Hygienic design and assessment

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When assessing valves for use in safe food production there are a number of considerations to be made. This article discusses the implication of EHEDG guidelines.

The guidelines are written with European conditions, standards and laws in mind. Therefore valves for hygienic or aseptic use should conform to EHEDG guidelines as follows:

- Doc. 8: Hygienic Equipment Design Criteria
- Doc. 9: Welding Stainless Steel to meet Hygienic Requirements
- Doc.10: Hygienic Design of closed Equipment for the Processing of Liquid Food
- Doc.13: Hygienic Design of Equipment for Open Processing
- Doc.14: Hygienic Design of Valves for Food Processing
- Doc.16: Hygienic Pipe Couplings
- Doc. 20: Hygienic Design and Safe Use of Double-Seat Mix proof Valves

This will ensure, amongst other things, adequate surface finish, cleanability and absence of crevices and sharp corners and absence of metal-to-metal contact surfaces. Where the valves are powered, they must also conform to the Machinery Directive and be CE-marked.

Origins of valve-types used in food manufacture

Historically, there has been widespread adoption and adaptation of existing types of equipment components, including valves, for food applications. In some cases, usually where the product is resistant to spoilage, this has been relatively successful even though the design may be relatively weak in hygienic terms. However, given that such valves were originally designed neither for hygienic applications nor with the benefit of modern hygienic design knowledge, variable levels of hygienic success and failure have resulted.

Sliding seal valves

Ball, gate, plug and other sliding-seal valves have been used, but these rely on seat shut-off and, in some cases, body sealing on comparatively large sliding seals that may easily become scored and/or fouled. The sliding seals commonly contain a thin, stagnant film of product and there may also be stagnant product in spaces behind the sliding seals. They usually need to be dismantled each time for cleaning, except perhaps when used with very clean products such as water or ethanol. Some manufacturers have adapted them by providing drainage to these cavities, but it is up to the users to satisfy themselves as to whether this really works successfully with their own products and conditions. Generally there are better options.

In a special case, sliding seal configurations have often been chosen for integral aseptic block and bleed sampling designs, primarily in order to permit single-step manual operation of the block-and-bleed, together with the product seat opening. However, the sliding seals are not bacteria-tight, even though this is usually a requirement for aseptic performance. Generally, butt sealing is preferable for shut off applications.

Metal-to-metal seated valves

Although some suppliers have offered these types for hygienic duties, a clear category that is normally unsafe for hygienic or aseptic duties is that based on metal-to-metal seat seals. Such seals are not bacteria-tight and therefore should be used only where bacteria-tightness is not required.

Butterfly valves

Butterfly types can be hygienic and cleanable in place if designed according to EHEDG guidelines. They are useful where a low-cost single or double seat solution is required and have the advantage of occupying a very short length of pipe-run. However, as they are not hermetically sealed, they are not suitable for aseptic duties.

Weir-type valves

Weir-type diaphragm valves were originally designed as an alternative where hermetic sealing was required. They have been widely adopted for aseptic duties because the diaphragm seal provides a permanent hermetic body seal as well as a seat seal. However, as they were not designed specifically for hygienic and aseptic application, care needs to be exercised with respect to a number of points:

There is usually no fixed compression-stop on the bonnet fastening screws, so these are commonly over-tightened. This may lead to shrinkage and hardening (compression-set) of the membrane, with consequent crevice and/or leak formation. The common fix of re-tightening the fittings to combat leaks leaves the risk of unseen crevices and aggravates the compression-set. In the worst cases, a circular disc is cut out of the rectangular membrane.

This configuration of valve is often supplied with an adjustable compression-stop on the seal travel to allow for interchangeable fitting of membranes of different thickness. This provides significant opportunity for error that is often realised in practice. In the worst case, the membrane may be punctured by the valve-stem. It can be safer to opt for valve tops with fixed stops if available, even though this would mean a change of top if the membrane were changed to a different thickness.

