

Dizajn procesných zariadení

Hygienic Design

Prednáška

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Bratislava, november 2019

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Oblasť priemyslu

Predovšetkým farmaceutický a potravinársky priemysel.

Legislatíva

- Národné a medzinárodné normy / napr. BPE, EN 1672-2, ISO 14 159 /
- Interné firemné štandardy / audit technického riešenia /
- Nezávislé organizácie ako napr. The European Hygienic Engineering & Design Group (manufacturers, food industries, research institutes as well as public health authorities and was founded in 1989 with the aim to promote hygiene during the processing and packing of food products. EHEDG) is a consortium of equipment

Dobrý hygienický (sanitárny) návrh zabezpečuje minimalizáciu možnosti kontaminácie

- Mikroorganizmy / patogény – choroboplodné organizmy /
- Nežiaduce chemické látky / mazacie oleje, čistiace prostriedky atď. /
- Fyzických predmetov / kusy skla, kovu, plastu atď. /

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ASME BPE-2016
 (Revision of ASME BPE-2014)

Bioprocessing Equipment

EUROPEAN STANDARD
 NORME EUROPÉENNE
 EUROPÄISCHE NORM

EN 1672-2:2005+A1

March 2009

ICS 67.260

Supersedes EN 1672-2:2005

English Version

Food processing machinery - Basic concepts - Part 2: Hygiene requirements

INTERNATIONAL
 STANDARD

**ISO
 14159**

First edition
 2002-04-01

AN INTERNATIONAL STANDARD



The American Society of
 Mechanical Engineers

Safety of machinery — Hygiene requirements for the design of machinery

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Základné /všeobecné/ požiadavky pre hygienický dizajn

- Voľba vhodného materiálu
- Kvalita povrch, ktorá je v kontakte s výrobným procesom
- Dizajn neobsahuje oblasti kde môže dôjsť k zachyteniu a rastu mikroorganizmov
- Čistenie
- Preferovať nerozoberateľný spoj /zvar/. V prípade nutnosti rozoberateľnosti – vhodný návrh napr. šróbenie, prírubu, klamp.
- Zabrániť konštrukčným riešeniam s dierami a uzavretými otvormi.
- Zabrániť konštrukčným riešeniam s kde sa kumuluje špina a nečistoty.



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Základné /všeobecné/ požiadavky pre hygienický dizajn

- Zabrániť tvorbe mŕtvych zón kde by sa mohol zachytiť vyrábaný produkt.
- Eliminácia ostrých hrán
- Samospád a čistiteľnosť plôch / prístup/
- Zabrániť tvorbe kondenzátov / vodná para/, ktoré môžu kontaminovať produkt.



Rádius

Vyspádovanie

Čistiteľnosť

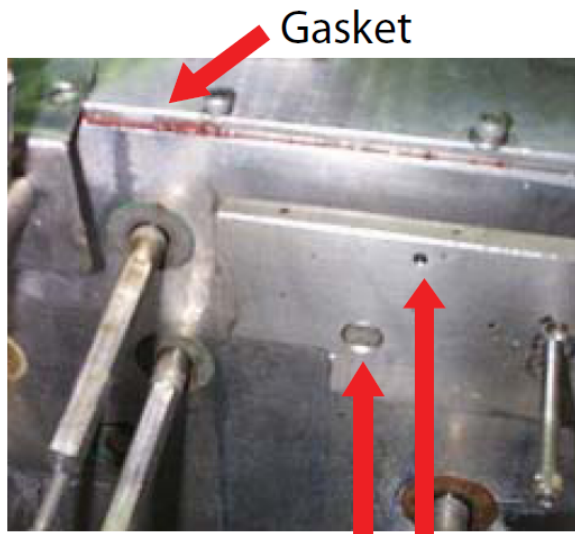
Prístup

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Základné /všeobecné/ požiadavky pre hygienický dizajn

- Všetky dôležité plochy musia byť prístupné pre vizuálnu inšpekciu a manuálne čistenie .
- Armatúry, meracie členy vhodné pre hygienický dizajn – dôležitá je aj inštalácia
- Ložiská, prevodovky, motory atď. mimo pracovný priestor. / zamedziť možnosti kontaminácie mazadlom /
- Ovládacie panel zariadení v hygienickom prevedení – čistiteľnosť.

From This  To This



Gasket

Non-Functioning Openings



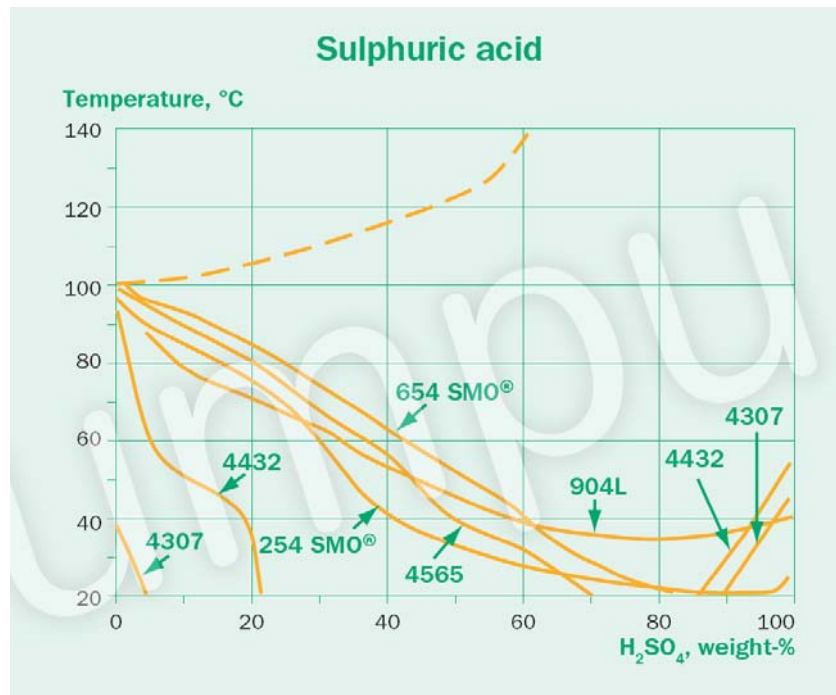
Continuous Welds



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Výber vhodného materiálu

- Uhlíková oceľ- všeobecne nevhodné / korózia/. Náter /obsahujú Zn, Pb, Cd/, galvanizované /časovo nestabilné/
- Nerezové ocele – najpoužívanejšie. / AISI 304, AISI 304L, AISI 316 /. Je nutné preveriť koróznú odolnosť voči niektorých látkam / napr. NaClO chlórnan sodný , H₂SO₄ /, odolnosť pri vysokých teplotách a zaťaženiach .



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Výber vhodného materiálu

- Meď /Cu/ - vo všeobecne vhodný materiál pre potravinársky priemysel. Častý v liehovarníctve a vo výrobe piva. Organoleptický efekt /vnímateľný zmyslami /- pozitívny aj negatívny. Nevhodný pre kyslé a slané látky.
- Hliník . / hlavne obalové fólie /.
- Ostatné neželezné kovy sú zväčša zakázané / olovo, cadmium, ortuť ... /. Obsahujú ich hlavne obslužné ele. zariadenia.



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Výber vhodného materiálu

- Plasty - hlavne oblasť použitia je na tesniace a trecie plochu / ložiská, tesnenia / vo všeobecne vhodný materiál pre potravinársky priemysel. Pri použití plastov v potravinárstve je dôležité poznať hlavne teplotný limit / mali by vydržať minimálne 121 °C – sterilizácia / a mali by spĺňať ostatné náležitosti / nepórovitý, pevnosť, odolnosť voči oteru, atď. / .
- Guma / hlavne tesnenia /.



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Výber vhodného materiálu

TABLE 26.1 Resistance Characteristics of Different Rubber Materials (Plett and Graßhoff, 2006)

Contact Medium	Natural Rubber	Acrylonitrile Butadiene Rubber	Silicone Rubber	Ethylene Propylene Diene Monomer	Neoprene Chloroprene	Fluor Elastomer
Temperature range	-60 to 80°C	-35 to 120°C	-70 to 200°C	-60 to 135°C	-40 to 230°C	-30 to 180°C
Hot water (120°C)	-	+++	+++	+++	+++	+++
Hot water (145°C)	-	-	+++	+++	-	+++
NaOH (5%; 90°C)	++	+++	+++	+++	++	+++
NaOH (5%; 140°C)	-	-	-	++	+	+++
H ₃ PO ₄ (2%; 90°C)	-	+++	+++	+++	+++	+++
H ₃ PO ₄ (2%; 140°C)	-	-	-	++	-	+++
HNO ₃ (1%; 70°C)	--	-	++	++	++	++

+++ = unlimited resistance; ++ = limited resistance; + = only short contact; - = non-resistant; -- = absolutely non-resistant.



Teflón /PTFE/ Polytetrafluóretylén

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Výber vhodného materiálu

- Drevo - nepoužíva sa. / potravinárstvo napr. sudy /
- Sklo. Množstvo výhod, hlavná nevýhoda je krehkosť. Stále v miestach kde je potrebná vizuálna inšpekcia deja. Prípadne nahradený priehľadným plastom napr. PERSPEX /prepúšťa viac svetla /
- Keramika. Nevýhoda krehkosť a pórozita. /napr. filtre, membrány /



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Kvalita povrchu

-Kvalita povrchu je veľmi dôležitým parametrom. Vo všeobecnosti by mala byť menšia ako $0,4 \mu\text{m}$ pre farmaceutický priemysel, pre potravinárstvo je prijateľná hodnota menšia ako $0,8 \mu\text{m}$. Materiál by nemal obsahovať žiadne dutiny, trhliny aby nedochádzalo k tvorbe úsad.



Figure 5:10. Hot rolled 1D/No. 1 finish surface.



Figure 5:11. Cold rolled 2B/2B surface.



Figure 5:12. Cold rolled 2E/2D surface.

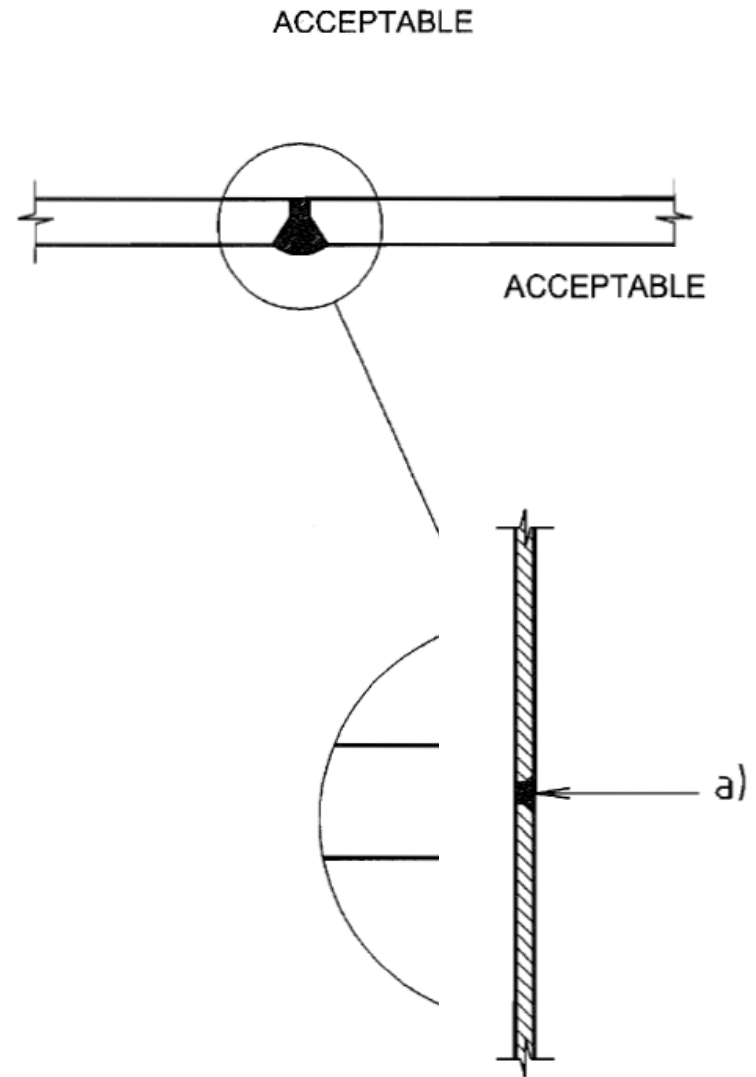
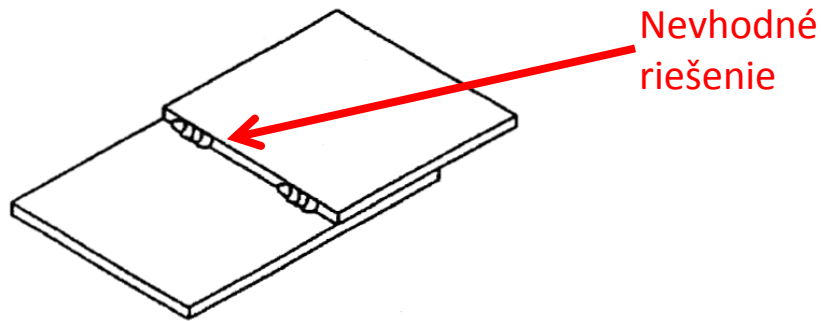
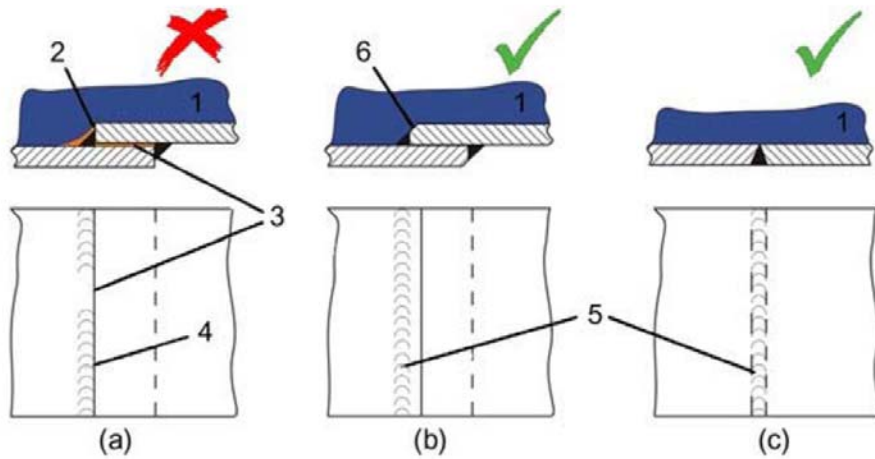


Figure 5:13. Cold rolled 2R/BA surface.

