed or database stored is best handled by a separate computer. A Manufacturing Execution System is dedicated to handling large volumes of data. It computes and processes the data to produce various types of reports, to analyse production economy, etc., to assist in planning and to make preventive maintenance forecasts.

A recommended working process is outlined below.

1. Stakeholder requirements specification

Consider:

- Legal demands
- Production requests

- Product quality and its assurance
- Level on traceability
- Level of automation (manual, semi-automatic and/or fully automatic production)
- Demands on level of control
- Feedback from the system and use of the information
- Use of bus system and its communication demands

Use the above to:

- Transfer the stakeholders requirements into identifiable objectives and parameters
- Make a structure of the objectives separating legal demands and contractual demands
- Make a structure of parameters and identify performance parameters
- Document the Stakeholder Requirement Specification, with careful version control

2. Analyse and specify the design

Consider:

- Legal demands regarding traceability must be fulfilled.
- Functional solution regarding flexibility and transports must meet the Stakeholder Requirement Specification.
- Interlock provisions must meet the production specifications and ensure hygienic production.
- Equipment functionality must fit the specified system functionality.
- The control system should go to a “safe and hygienic” state, if any malfunctions occur in the control system or in the electrical system.
- No part of the function must conflict with hygienic demands.

3. Design then qualify the design, including instructions and documentation

The control system should be designed using open standards.

- It should have a high accessibility.
- It should be autonomous, not operable from other computer-based systems.
- It should be designed to go to a “safe” state, if any malfunctions occur in the control system or in the electrical system.
- It should fulfil anticipated electrical demands.
- The control system should be fully documented for installation, commissioning and maintenance, with full regard for hygienic function.
- The design of the operator interface involves also parts such as graphics layout, use of colours, display navigation, and content and sequence status. Indications to be displayed. Configuration standards should be used.
- Recording and reports, with their content and formats.
- Make risk analysis for working safety for the complete plant.

- Make risk assessments for the system (FMEA, HACCP, HAZOP, etc.).
- Include data backup and data security in the risk assessments.
- Consider the hazard of malicious actions.
- Take actions to eliminate hazards, or failing this, to control the risks.
- Use equipment with an open standard delivered from trustworthy, long-term suppliers.
- Ergonomics for operators’ panels.
- Ergonomics and location of local controls and central control rooms.
- The equipment should fulfil applicable directives.
- The equipment should fulfil applicable national electrical standards.
- The hardware and its system should be fully documented for installation, commissioning and maintenance.
- The instrumentation should comply with legal demands.
- The equipment as installed should have a hygienic design, as determined by risk assessment for its location.
- Sensors and transmitters should be resistant to the conditions of use, typically diluted caustic and acid solutions, hot water and steam.
- The instrumentation should comply with installation and maintenance demands.
- The instrumentation should be suitable to connect to the control system.
- Use of standard tested and verified application software.
- Use of configurable software.
- Use of custom-built software.
- The control system should be built in modular fashion from validated subsystems provided by one or several of the above software solutions and the complete system should be validated, which is highly important if custom-built software is used.
- Number of I/O points for both analogue and digital communication.
- To satisfy EAA legal requirements, provide traceability of the materials and articles at all stages of manufacture, processing and distribution, for example, via a batch programming language.
- Mathematical or statistical functions required.
- Use tested and verified automation control equipment when implementing the software.
- Simplification procedures.
- Qualify the design once all results are conform to the SRS.
- Provide instructions and documentation to assure hygienic performance.

4. Install, then qualify the installation

- Install the equipment and software.
- Make an installation qualification to ensure that the process and utility installation is ready before switching on

the control system (that is, after validating it for conformance to specifications, provide an authorised and dated signature.).

- The electrical connections must be designed to allow proper maintenance including full accessibility to junction boxes and outlet boxes.
- Conduits and raceways should be labelled for ease of identification.
- The electrical installation shall be made according to national electrical regulations.
- Signal and power wiring should be isolated to avoid electromagnetic interference.
- All wiring and cable conduits in high hygienic areas should allow for cleaning of exposed surfaces. Sealing of conduits between different hygienic areas may be required in some cases.
- Make all necessary supplier maintenance documentation available.
- Ensure that actions to eliminate or reduce the risks are implemented.
- Implement system for preventive maintenance, training, spare parts.
- Make calibration and maintenance plans.

5. Validate and qualify the operation

- Validate the subsystems against parameters set initially in the design specification.
- Non-critical functions of the operator interface should be designed and tested following Good Engineering Practice. They should be designed and tested in conjunction with the software.
- Test the complete control system alone, to make sure that all automation systems are working as planned.
- Make an I/O-test of all control units connected to the control system.
- Test the calibration of instrumentation and document.
- Perform a Factory Acceptance Test simulating the control system functionality.

When commissioning the complete system, the following should be considered:

- Be very careful to observe safety regulations for personnel.

- Start commissioning with cleaning and water test.
- Adjust all necessary production parameters.
- Continue with product tests.
- Adjust all necessary production parameters.
- Minimize product losses (by producing a risk assessment).
- Perform a functional and operational qualification.
- Make sure that stated production data are fulfilled.
- Perform a performance qualification, including cleaning test.

6. Validate the hygienic performance

- Use the software to operate the equipment during the cleaning and sterility challenges.
- Record and document the test results.
- Correct any faults.
- Record and document the successful test results.

7. Qualify the hygienic performance

The system *as finally built* must be tested and qualified to ensure that it satisfies the mandatory and stakeholders hygienic requirements.

8. Verify the hygienic performance

One of the advantages of an automation system after it reaches this stage of its life cycle is that its hygienic performance is not usually subject to wear and tear. Its performance may incidentally be verified in conjunction with the equipment it controls, for example during a microbial challenge test of the equipment.

9. Arrange disposition

The system must at all times, including start-up, emergency stoppages and shutdown, operate in a safe and hygienic manner. Control, authority and responsibility for the system must be designated to qualified individuals. They must assure that only current, valid, software and data are used. If this system is subsequently transferred as a part of a food production system to new management or ownership, then the documentation, instructions and training must be adequate to maintain hygienic safety.