In vertical piping, this type of valve is normally free draining, but when the pipe axis is approximately horizontal, there is a critical tolerance on orientation for drainage past the weir. Typically the valve-stem has to be inclined from the vertical within a narrow arc of tolerance. The exact angle is in the range 60-70 degrees from the horizontal. Unfortunately, this angle can differ according to the valve-size, giving further opportunity for error where multiple valve-sizes are used in the same installation.

Blocks of steel can be machined-out to provide multi-axis, multi-seat valve blocks, but care needs to be taken to ensure that all of these seats are free draining.

Weir-type diaphragm valves are, more than any other, often supplied and installed with couplings on both sides. Apart from increasing the number of vulnerable seals, this carries a very high risk that the valve will be re-installed in the wrong orientation, because the couplings allow rotation outside the safe angle of inclination.

Pinch valves

Pinch-type valves, where a reinforced flexible elastomeric tube is externally compressed to close it off, are intrinsically hermetic and therefore potentially hygienic and aseptic. This type is compact, can give full-bore flow and has the widest range of orientations for self-draining. It is currently available in a hygienic implementation only in small sizes. It is not found in multi-seat versions.

Circular seal valves

The introduction of flush circular seals has allowed valves to be purpose-designed for hygienic and aseptic applications. The entry of a number of competitors, principally based in Europe, has led to a family of improvements and advantages for this type and they are now used widely where demanding hygienic performance is required, such as in food, (bio) pharmaceutical and even paint processing. Figure One gives an example of a double-seat variant (the most important variant) of this configuration of valve:

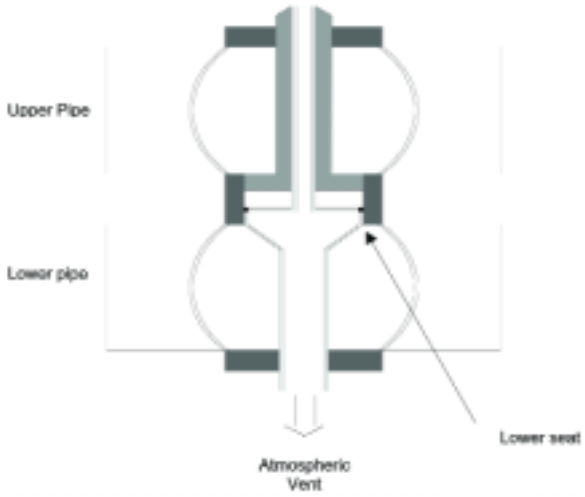

Figure One: Schematic of a Double-Seat Circular Seal Valve

Characteristics include:

- They are self-draining in a wide range of orientations
- This is the most flexible design for multiple seat versions, with unique integration capabilities that permit highly efficient and hygienically safe plants
- Because of their flush-fitting seals, multiple seat versions permit the elimination of stagnant zones in a way not possible with single-seat valves
- It is possible to integrate several valve functions into a single, factory-made multiple-seat valve module, eliminating the vagaries of site-assembled equivalents. An example would be an aseptic block-and-bleed module such as an aseptic barrier

- Hermetically sealed aseptic versions incorporating flexible polymeric diaphragms or stainless steel/polymeric bellows are now commonplace

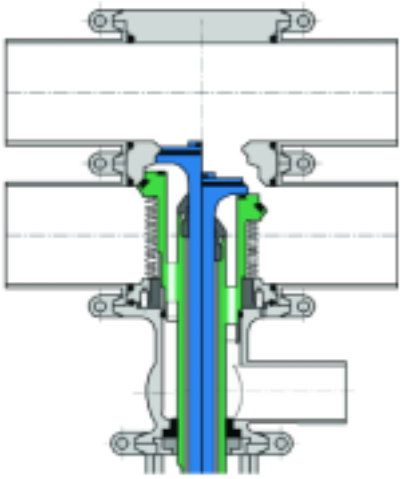

Figure Two: Aseptic Mix proof Valve

Balanced pressure versions are available that prevent the valve being forced open by hydraulic shocks. The combination of powerful return springs with fixed compression-stops provides fail-safe operation without over compression of the elastomeric seals. The use of sensors on the valve-top permits positional feedback, critically confirming when the seat is properly closed.