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Spoje

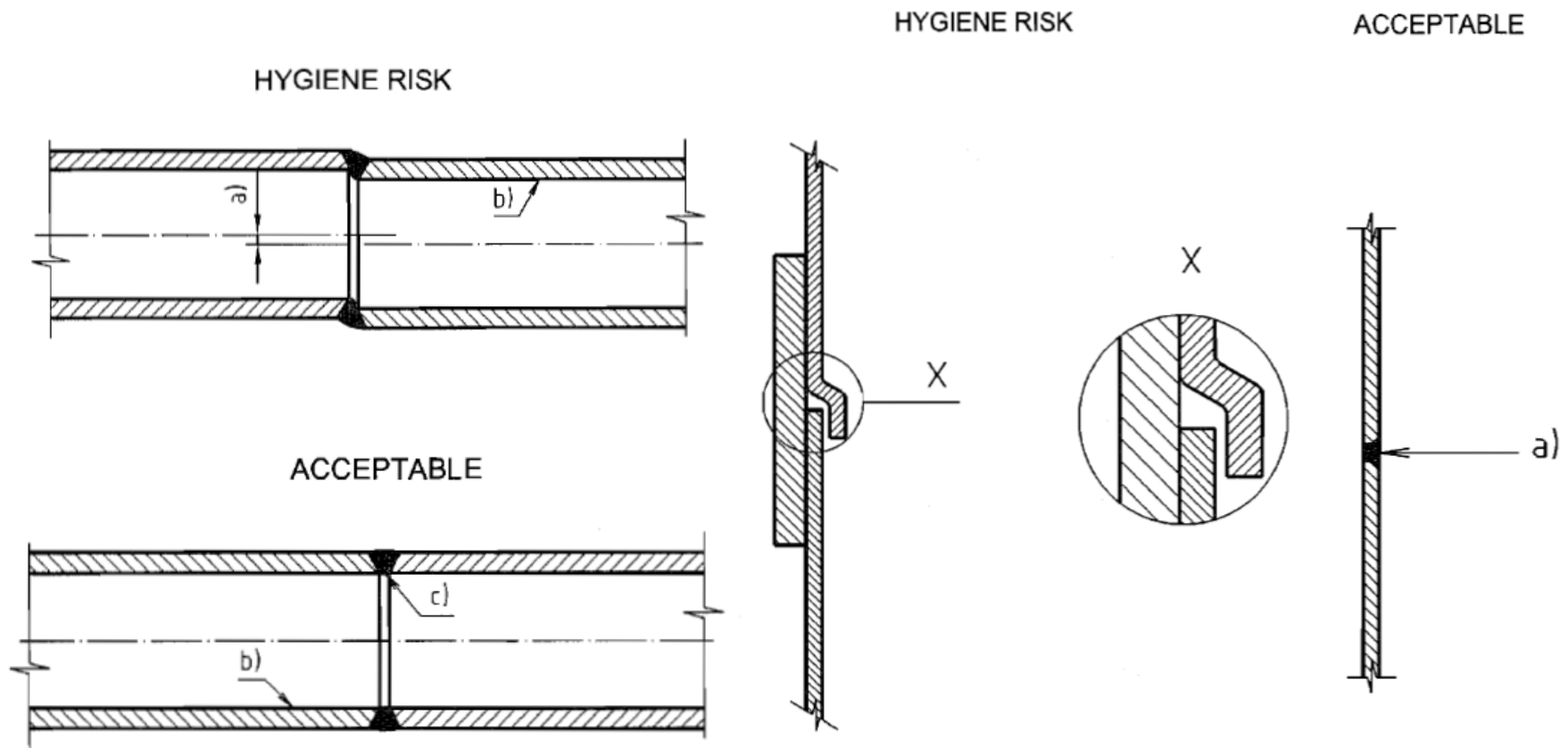
- rozoberateľné /nerozoberateľné



Hygienic Design

Spoje

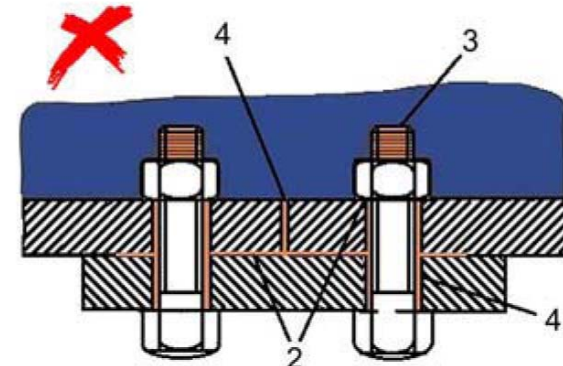
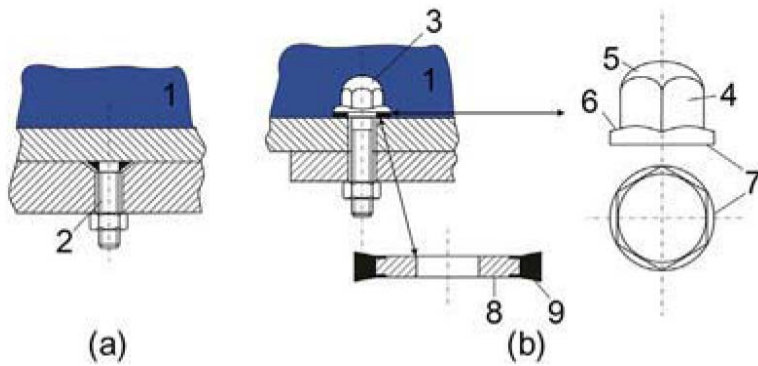
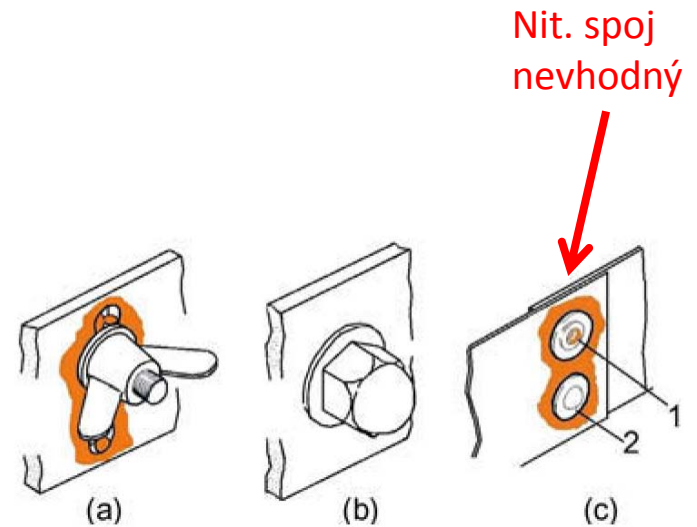
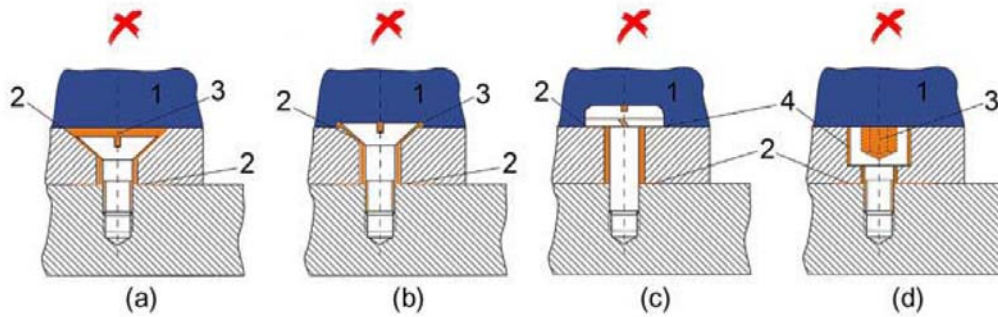
- rozoberateľné /nerozoberateľné



