SubCom Product Portfolio

WGC
Supplementary Testing & Certification Requirements

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Scope

1.1 The evaluation and testing of equipment intended for certification that is presented to EHEDG covers a wide range of EHEDG Guidelines, individual designs, and fabrication features that are often unique to the item being evaluated. The EHEDG maintains this document of all elements that are important to the interpretation, evaluation, and certification process in addition to the published guidelines to assure uniformity between the Authorized Equipment Evaluators (AEO), the Authorized Testing Laboratories (ATL), and the Certification Officer (CO).

1.2 This document is available to the public on the EHEDG website for easy access. The decisions documented in chapter 5 are to be considered for incorporation into scheduled updates of the relevant guidelines to assure transparency and to maintain the guidelines with the most current information available for certification.

2. Authority

2.1 The development and maintenance of this document reside with the Working Group Certification (WGC) with the assistance of the CO and under the authority of the SubCom Products Portfolio (SCPP). The WGC comprises the expert body that makes the determinations as to when special techniques of evaluation, testing, and certification are necessary to assure uniform evaluations.

2.2 The WGC is to notify the SCPP Chair/Co-Chair when a new item is to be added to this document. SCPP are to provide any comments on the proposed addition within 7 days. If comments are raised, they will be discussed with the WGC and SCPP for timely resolution. If no comments are received, the CO will initiate the Website up-date.

2.3 This document is maintained by the CO on the EHEDG website https://www.ehedg.org/guidelines/ at the “free documents” list of the Guidelines.

2.4 As appropriate, entries may be further explained with the publication of a Position Paper. (See SCP 4-9)

3. Structure

3.1 This document is maintained as a MSWord document that is also converted to an Acrobat .PDF format for distribution and posting on the web site.

3.2 Reference Documents

- EHEDG Doc. 2
- EHEDG Doc. 5

- EHEDG Doc. 7
- EHEDG Doc. 8
- any other EHEDG Docs as appropriate

3.3 Procedures

3.3.1 Any special conditions in the test procedure that WGC has decided must be documented. This includes procedures of testing of certain pieces of equipment, exclusion of tests and any unpublished changes relevant to EHEDG Guideline no. 2.

3.3.2 Any unpublished supplementary design requirements proposed by the WGC will be included in this document and must be agreed by the SCPP.

4. Updating of Requirements in Guidelines

The Chair of the WG responsible for the preparation of an EHEDG Guideline in which a requirement of this document is to be incorporated shall consult with the WGC to assure the accuracy of the reference in the specified guideline.

The WGC shall, upon final approval of the guideline, reissue this document without the requirement that is now incorporated into the published guideline.

5. Requirements

5.1 Supplementary requirements for the design

5.1.1 Mechanical force seals

When an elastomeric seal is pressed into a specially shaped groove machined in a one-piece component, the seal shall fill the groove completely. Expansion/contraction of the seal will only be possible in the product contact area and it must be ensured that the seal maintains a crevice free joint at the product contact interface under the intended conditions of use. Finite Element Analysis provided by the customer may be used as one means for validation in conjunction with compulsory cleanability testing according to Doc. 2. This type of mechanical force seal is not intended for routine disassembly for cleaning and the manufacturer must provide routine inspection and replacement instructions to ensure hygienic integrity is maintained.

5.1.2 O-ring groove design

O-ring joints with one flat face can be acceptable for cleanability testing only if technical or functional reasons are justified.

Square grooves designed according to 3-A requirements are acceptable if the doc. 2 test shows easy cleanability.
O-rings for sliding seals are not acceptable: except for the valve disc seal of a mixproof valve with compulsory cleanability testing according to doc. 2.

5.1.3 shrink-fit / press-fit (metal to metal/metal to ceramic)

Press-fits using metal-to-metal components are not allowed according to the doc. 8.
Press-fits using plastic and metal have to be tested according to doc. 2.
A shrink-fit may be used for joining similar or dissimilar materials and the assembly has to be tested according to doc. 2.

5.2 Testing of equipment

This chapter is about testing requirements and procedures related to specific equipment and the consequence for certification.