With double-seat mix-proof types, there must be atmospheric leakage detection. However, this means that a small amount of product can be lost at each changeover unless the design incorporates axial seals. These are circular seals that maintain a sliding seal during movement, followed by a butt seal at closure (See EHEDG Doc. 20 Hygienic Design and Safe Use of Double-Seat Mix proof Valves).

Note however the emphasis has been on larger-size piping (>DN50) and that most of the pneumatic actuators currently available are not compact, relative to the smaller sized versions. This may be problematical in confined spaces or where small valves are required. Some more compact non-pneumatic actuators are available which may allow them to be employed.

Assessment and selection

Inadequate selection practice

In real life, the choice of valves for hygienic applications may often be made on the basis of custom and practice, tradition or even dogma rather than on a systematic technical and hygienic appraisal. This can result in designs that are relatively expensive to run and maintain and have failure-rates well below best practice.

To counter this and to make assessment and selection more objective and scientific, the EHEDG

has pioneered the provision of guidance on hygienic design and the establishment of standardised challenge tests and corresponding certification facilities.

Concurrent design

Hygienic considerations need to be made concurrently with all other legal, design and performance requirements when assessing valves for hygienic use, so that the valves fulfil the global user specification as comprehensively as possible.

Valves for dry materials

Valves for use with dry materials may follow a much more relaxed set of design rules. For example they often have extensive sliding contact surfaces. They will not be considered here, but note that if any valve is expected to be wetted at any time, for example cleaning between successive batches to remove a strong flavour or to Kosherize, then all the considerations of this article apply.

Defining the required hygienic performance level

An early consideration determining the performance specification is whether aseptic or hygienic performance is needed. (It may be that a valve for use in food production etc. does not even need to conform to a 'full' hygienic specification, for example if the product is edible oil, vinegar or rice grains). The documented risk assessment phase as described in EN 1672-2 and ISO 14159 or the Hazard Analysis and Critical Control Points (HACCP) study of the process/product design can be an opportunity to justify a relaxation of some prescriptive requirements of these standards. For example many potable water valves are not made of stainless steel, but instead brass, copper and chrome-plated brass.

Durability and reproducibility of hygienic performance

A major factor is the durability and reliability of hygienic performance for the application in question. This is covered to a large extent by the guidance in the above EHEDG guidelines. However, issues such as materials compatibility are often poorly considered, especially at design changes such as the introduction of new products/formulations or expansions of heat- and temperature -exposure limits.

In this context, the availability of a good selection of seal elastomers can be very important in allowing such variation to be accommodated. A restricted range can mean that a branded valve range is unable to perform to its full potential with certain products and/or conditions. Elastomers do age and are relatively perishable, therefore their handling, composition, packaging, labelling and surface finish are critical for reproducible performance. It has also been known for critical attributes of original seal parts to be varied by the moulding company without the knowledge of the valve manufacturer. Therefore it is important that the valve supplier can provide documented evidence and control of composition, traceability, storage and handling. Seals should also be supplied individually labelled and have an expiry date. Colour-coding via elastomer pigmentation can be a helpful fail-safe, but only if it does not impair performance of the elastomer compound. Non-original supplies of non-proprietary seal shapes such as 'o'-rings can cause serious problems unless they comply exactly with the valve manufacturer's specifications and all the above quality assurance provisions are implemented.

Seals made of fluoroplastics have been introduced for use in general applications where much higher chemical and heat resistance is required. In some cases, these are also offered for hygienic applications. Bacteria-tight seals for liquids require that at least one part of the seal is elastic and can flow into the microscopic imperfections of the seal face and maintain this seal during expansion, contraction and vibration of the equipment. It is questionable whether a plastic seal-face contacting a metal seat can do this, even when backed by an elastomer for resilience. A more recent adaptation has been to use a fluoroplastic-on-elastomer seat, which is likely to be more successful. However, careful designers and users will satisfy themselves by challenge testing that any seals required to be bacteria-tight still give a bacteria-tight seal after a simulated normal lifetime of use.