Hygienic Design

Spoje

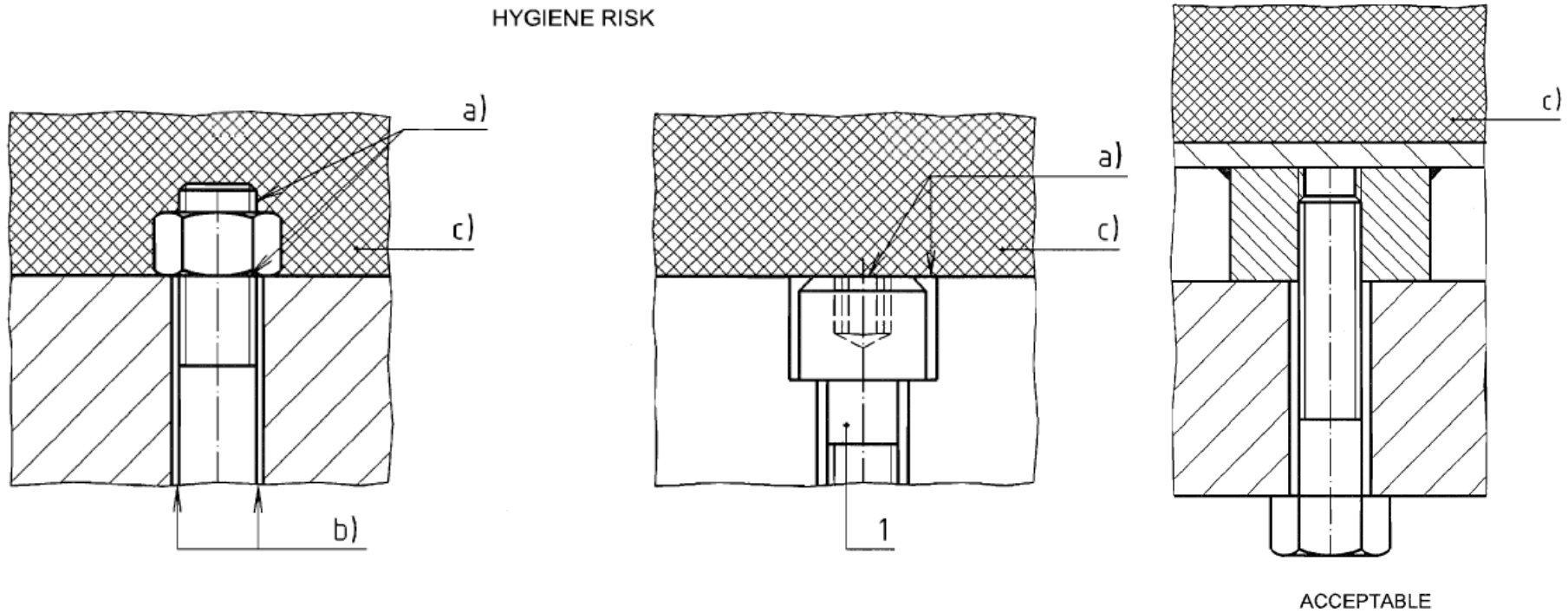
- rozoberateľné /nerozoberateľné



Hygienic Design

Spoje

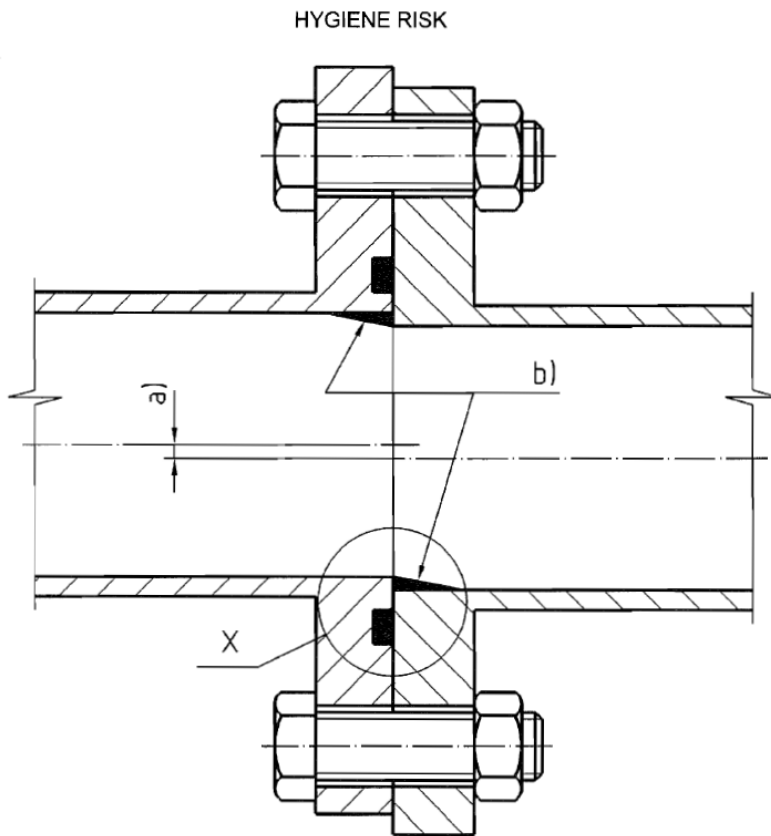
- rozoberateľné /nerozoberateľné



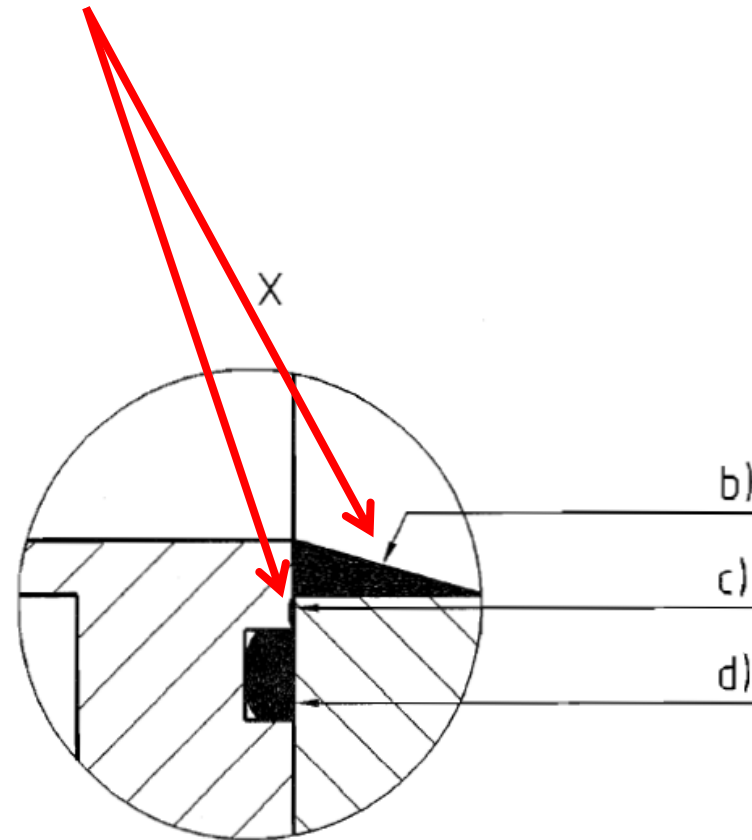
Hygienic Design

Spoje

- rozoberateľné /nerozoberateľné



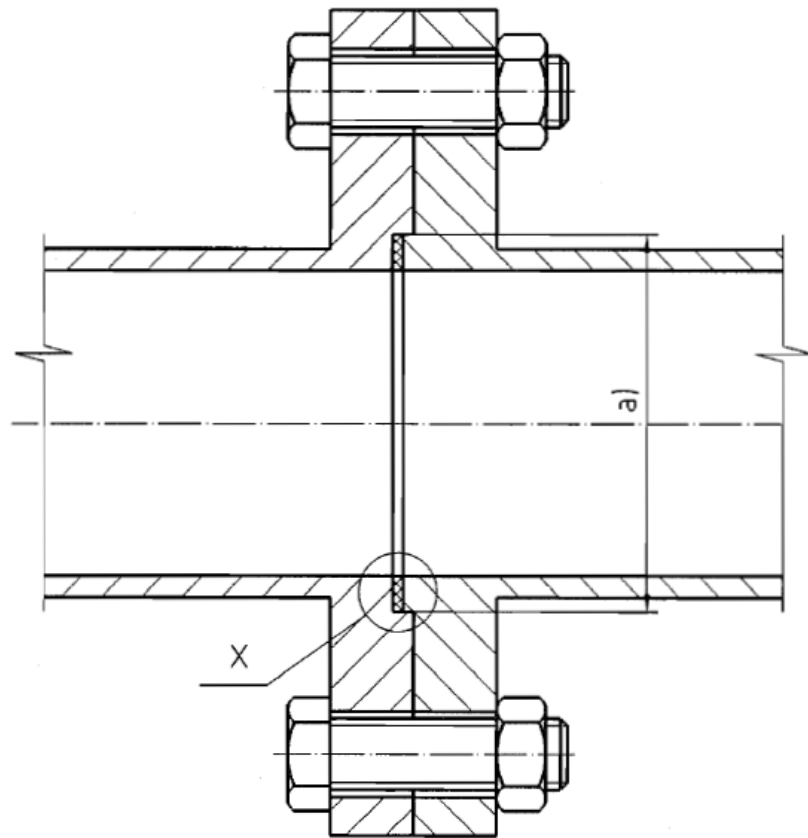
Nevhodné riešenie



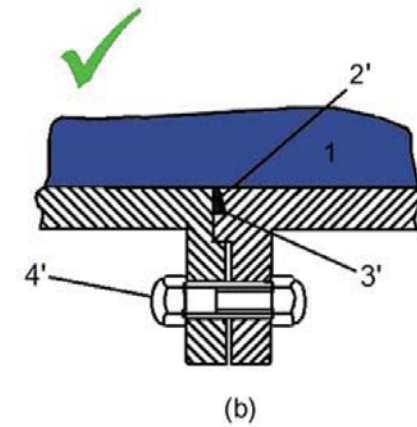
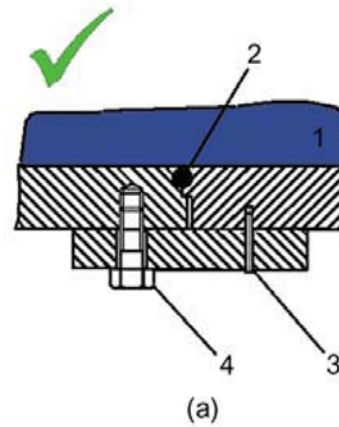
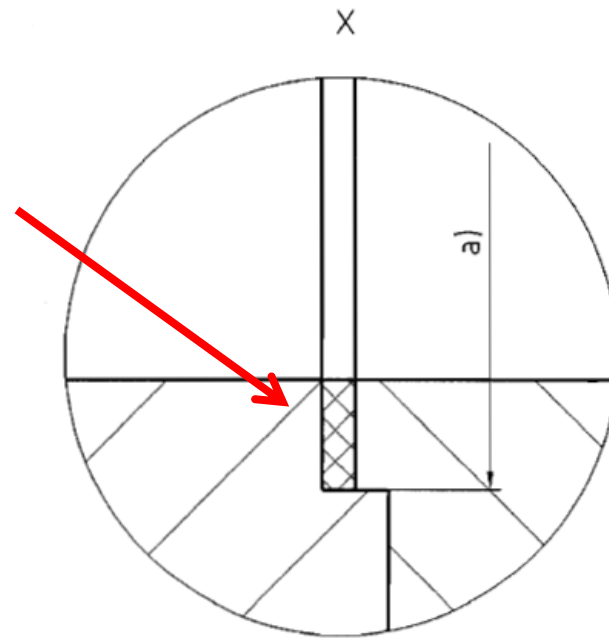
Hygienic Design

Spoje

- rozoberateľné /nerozoberateľné



Vhodné riešenie



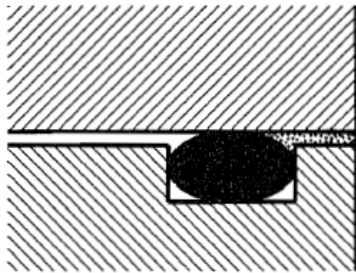
Hygienic Design

Spoje

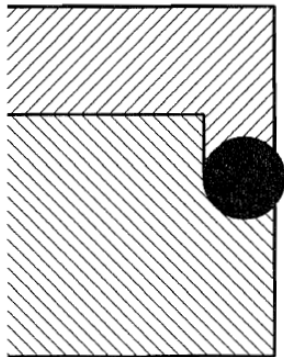
- rozoberateľné /nerozoberateľné

STATIC SEALS

O-rings



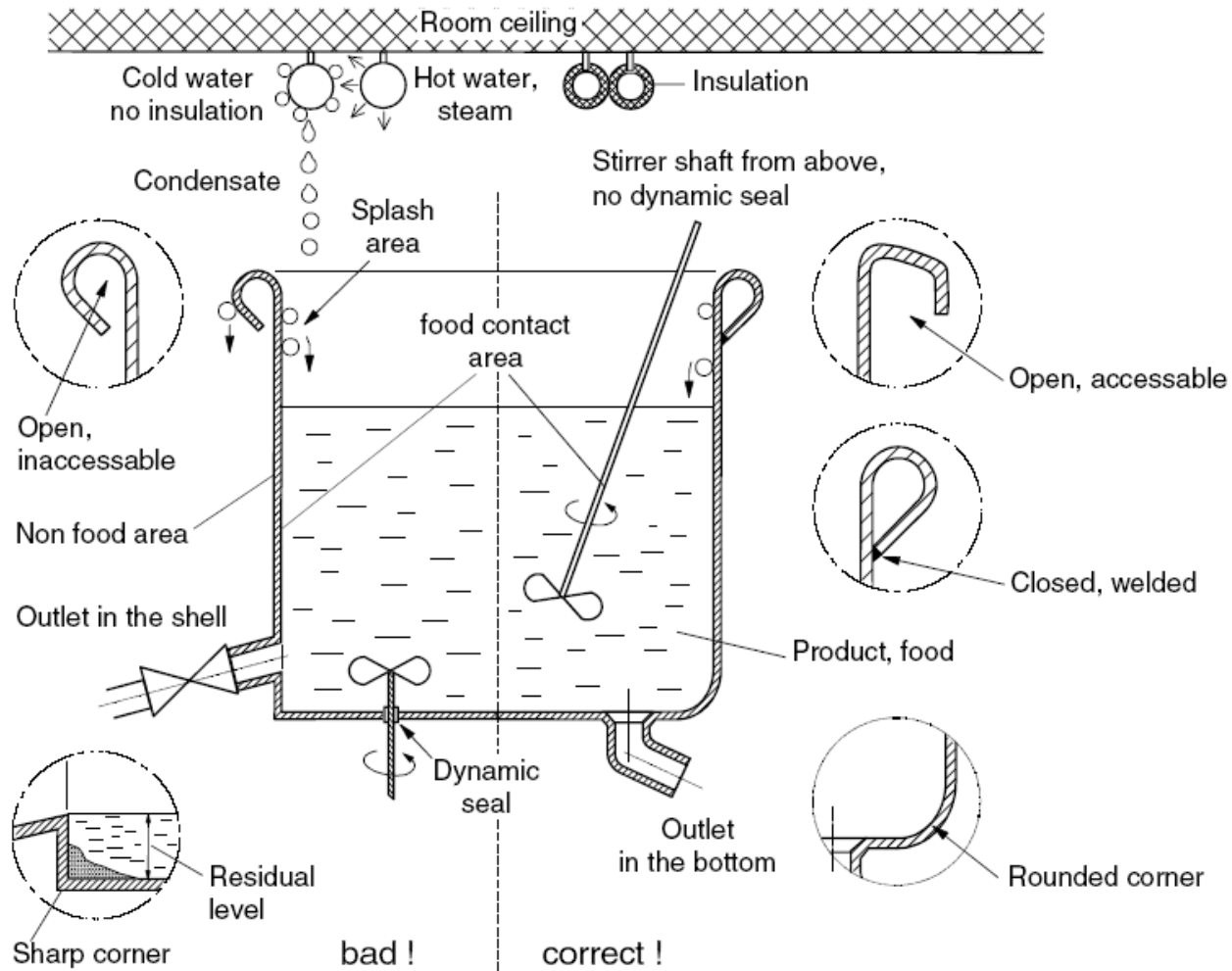
O-ring seals usually require a narrow gap which is very difficult to clean.



As a rule the seal should be as close to food product as possible to provide acceptable cleanability.

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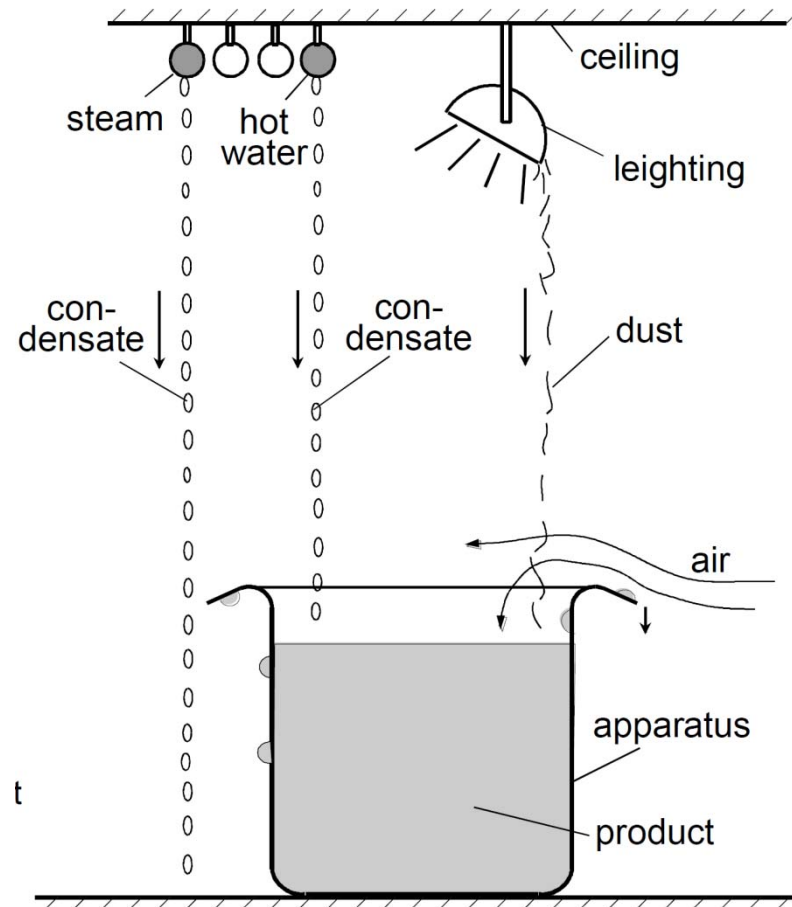
Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

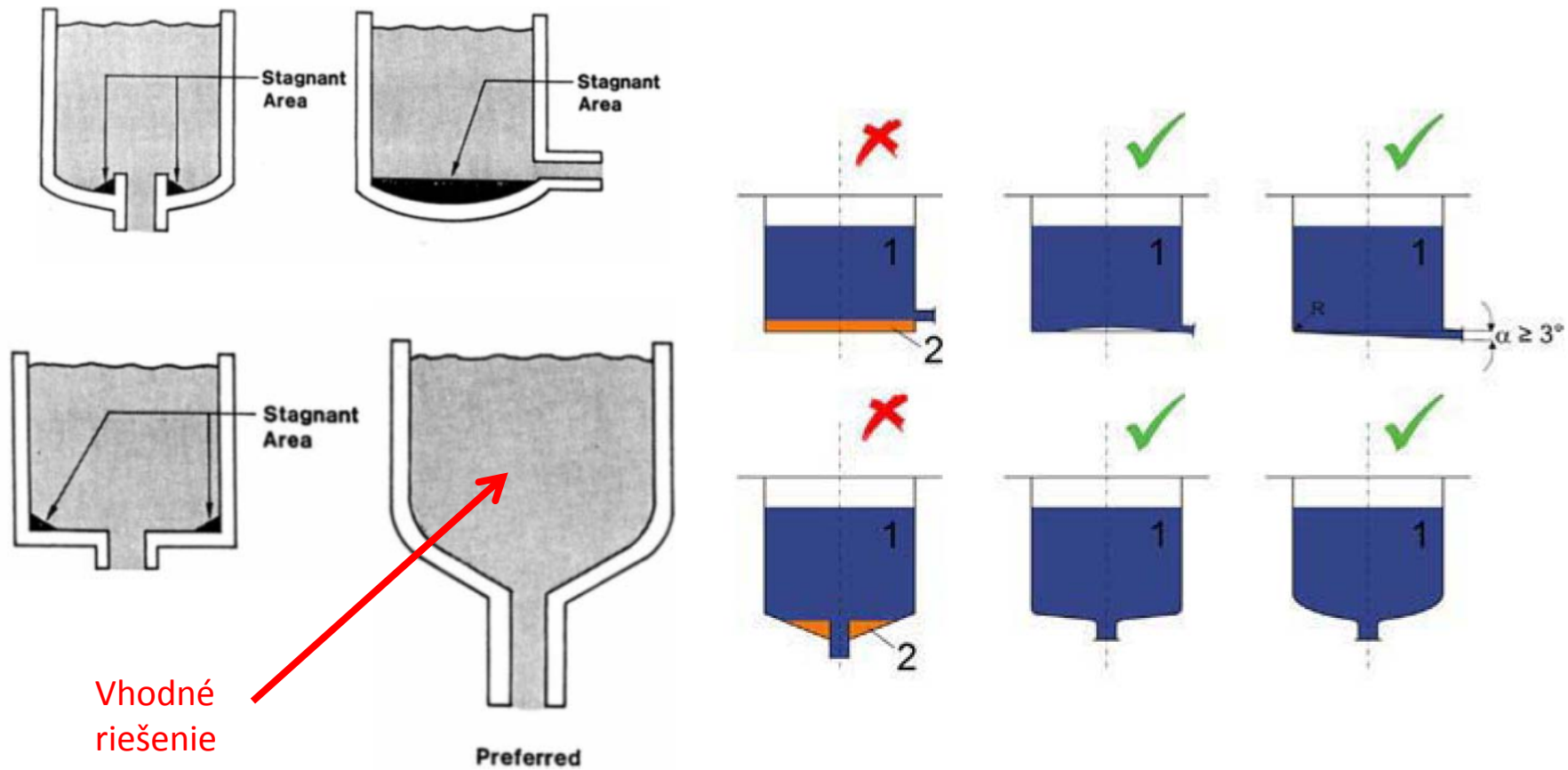
Konštrukcia nádob, zásobníkov, prevozných kontajnerov