5.2.1 different sizes of equipment

The result of the cleanability test can be transferred to other sizes of the equipment as long as they are similar in geometry. The worst-case size, in terms of cleanability, has to be tested.
Computational fluid dynamics (CFD) simulation provided by the customer may be used to select the worst-case size in equipment without rotating parts during cleaning (e.g., not for pumps).
Flow velocity and wall shear stress is the information to find the worst cleanable size of the equipment to test. CFD calculation should be done in a steady state with 1.5 m/s speed and with water at ambient temperature.
CFD calculation should take into consideration that the inlet is according to the reference pipe diameter or a pipe diameter according to a tube standard (e.g., reducers must be included).
In the following sections, additional specific criteria for the selection of the worst case are stated.
A consensus between the customer and the WGC is required to determine the worst case and consequently to decide upon the size and configuration to be tested.

5.2.2 Supplementary requirements for testing according to Doc 2

5.2.2.1 elastomeric material testing including false-positive results

The behaviour of different elastomeric materials and recipes in the same groove design of the joining parts can affect cleanability, therefore, only the tested materials can be certified.
The tested materials are mentioned in the test report and the evaluation report.

A test on pH-change due to acid leaching can be necessary to identify false positive results in the doc. 2 test, especially with silicone. For that assessment, the material is incubated in agar at 58 ºC without microorganisms.

5.2.2.2 valves

Valves are normally tested in all flow directions. When a specific flow direction is mentioned in the user's manual and/or a flow arrow is marked on the outside of the valve body, valves can be tested and certified only for that one direction.
A 45°-housing is different in geometry to a 90°/180°-housing and must be tested independently.
Worst case determination:

- Worst-case for different housings: double body valve (LL housing) is considered worst case compared to single body valve (L housing). Split flow (T housing or diverter valve) is not possible to test. In this case, the manual must specify how to clean (full flow through the valve by shutting off one outlet), and the test will be conducted accordingly.
- Worst-case for different sizes with similar geometry: alternatively to the CFD option mentioned in section 4.1, the worst case could be determined based on the Kv-value: take the Kv-value (m^3/h) and divide it by the flowrate needed to get a velocity of 1.5 m/s in the valve inlet) -> highest ratio number determines the worst-case size.
- In certain cases, where geometry changes (e.g., plug design), CFD simulation may be the most appropriate way to determine the worst case.

5.2.2.2.1 sample valve

Sample valves with one or two outlets must all be opened to drain or back into the cleaning tank during the cleaning step of the cleanability test. The flow in the outlet is depending on the backpressure of the main pipe with the reference pipe. This should be 1 bar.

5.2.2.2.2 butterfly valve

Large steps at the gasket in the area of the shaft sealing are not allowed.
Worst case determination:
Alternatively to CFD, the calculation of the flow-through area in the middle of the valve is possible. The worst case will be that with the largest area in comparison to the pipe diameter.

5.2.2.2.3 seat valve (L-shape housing)

Seat valves with L-shape housings must be cleaned in both directions (if intended to be certified for both flow directions).

5.2.2.2.4 diverter valve

All possible flow directions must be tested separately. No split of the flow is necessary.
Worst case determination:
Worst-case if 3 housings are together:

(middle in to outlet top / middle in to outlet bottom
/ top in to outlet middle/bottom in to outlet middle)

5.2.2.2.5 double seat mix proof valve

These valves with 4 ports must be tested in the following way:
- build a pipeline loop to go through both housings, lower first to get the air out
- only one flow path to examine (3 tests)
- soiling with the valve opened (main stroke), operating (closing) the valve several times during the soiling step
- cleaned in the closed position with seat lift; the number of seat lifts according to the manual
- filling with agar and incubation in the closed position
- attention to a straight unimpeded inflow section in the pipeline loop

Worst case determination:
The highest leakage flow (during seat lift) in comparison to the inlet flow through the valve.

5.2.2.2.6 dosing valves (filling machines)

A CIP-circuit must be built to test the valve. Reference pipe according to valve inlet diameter and worst-case according to lowest speed in the valve.
Soiling: fit a CIP return connection and pump/dose the soured milk in the loop
Drying: dismount the CIP return connection, clean and sterilize it; dry the unit in an open position
Cleaning: fit the sterile CIP return connection, then clean the loop

5.2.2.2.7 relief valve with vent to atmosphere

A relief valve will be tested only on the product contact side. The atmospheric side is not included. It must be possible to actively open the valve. Soiling with valve movement, cleaning with open valve, incubation with a closed valve.