Maintenance

Ease, speed and reliability of maintenance are important issues for users. It is important in an installation with many valves that each valve can be overhauled reliably and quickly to avoid expensive downtime. Useful enhancements here are the provision of single-armature multi-seat valve modules (you can replace several seat seals at once), single-fastener body clamps and fail-safe aids such as fixed compression-stops on all seals. For a realistic appraisal of such features it is wise to involve the maintenance technicians and even for them to conduct replacement tests to estimate the replacement time per seal and the frequency of correct body and seal compression.

Life cycle costs

As with all equipment purchases, the buying

strategy can vary between an emphasis on low initial cost to one on low life-cycle costs. Life-cycle costs can be strongly dependent on maintenance frequency, because a major component of valve change-out costs stems from the loss of production time and output. It is important therefore to take this into account when considering maintenance costs. Comparison of replacement costs will also show that for the larger pipe-size, a comparable membrane for a weir-type valve is considerably more expensive than the seal kit for a circular seal valve. In my experience, the seals of circular seal valves also last far longer under the same conditions than those in weir-type valves. This can probably be attributed to the minimisation of the tension forces on the elastomeric seals, assisted by the use of non-adjustable metal compression stops. (In the past, the single-diaphragm circular seal valve was modified so that the body seal was separate from the seat seal. This eliminated the cycle of simultaneous stretching and compression of the elastomer, and was found to increase the seal lifetime. Such a modification is not at present available for the weir-type, to my knowledge).

It is therefore important to ensure that the cost/benefit assessment is based on a comprehensive identification of all costs rather than just the cost of the valve and its service parts.

Body stiffness

Valve-body stiffness may be a key defence against torsion, compression and pipe-stress, for example from thermal expansion and contraction or from poor installation practices. Instances are known where the valves distorted and there was an intermittent failure to close fully. Although the use of pipe-stress software calculations can minimise this risk, variations from plan do occur during installation and a strong, stiff valve-body construction is therefore less likely to run into trouble.

Materials compatibility under non-routine conditions

Assuring materials compatibility is a requirement of EHEDG guidelines, but in practice this is not always as simple as it may seem. It is important to consider all operations such as fail-safe modes, shutdown, cleaning and maintenance. For example, where high temperatures and/or halides are present, drying-out can lead to very corrosive conditions, even though normal operational conditions are much less severe. Intelligent changes to operational procedures and the integrated design can mitigate these kinds of stresses but in other cases the cost of using higher-grade materials may have to be

balanced against the cost of failure during production.

Design principles

Apart from the requirements for conformance to the more generic EHEDG guidelines 8 and 10, valves have some specific hygienic design requirements. Whilst it is not intended to duplicate the EHEDG guidelines Doc.14: Hygienic design of valves for food processing and Doc. 20: Hygienic Design and Safe Use of Double-Seat Mix proof Valves, some examples of specific requirements are:

Leak detection

Continuous leak detection for the seat seal is normally required for assurance of safe operation and should be an integral part of the design. As a minimum, this takes the form of an atmospheric leakage port, though some automatic detection and feedback systems are in evidence, especially for aseptic barrier modules, where the barrier zone has to be pressurised. Note that in the case of plastic-faced elastomeric membranes, an unacceptable crack in the plastic face will usually not be detectable because it will still be sealed from the leak-detection port by the elastomeric component. Note that if such a penetration is accompanied by delamination, then a hazardous crevice will form between the plastic and elastomeric layers.

Seat-lift actuation

The ability to clean the face of each seal seat has to be facilitated in multiple seat and mixproof valves by the provision of seat-lift actuation during CIP operations, independently of concurrent product operation.

Safe closure

Valve seats are usually sprung closed and opened by powered actuators, so that in the event of power failure, the valve fails in the closed position.