According EHEDG



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Konštrukcia nádob, zásobníkov, prevozných kontajnerov

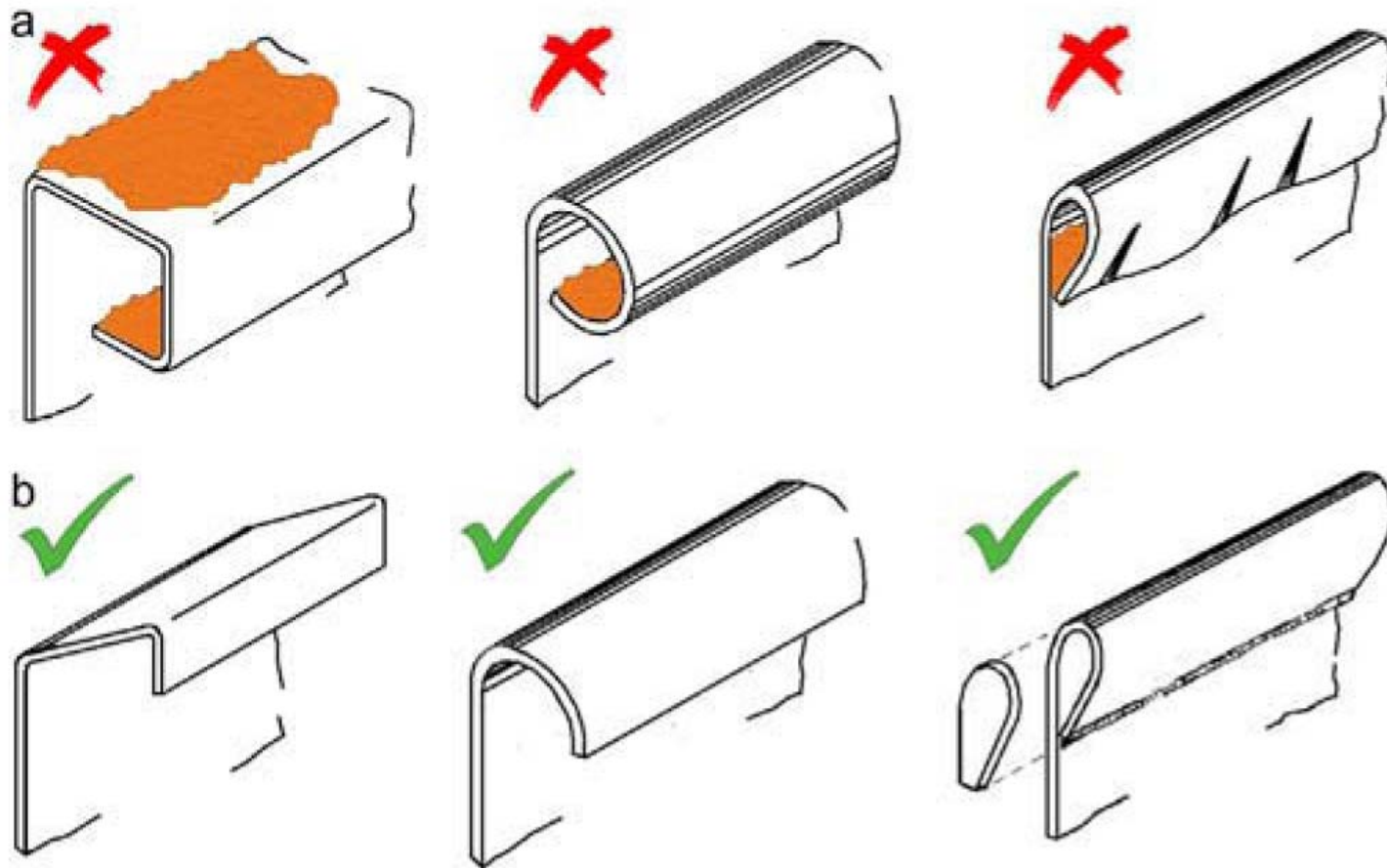


Vhodné
riešenie

Preferred

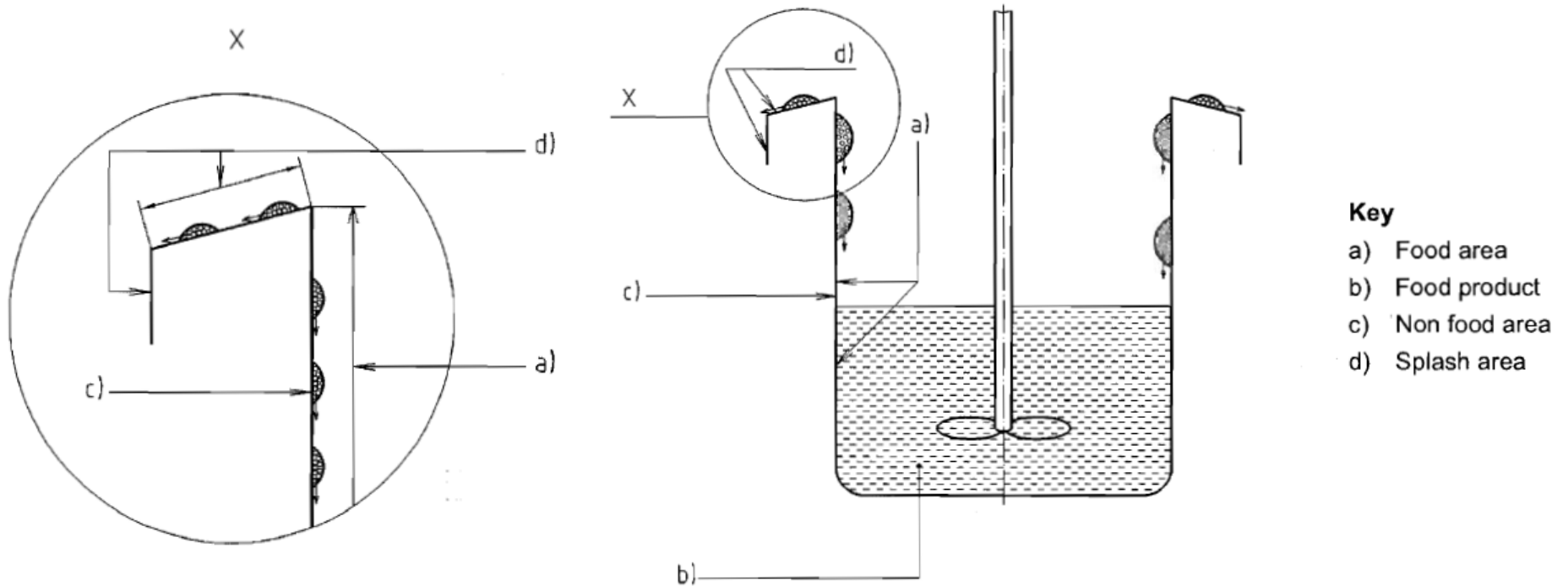
Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



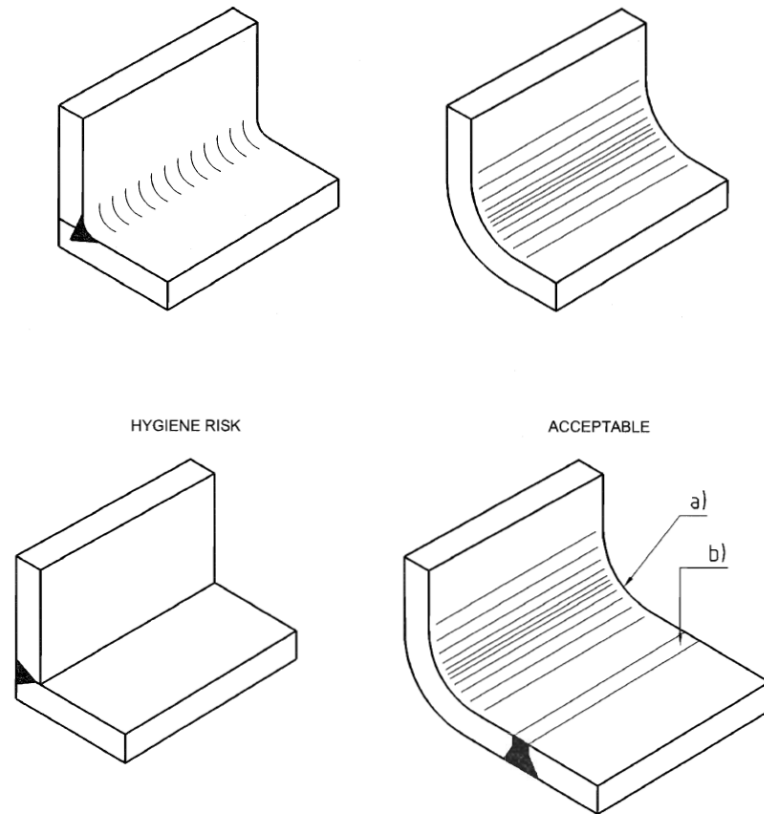
Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Key

a) $R_{\min} = 3 \text{ mm}$

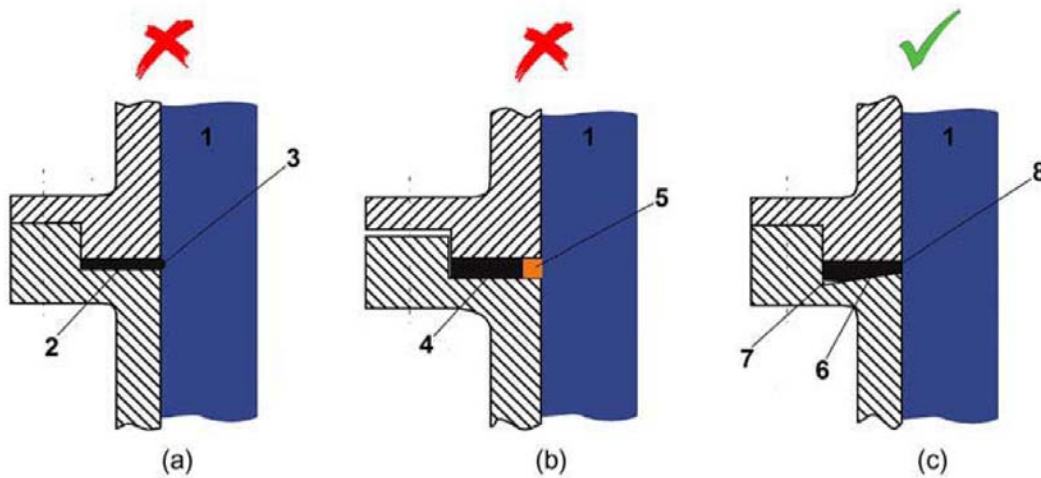
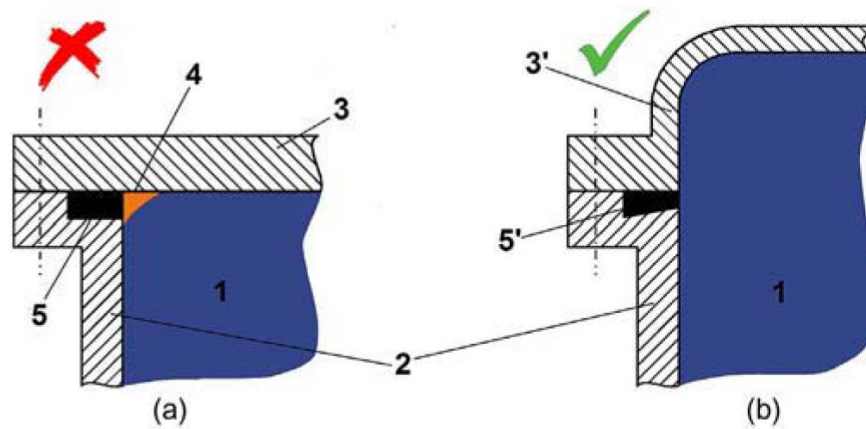
b) Smooth surface

Cleanability improves up to $R = 20 \text{ mm}$

Figure A.14 — Internal angles and corners

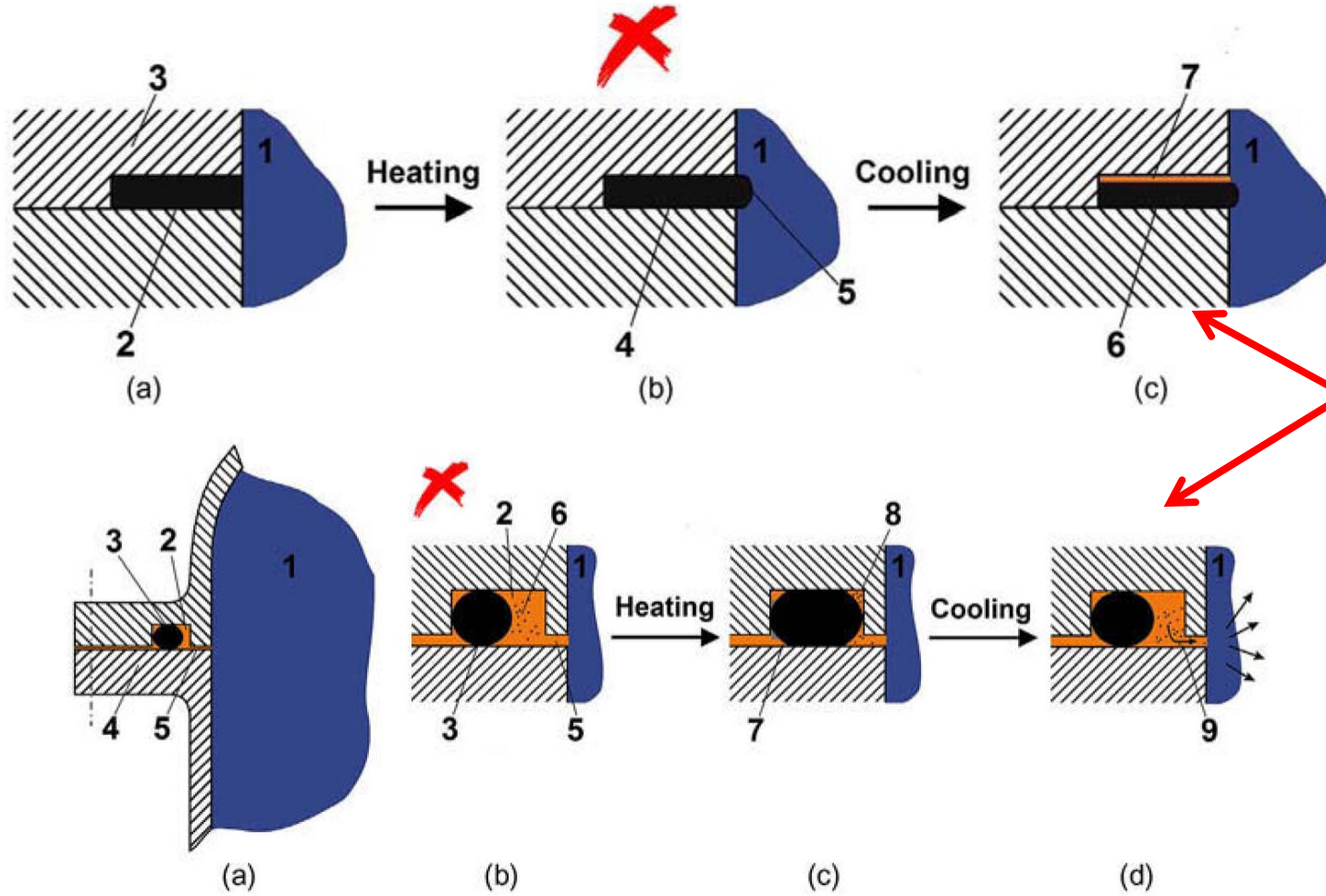
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Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov

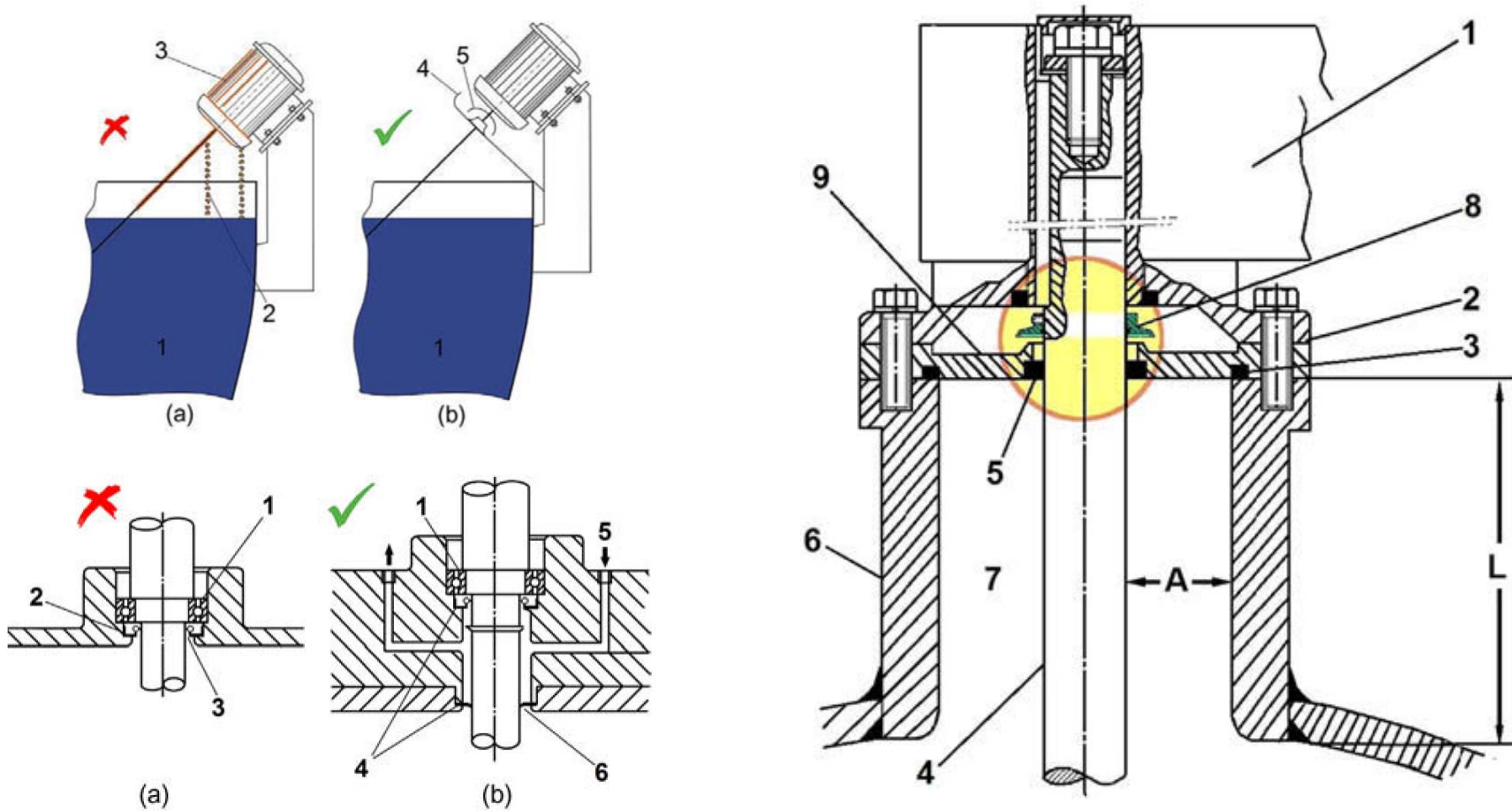


Rozdielna
 tepelná
 rozťažnosť :

- SS
- 16.E-06 1/°C
- PTFE
- 100.E-06 1/°C

Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov

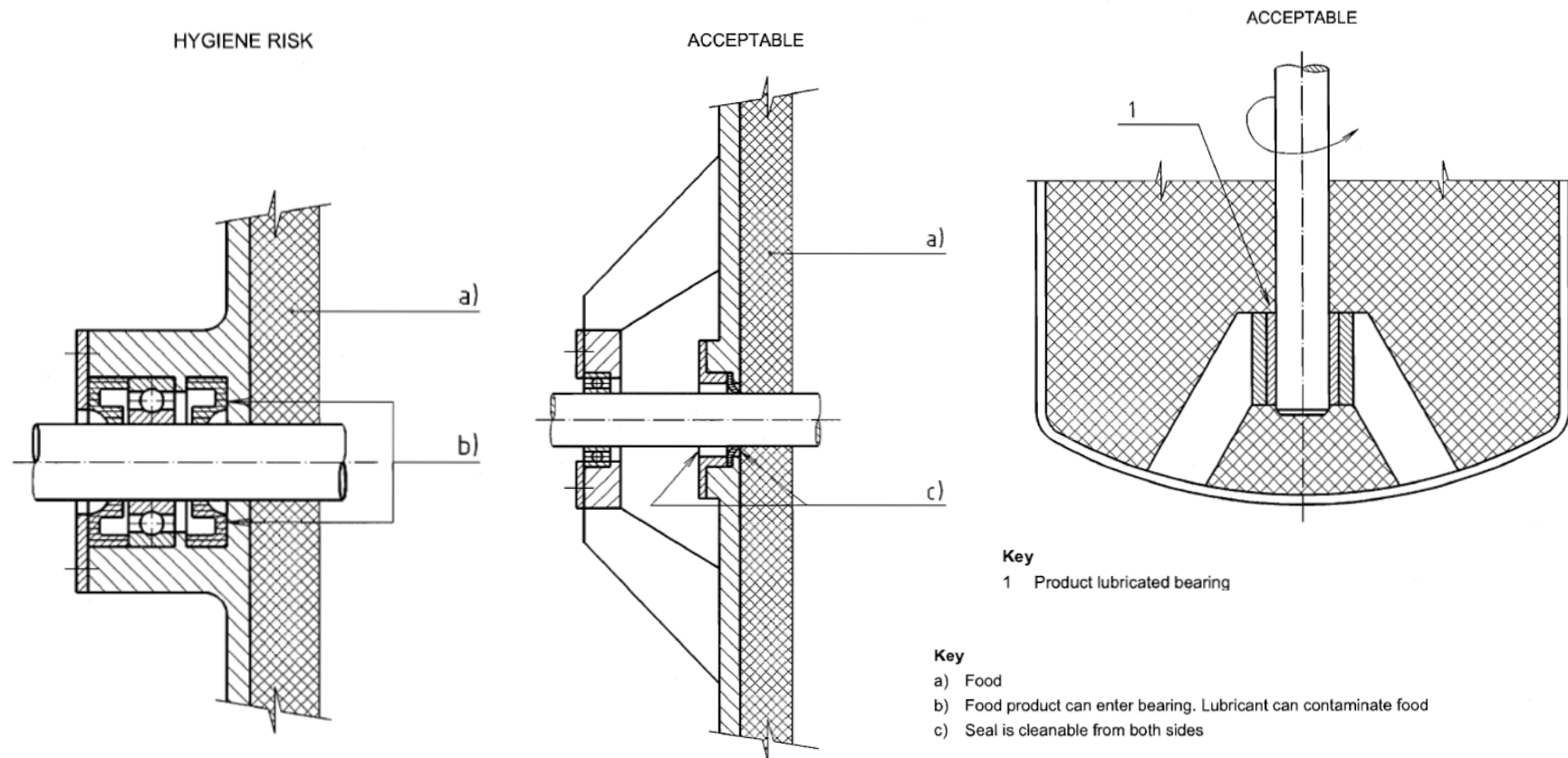
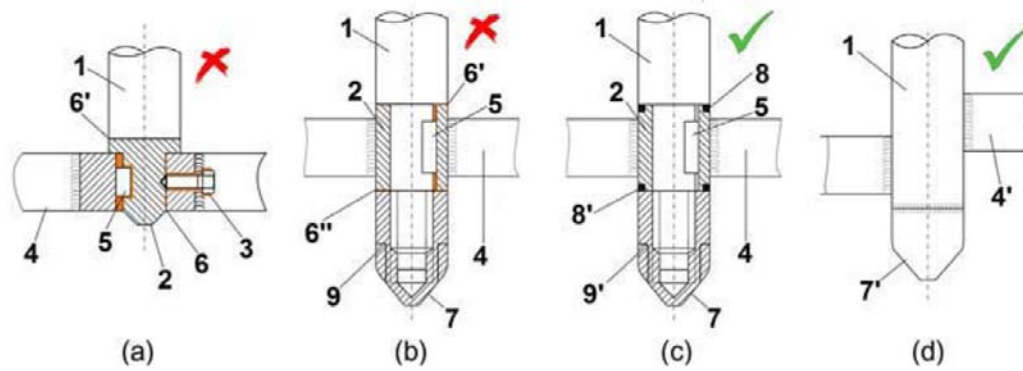


Figure A.17 — Bearing and shaft entry point

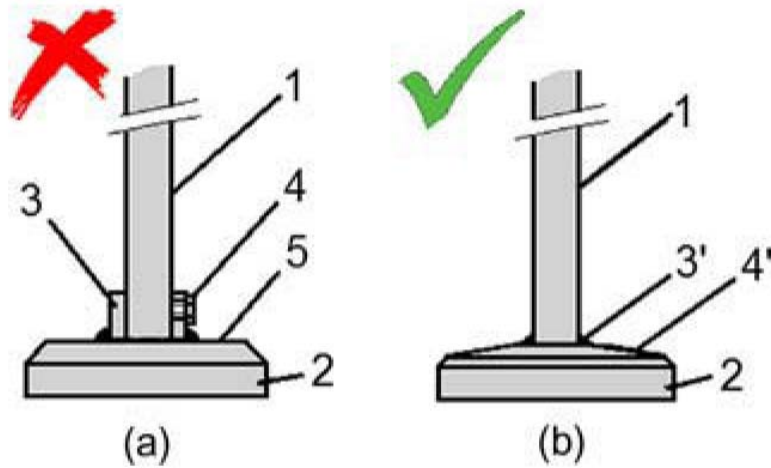
Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

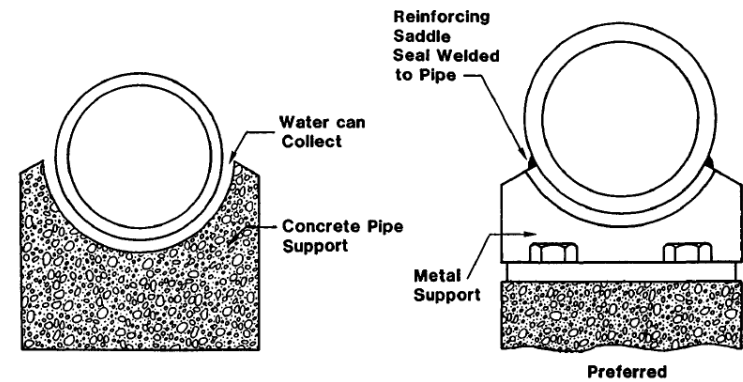
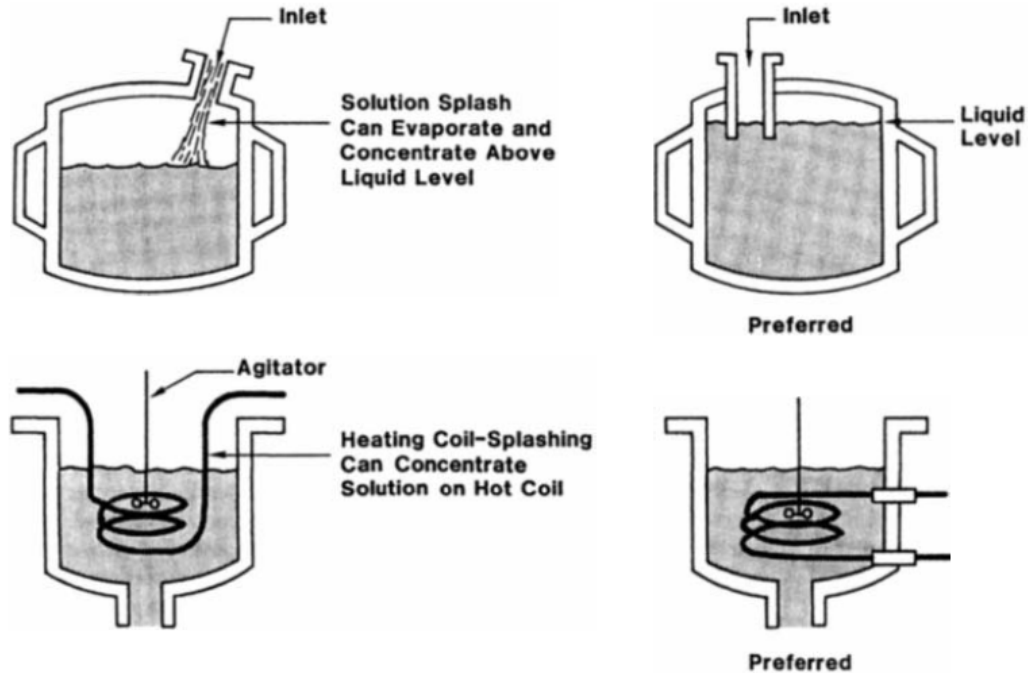
Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