5.2.2.3 pumps

“Static“ CFD of pumps in dynamic situations is not relevant. Smaller or larger sizes can be certified if the design review concludes that they are geometrically equivalent / scalable.
Cleaning instruction: The use of a speed controller to realize 1,5 m/s in the reference pipe and 1 bar minimum backpressure is required. It is possible for the manufacturer to specify a higher backpressure during cleaning if it is specified in the cleaning instructions. This backpressure must be used during the testing program.

5.2.2.3.1 peristaltic pump

To conduct the test, the pump can only be dried if the rollers are dismantled or moved away from the hose and the air can flow through the hose. If this is not possible, the pump cannot be tested.

5.2.2.3.2 centrifugal pump

Drainage valve:
If a pump has a drainage port, the valve must be tested together with the pump. For Class I certification the drain valve must be automatic.
Testing procedure: soiling only the seat area of the valve (closed and not operated during soiling and drying), pulsed during cleaning. A statement in the manual indicating that the valve should only be used as a draining valve and not as a sampling one shall be included.
Exception: drainage valve also used as a sampling valve: The valve must be actuated during soiling, drying, and cleaning in a fully open position.
Worst case determination:
The worst-case is: smallest ratio of inlet pipe diameter to case diameter by choosing the least efficient impeller

5.2.2.3.3 screw pump

Test only one direction (flow direction towards the mechanical seal), even if the pump is used in both directions.
Worst case determination: smallest ratio of inlet pipe cross section to case cross section in combination with choosing the screw with a pitch giving to the slowest revolutions per minute for 1.5 m/s

5.2.2.3.4 lobe pump

Worst case determination:
Primary criterion: lowest rotation speed to achieve 1.5 m/s at min. 1 bar backpressure.
Additional criterion: minimum slip flow in relation to theoretical displacement per revolution at the recommended backpressure for cleaning
If certain sizes within a pump series are not able to achieve the 1.5 m/s and would require a booster pump, then the worst-case is chosen from the sizes which do not need a booster pump. For certification of the smaller sizes, the cleaning instruction must specify the use of a booster pump and/or by-pass loop to achieve the required flow for cleaning the reference pipe.

5.2.2.3.5 progressing cavity pump

Pumps with and without by-pass port are considered two different versions and both must be tested.
Worst case determination:
smallest ratio of inlet pipe diameter to housing diameter;
pump without by-pass: rotor with the slowest RPM to achieve the 1.5 m/s

5.2.2.3.6 in-line mixer

Worst case determination:
The worst-case is: smallest ratio of inlet pipe diameter to case diameter by choosing the least efficient pump

5.2.2.3.7 diaphragm pump

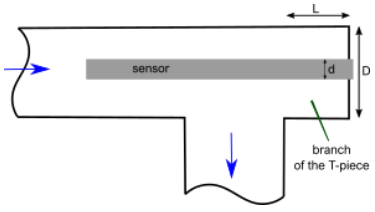
Drainability is required. It could be achieved with magnetic ball valves to open the pipeline or by a system that allows turning the pump using hoses to connect it to the process.
The reference pipe diameter is chosen according to the single inlet diameter of the pump.
An additional centrifugal pump (booster pump) can be used to achieve the required velocity of 1.5 m/s through the pump inlet.
Worst case determination:
Lowest flow rate in the pump; size selection for testing can be based on the largest ratio of the diaphragm to port size (i.e., largest diaphragm/smallest port size).

5.2.2.3.8 bellows pump

Worst case determination:
If cleaning without rotation: static CFD is accepted.
If cleaning with rotation: largest clearance between bellows and inlet casing in combination with lowest revolutions per minute.

5.2.2.4 sensors

Sensors must be tested in the configuration according to the EHEDG Position Paper "*Easy cleanable pipe couplings and pipe connections*". The process connection (gasket) is not evaluated as long as it is a connection listed in the Position Paper. If a T-piece is used for testing, it must have the same diameter in the branch (sensor adapter) as the main pipe.
The T-piece (branch T in 90°) used must have the maximum L according to the criteria L < (D-d). Sensors (very long ones for essential functional reasons) can be tested in a T-piece with the sensor branch parallel to the flow (see fig.).