Validation

Challenge-testing – where and when

It is not unknown for organisations to test or even implement new valve designs, brands or components in their production equipment under working conditions after only a cursory inspection of the design. This can be a hazardous and potentially expensive strategy. In the majority of cases it is safer to challenge-test the equipment off-line (following simulation of a required cycle and conditions of use) before testing a sample in the production environment. A useful aid to this can be where the manufacturer has had the valve type-tested and certified by an EHEDG-accredited laboratory, to the EHEDG guidelines. See 'EHEDG certification' below.

Appropriate specification and selection

Suppliers are regularly confronted with complaints about their valves from users who have made inappropriate selections from their range of models and components. For example use of Ethylene Propylene Diene Terpolymer Rubber (EPDM) with oily or fatty material such as antifoam or use of low temperature EPDM with steam sterilisation. It is important prior to design changes or validation of any equipment to define and document the exact requirements and conditions of use (temperatures, chemical exposure, maintenance availability, available space, temperatures, pressures, etc). It is also necessary to make the optimal selection from the supplier's available body and seal materials for these requirements.

Legal compliance

Any power-actuated valve is subject to the EU Machinery Directive and CE-marking. EN 1672-2 was produced in support of the food safety aspect of the Machinery Directive and provides guidance on prescriptive equipment design, augmented and potentially modifiable by a documented hygienic risk assessment. (ISO 14159 is effectively a more recent update of EN 1672-2 and could be used instead if desired). Users should ask for a copy of a manufacturer's risk assessment to support their initial appraisal and validation of the design. A key feature of such documentary evidence could be the provision of a documented EHEDG or comparable challenge-test or EHEDG certificate.

EHEDG certification

A considerable aid to validation and selection of valves is testing and certification by EHEDG-approved laboratories to EHEDG guidelines. The EHEDG tests are reference tests that challenge the equipment for cleanability, sterilisability and bacteria-tightness under defined test conditions. The certification qualifies compliance to EHEDG guideline number 8, supplemented by the cleanability test. Note that certification does not cover bacteria-tightness of the body or sterilisability, although there is no reason why a manufacturer cannot request this EHEDG test and provide a test-report. There is not yet an EHEDG test for bacteria-tightness of the valve seat, nor is there a period of simulated use prior to testing a specified requirement. The test and/or certification are for reference only and users should request both test reports and certifications to confirm exactly what was done. User's conditions may in some

respects be more challenging than the test conditions and this should be taken into account. As described above, it is suggested that a period of simulated use is performed prior to challenge-testing and users with critical applications may be wise to have this done prior to testing in processes whose results or products are costly.

Integration characteristics

The manufacturer's instructions

It is essential that everyone involved in design and installation understands the manufacturer's installation instructions. For example, a frequent cause of hygienic failure of valves is the incorrect orientation of the valve, such that the valve body does not drain freely. (It is of no use to have selected and validated equipment, for example to a surface finish of 0.8 micron Ra on every component of a plant, only to have comparatively enormous sumps or weirs as a result of incorrect valve orientation. This is especially true where steam sterilisation is needed, as the collection of condensate will result in cold spots and an increased risk of microbial survival). Consequently it can be safer where feasible to select valves with weld-stubs rather than couplings and to prefer designs that have a greater range of orientations in which free draining is assured. Similarly, it is essential that valves can be and are operated within the manufacturers' recommended operating conditions. Excessive temperatures, pressures, and hydraulic shocks are common causes of hygienic failure and it can be frustrating for suppliers to receive complaints about their designs, sometimes via third parties, only to find that a sub-optimal selection or easily-avoided abuse was the root cause.

Integration flexibility

The flexibility and suitability of a valve design for integration into relatively compact precision fabricated modules/manifolds can be very important. Such modular constructions can eliminate dead-legs and eliminate vessel wait-times. This capability is most evident with circular seal type valves, particularly double-seat mix-proof valves, in which fluids that may not safely be allowed to contact each other can be isolated within a single valve-body.

Conclusion

This article has focused on some practical implications of implementing EHEDG guidelines with respect to the assessment of valves for hygienic and aseptic applications. For more specific and detailed information, readers should refer to the relevant EHEDG guidelines. ■