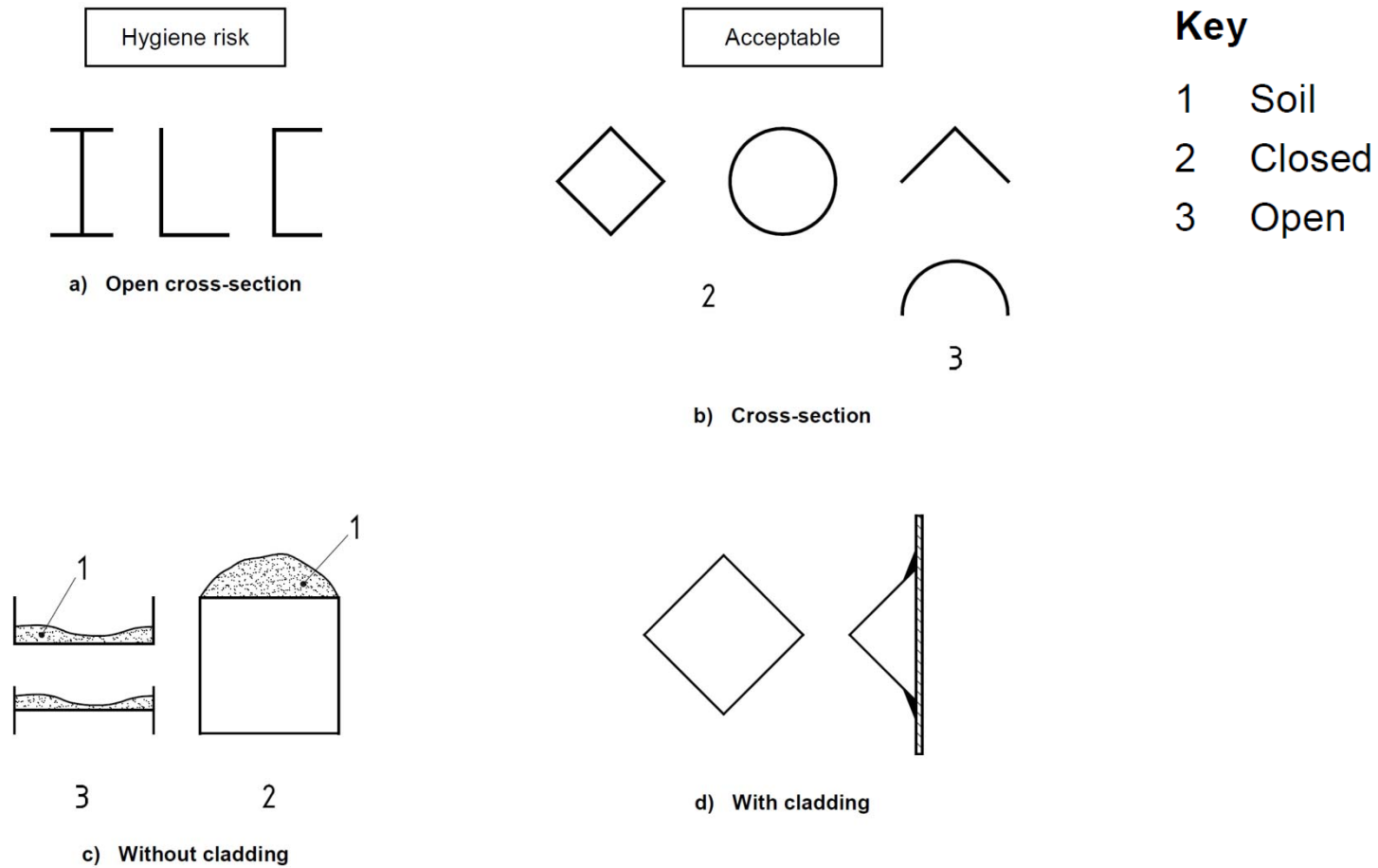
Konštrukcia nádob, zásobníkov, prevozných kontajnerov

PREVENT SOLUTIONS FROM EVAPORATING AND CONCENTRATING



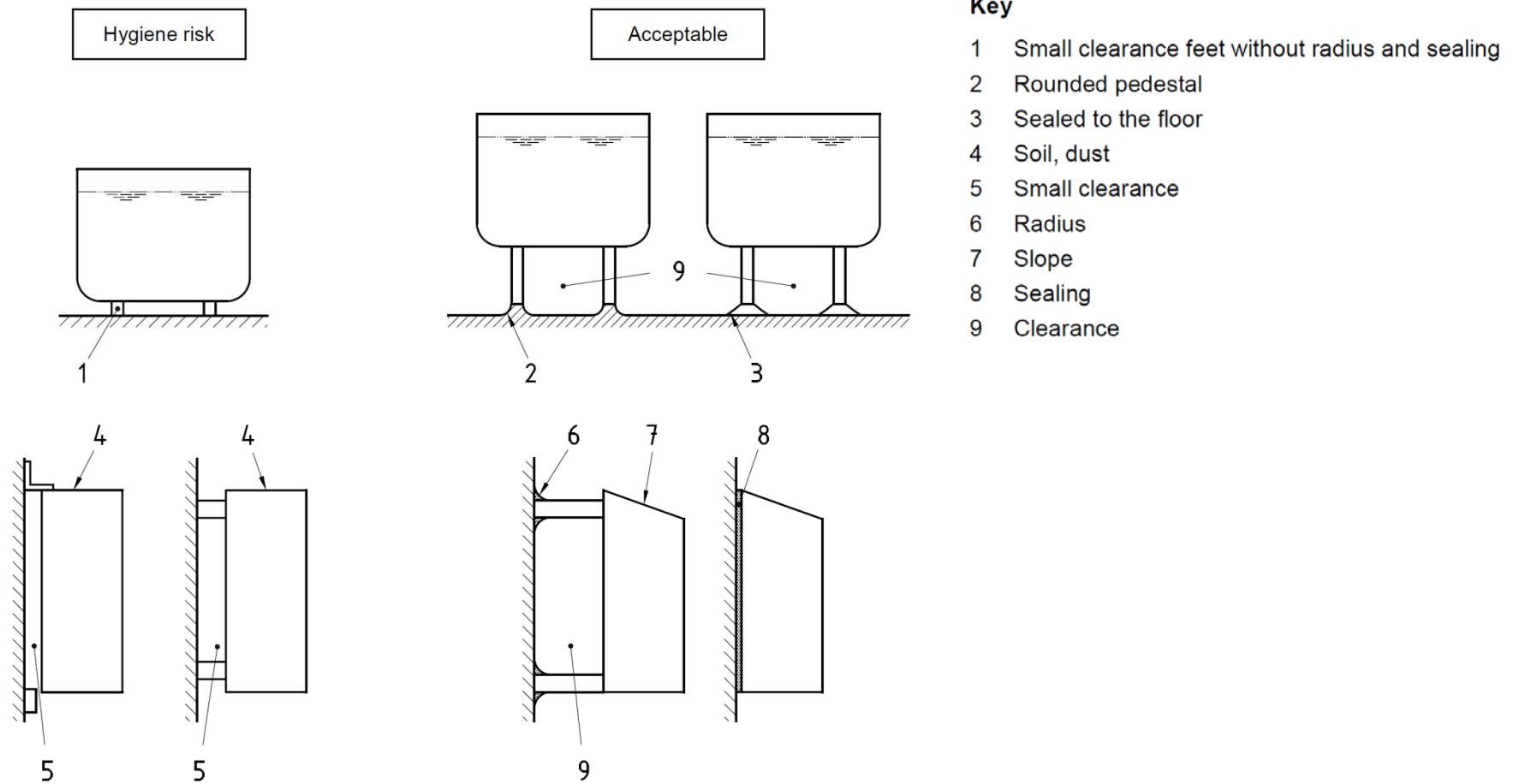
Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

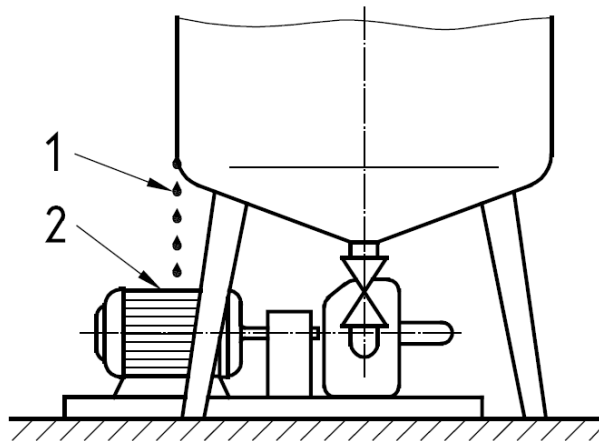
Konštrukcia nádob, zásobníkov, prevozných kontajnerov