5.2.2.4.1 temperature sensors

Temperature sensors manufactured inside a thermowell do not need to be tested if all Hygienic Design Criteria are fulfilled.

5.2.2.4.2 pressure sensors, diaphragm/inline

Diaphragm type pressure sensors with laser welding are accepted without testing as long as the welding seam is uniform and free from visible imperfections.
The internal radii in the convolutions of the diaphragm do not require a radius of 3 mm if the maximum peak to valley dimension within the profile does not exceed 0.8 mm.

5.2.2.4.3 magnetic inductive flowmeter

Worst-case determination:
If the size of the electrodes is the same within the size range of the flowmeter, the smaller flowmeter diameter is the worst-case due to the ratio between the electrode surface and the radius of the pipe.
In the case of different sizes of the electrode, the worst case is the largest size electrode in the smallest diameter pipe.
The intersecting angle formed around the electrodes must be checked.

5.2.2.4.4 Coriolis flowmeter

Radius in bends is not an issue about scalability. Pipe has to be sectioned to check the surface roughness.
Worst-case determination:
Double pipe meters: check all sizes and select the worst-case based on CFD for the splitter design in the inlet and outlet.

5.2.2.5 tank cleaning device

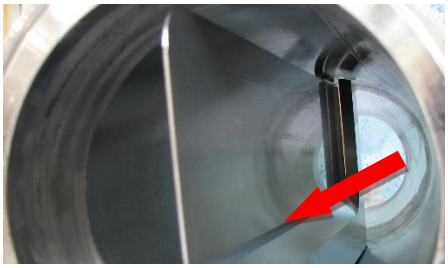
The tank cleaning device must rotate during soiling, according to Doc 2. E.g.:

- single component spinner: the soiling section can be shaken to move the device
- gear driven rotating cleaning devices: the soil can either be pumped through to rotate the device or the device can be rotated remotely.

Cleaning parameters (flow rate, pressure) must be according to the specifications in the cleaning instruction (minimum parameters). The diameter of the reference pipe will be selected according to this flow rate.
When a tank cleaning device is mounted using a stainless steel R-clip (spring) there must be clearance between all surfaces when installed. Therefore, this is not considered a metal to metal connection.

5.2.2.6 tank flanges for explosion vents

The sealing design of a tank flange can be tested as a sectional part supplied by the customer and installed in a pipeline to assess the cleanability.
Example of the test configuration: Only the product side of the gasket arrangement is evaluated.

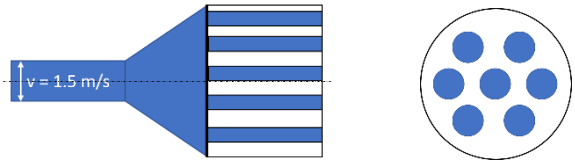


5.2.2.7 tubular heat exchanger

Coiled heat exchanger pipes, options:

a) seamless extruded -> visual inspection and check of roughness, no cleanability test required
b) longitudinal welded -> inspection according to Guideline no. 54 and check of roughness, no cleanability test required

Drainability: If multiple straight tube heat exchangers are mounted with return loops in horizontal stacks and are not completely self-draining, pressurized clean gas can be used to remove the residual water and dry the surfaces. This must be stated in the cleaning instruction.
Worst case determination:
Multiple tube heat exchanger: The diameter of the inlet pipe is used for selecting the size of the reference pipe.



The worst-case will be the unit that gives the lowest velocity in the inner tubes.
If this can be achieved with different configurations, the worst-case will be that with the highest ratio of the area of the distribution plate and the available flow area through the tubes (distribution plate, right figure).

5.2.3 Supplementary requirements for testing according to Doc 7

5.2.3.1 fully welded equipment

There is no need to perform the bacteria tightness test if a piece of equipment is fully welded and no joint exists where bacteria can enter the product contact area.

5.2.3.2 gasket with no access

Sensor: gasket in the front, but the hollow area behind (electronic) must be tested for bacteria tightness by filling the internal sensor with bacteria.

5.2.3.3 double mechanical seal

The double mechanical seal must be in operation and flushed with ambient sterile water. Soiling will be applied on the atmospheric side of the seal.