Hygienic Design

Konštrukcia nádob, zásobníkov, prevozných kontajnerov

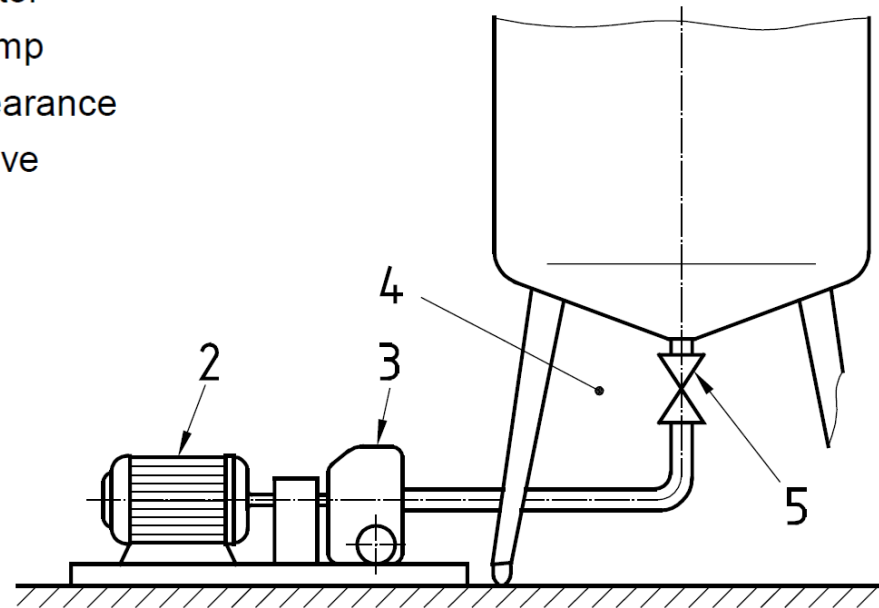
Hygiene risk



Key

- 1 Condensate
- 2 Motor
- 3 Pump
- 4 Clearance
- 5 Valve

Acceptable



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Potrúbné systémy

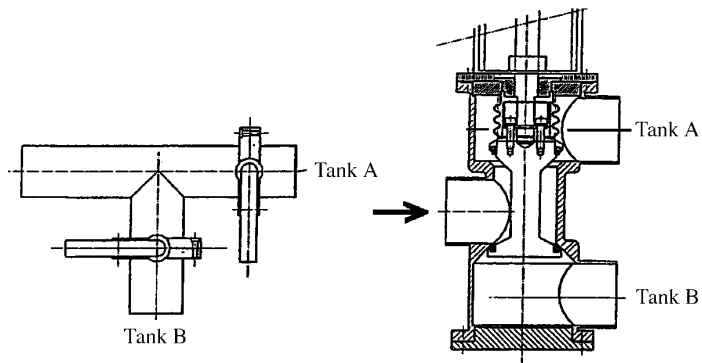


Hygienické prevedenie

- potrubia
- rozoberateľné spoje
- armatúry
- MaR
- zariadenia

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Potrúbné systémy - Armatúry



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Potravné systémy - Armatúry



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Potrúbné systémy - Armatúry

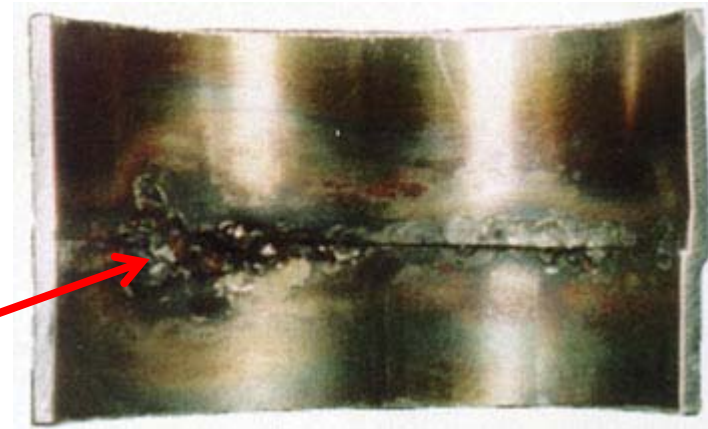


Hygienic Design

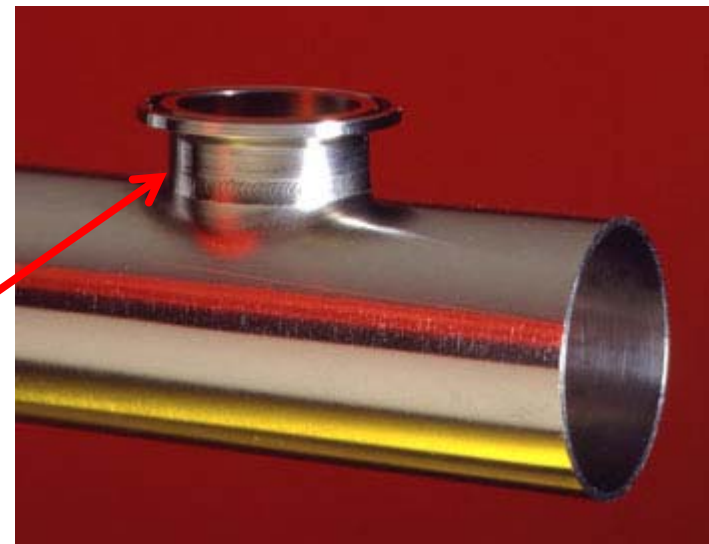
Potrubné systémy



Rúrka znútra,
 manuálne
 zváranie



Orbitálne
 zváranie



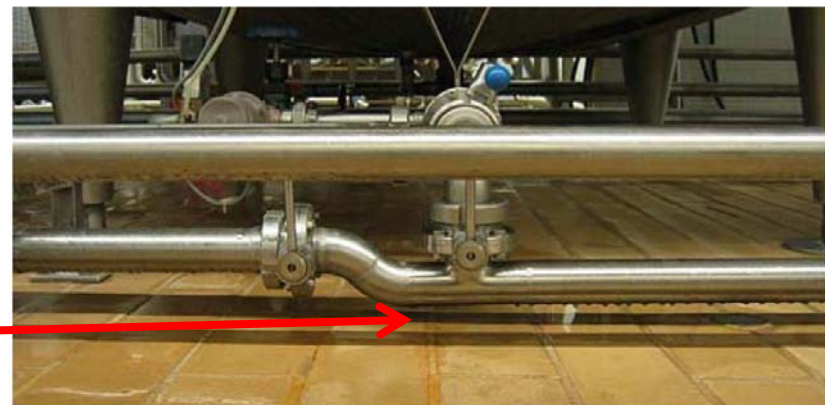
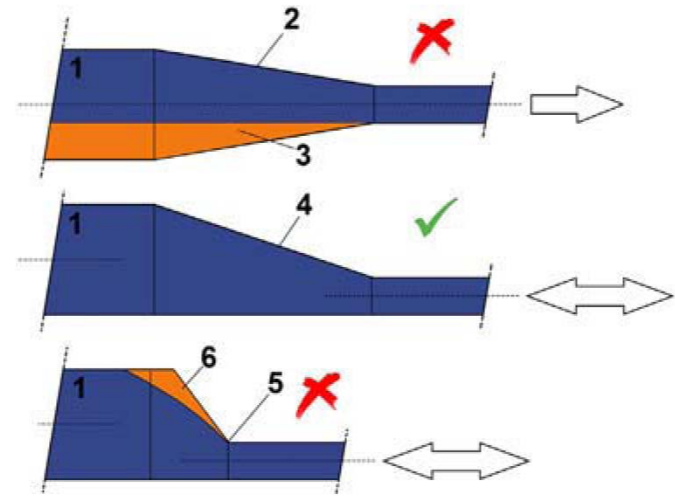
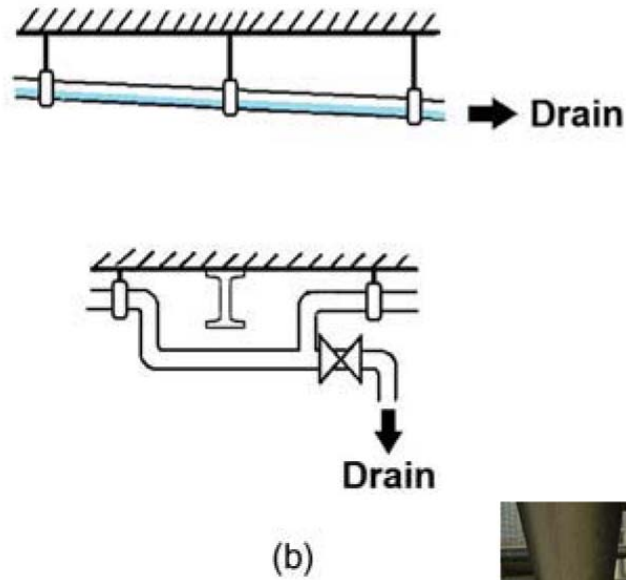
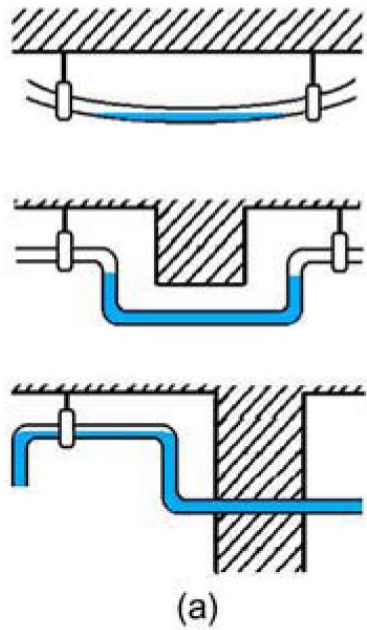
Hygienic Design

Potrúbné systémy



Hygienic Design

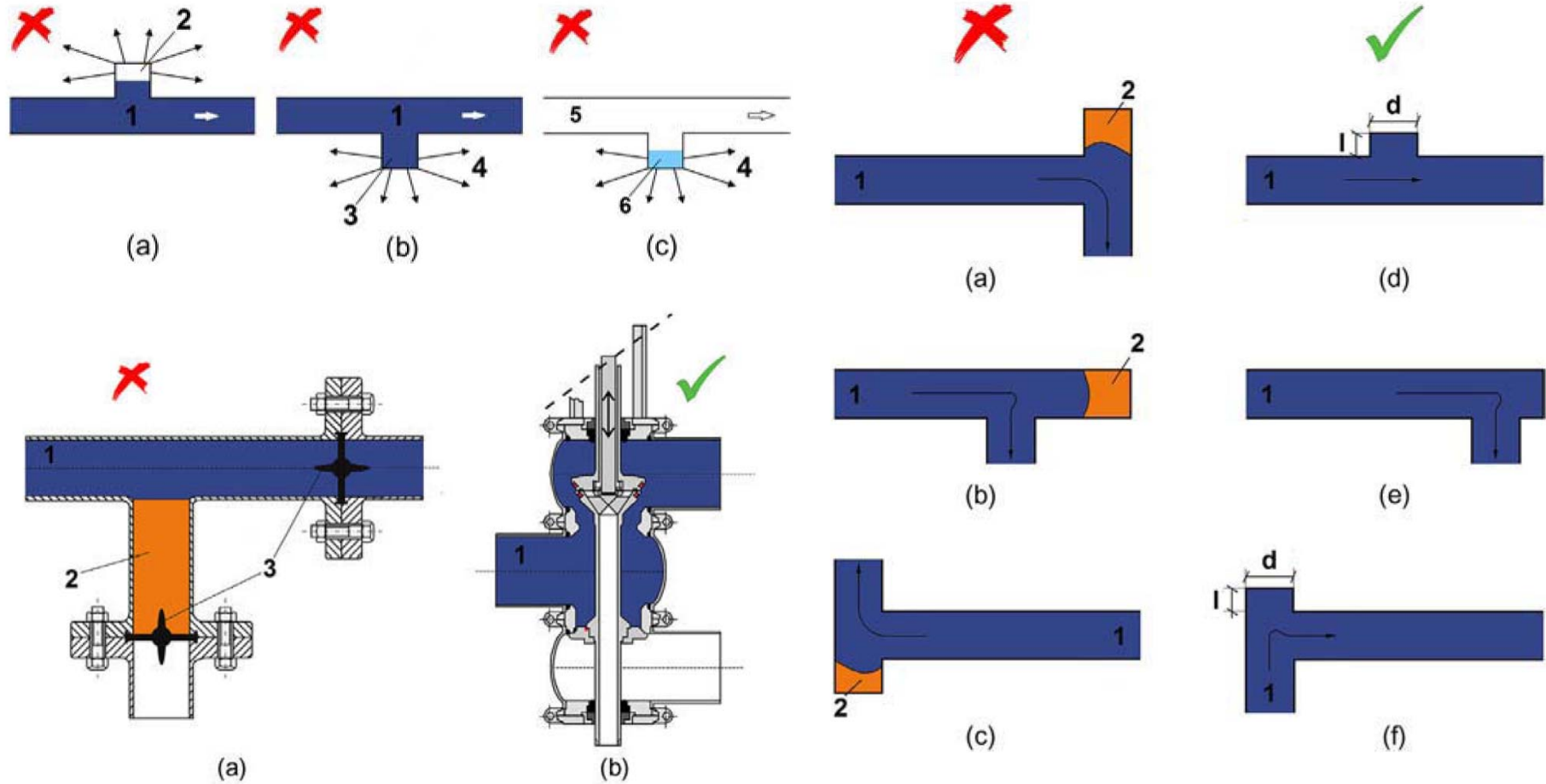
Potrubné systémy



Nedá sa odkaliť
/vypustiť /

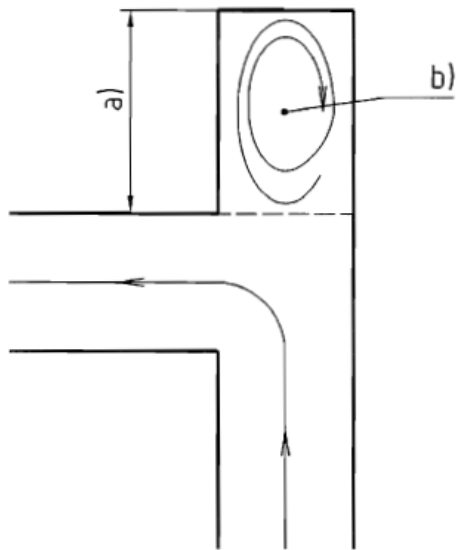
Hygienic Design

Potrúbné systémy

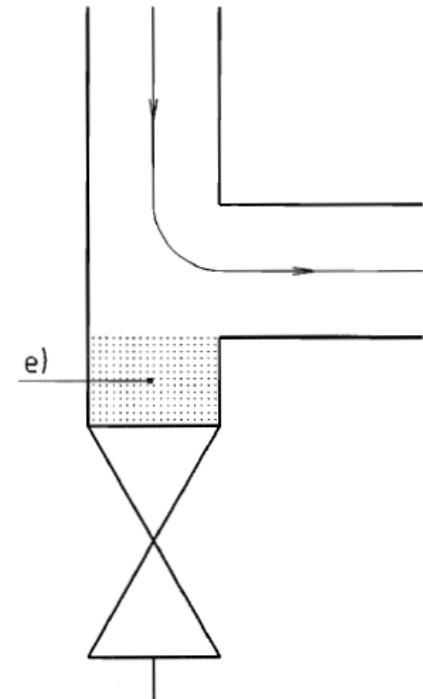
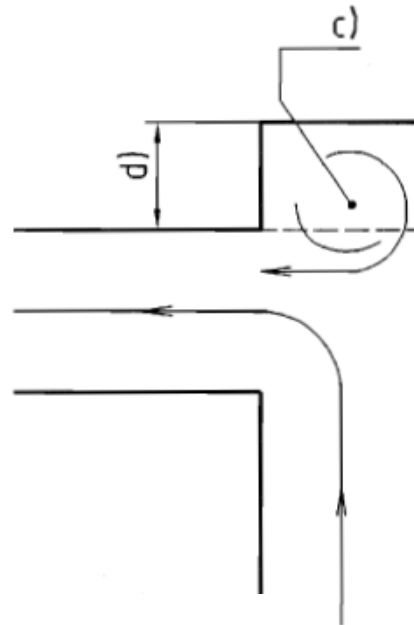


Hygienic Design

Potravné systémy



ONLY ACCEPTABLE IF UNAVOIDABLE



NOTE Acceptable length of deadleg mainly depends on viscosity and flow velocity and direction of flow.

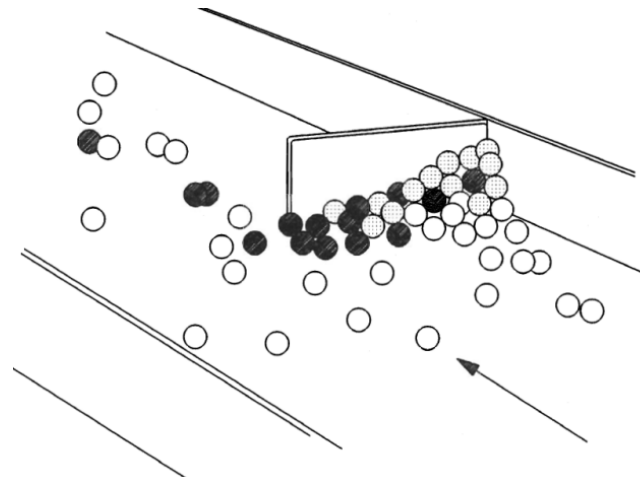
Key

- a) Too long
- b) Dead space insufficient exchange with mainflow
- c) Sufficient exchange with main flow
- d) Short
- e) Dead space can be drained

Figure A.15 — Dead space

Hygienic Design

Potravné systémy



In-line measuring nozzle

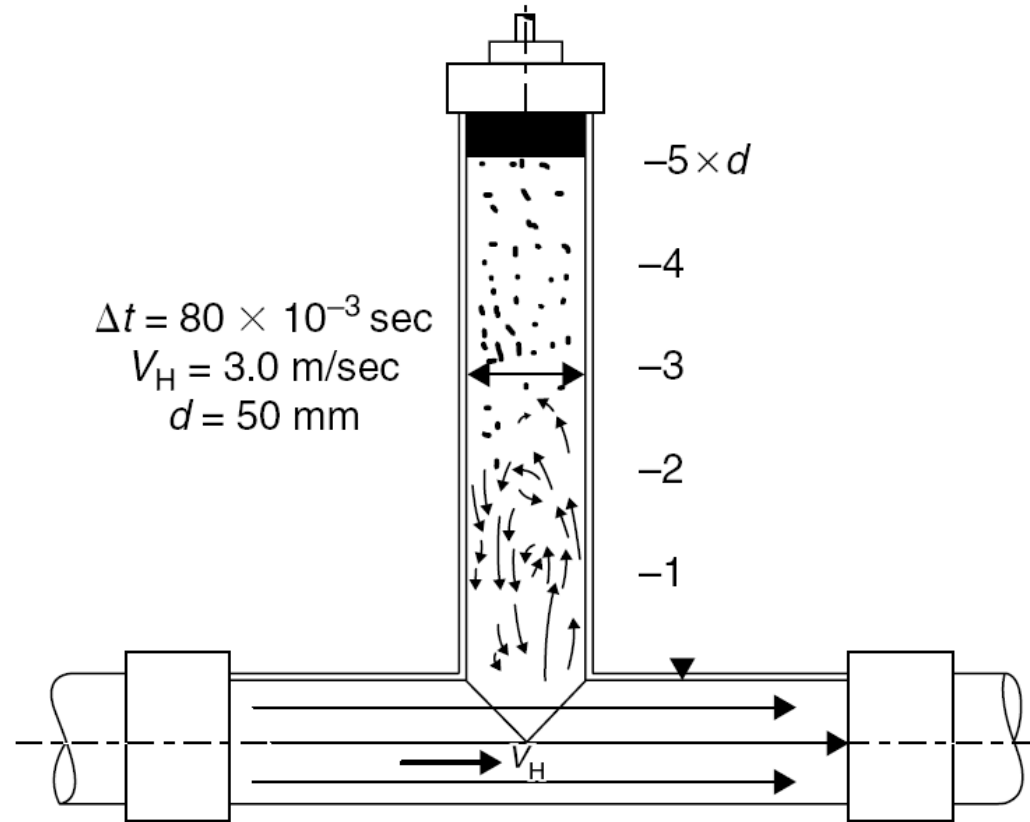
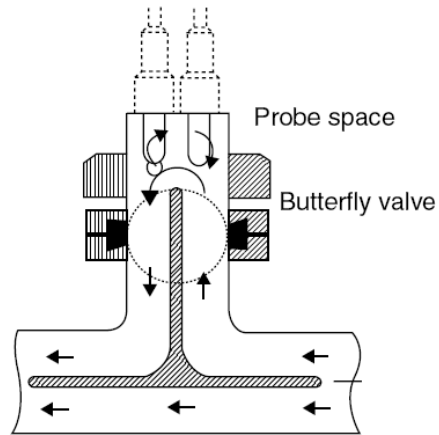
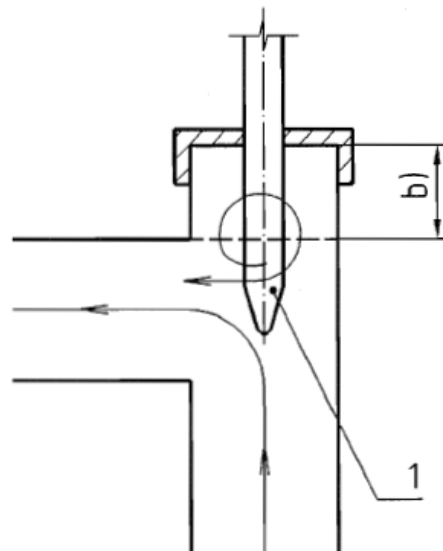
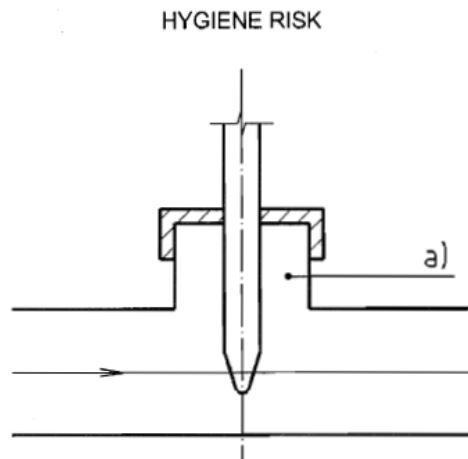


FIGURE 14.11 Fluid motion in a branched pipe. Marking the migration of particles which were photographed by a high speed cine camera within 80 msec. Frequency 500 frames/sec. (From Graßhoff, A. 1980. *Kieler Milchwirtschaftliche Forschungsberichte* 32: 273. With permission.)

Hygienic Design

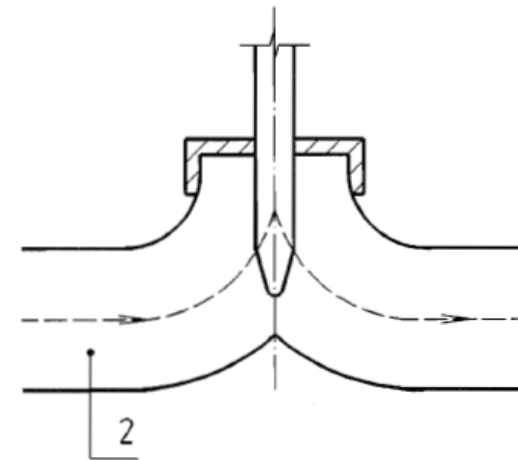
Potrúbné systémy



Key

- a) Dead space, air trap and condensation
- b) Short

ACCEPTABLE

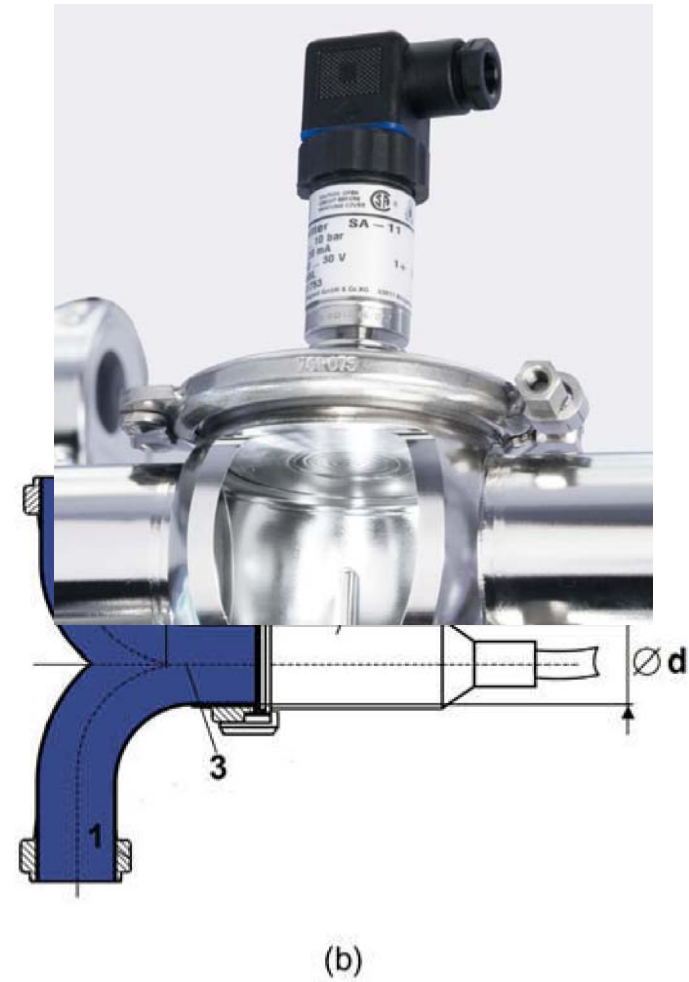
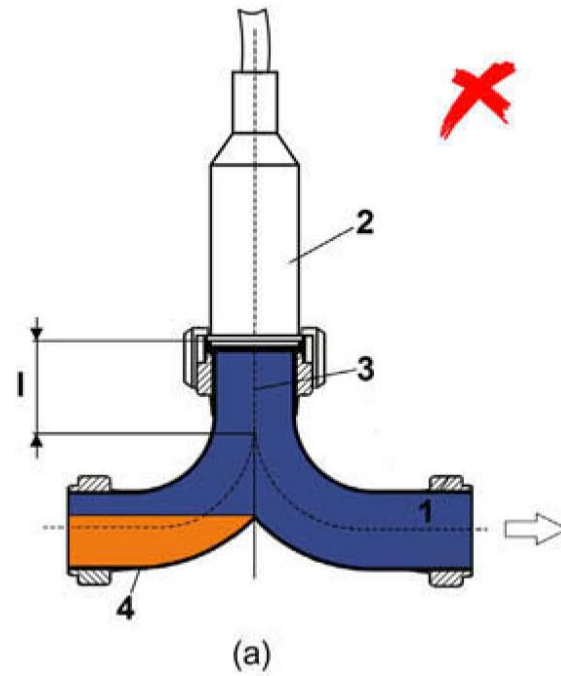


- 1 Probe
- 2 Swept T-piece

Figure A.19 — Instrumentation

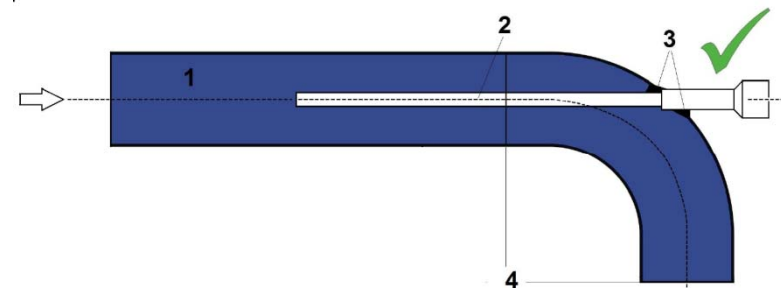
Hygienic Design

Potravné systémy



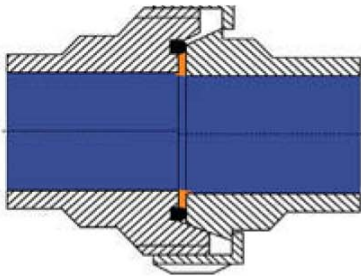
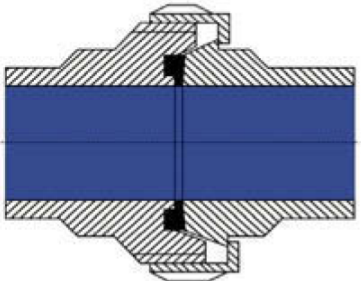
Hygienic Design

Potrúbné systémy



Hygienic Design

Potrubné systémy

Type	Hygiene Characteristics	Application
<p>Dairy coupling DIN 11851 – standard gasket</p> 	<p>There is an internal annular crevice between the ends of the coupling parts and the bore of the gasket. Product may be retained during production and/or after CIP. An additional potential problem with the design of this fitting is that it has a clearance on the cone fitting; as a consequence the two pipes are not automatically aligned. This could give rise to a potential step in the pipe joint. Does not comply with 3-A or EHEDG sanitary design criteria.</p>	<p>Often found in the food industry (pipes and tanks) due to the fact that it is reasonably priced. Not considered as suitable for CIP, which means that the fitting should only be used where the pipework is manually cleaned.</p>
<p>Dairy coupling DIN 11851 – non-standard collared gasket</p> 	<p>It provides a smooth crevice-free internal surface when correctly fitted and assembled. However, because of the mobility of this type of coupling and of the alternating expansion and contraction of the gasket, this gasket may be damaged by shear. Does not comply with 3-A or EHEDG sanitary design criteria.</p>	<p>Not recommended for use in hygienic plant process lines and CIP installations. Expensive and does not fulfill standard hygienic design criteria.</p>

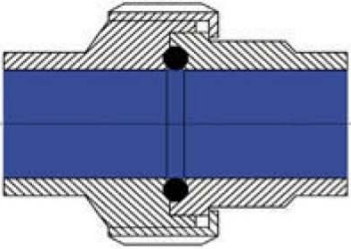
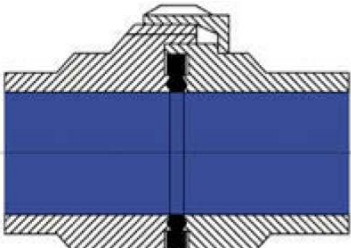
Hygienic Design

Potrubné systémy



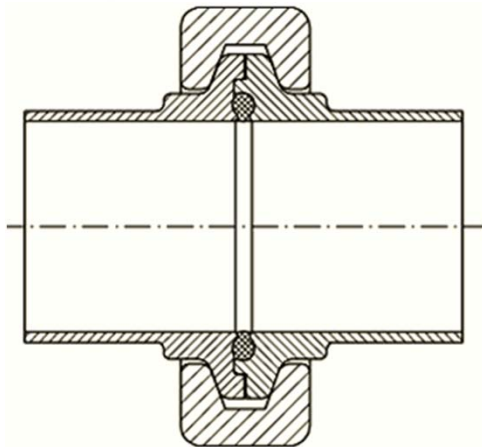
Hygienic Design

Potrubné systémy

Type	Hygiene Characteristics	Application
<p>Coupling DIN 11864 form A</p> 	<p>A smooth interface within the pipe work while simultaneously achieving a metal-to-metal seat behind the joint. A sufficient gap is created between the seal and the product space to facilitate rinsing in cleaning processes. This gap also serves as an expansion space that can accommodate volume expansions in the material as a result of heat or the influence of media without forces that can result in shearing. The groove is designed to minimize protrusion of the O-ring into the pipe bore. Complies with EHEDG and 3-A design criteria.</p>	<p>Optimal for aseptic operations because they are successfully tested for CIP-ability, steam sterilizability and bacteria tightness.</p>
<p>Coupling DIN 11864 form B</p> 	<p>The volume of the functional part of the gasket (diamond section) is minimal to limit the effects of thermal expansion. A small area of the gasket is exposed to the product. The width of the gasket is only 1 mm. The block of elastomer behind the seal will accommodate the thermal expansion, relieve stress build-up on the sealing faces and limit expansion into the product stream to a minimum. The small functional part of the gasket can expand in two directions. To prevent air from being trapped between the gasket shoulder and the male part groove small slits are provided on the outside, acting as vents.</p>	<p>Optimal for aseptic operations because they are successfully tested for CIP-ability, steam sterilizability and bacteria tightness.</p>

Hygienic Design

Potrúbné systémy



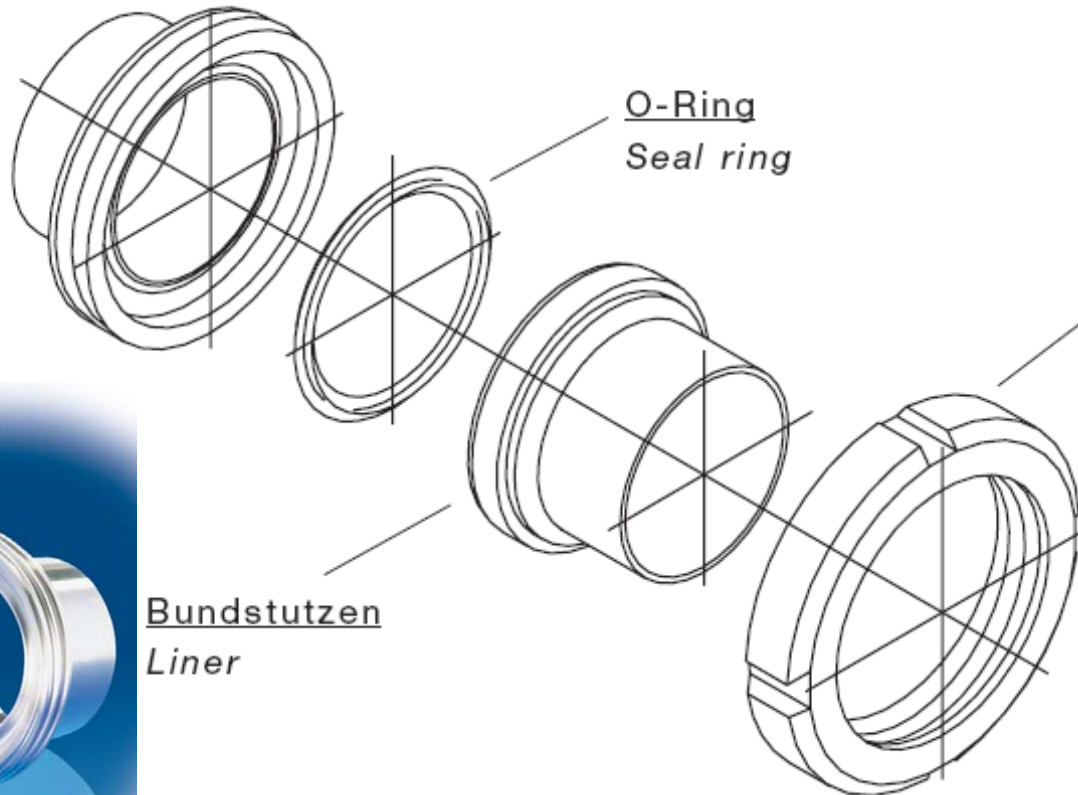
Hygienic Design

Potrúbné systémy – DIN 11864-1

Gewindestutzen
Male part

O-Ring
Seal ring

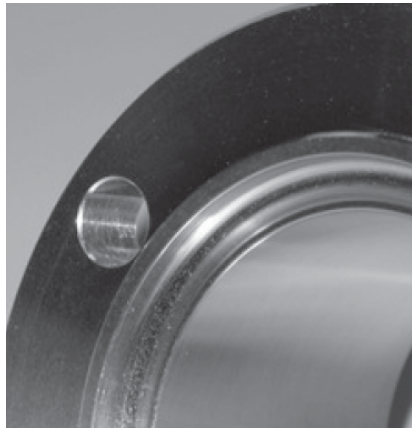
Nutmutter
Nut



Bundstutzen
Liner

Hygienic Design

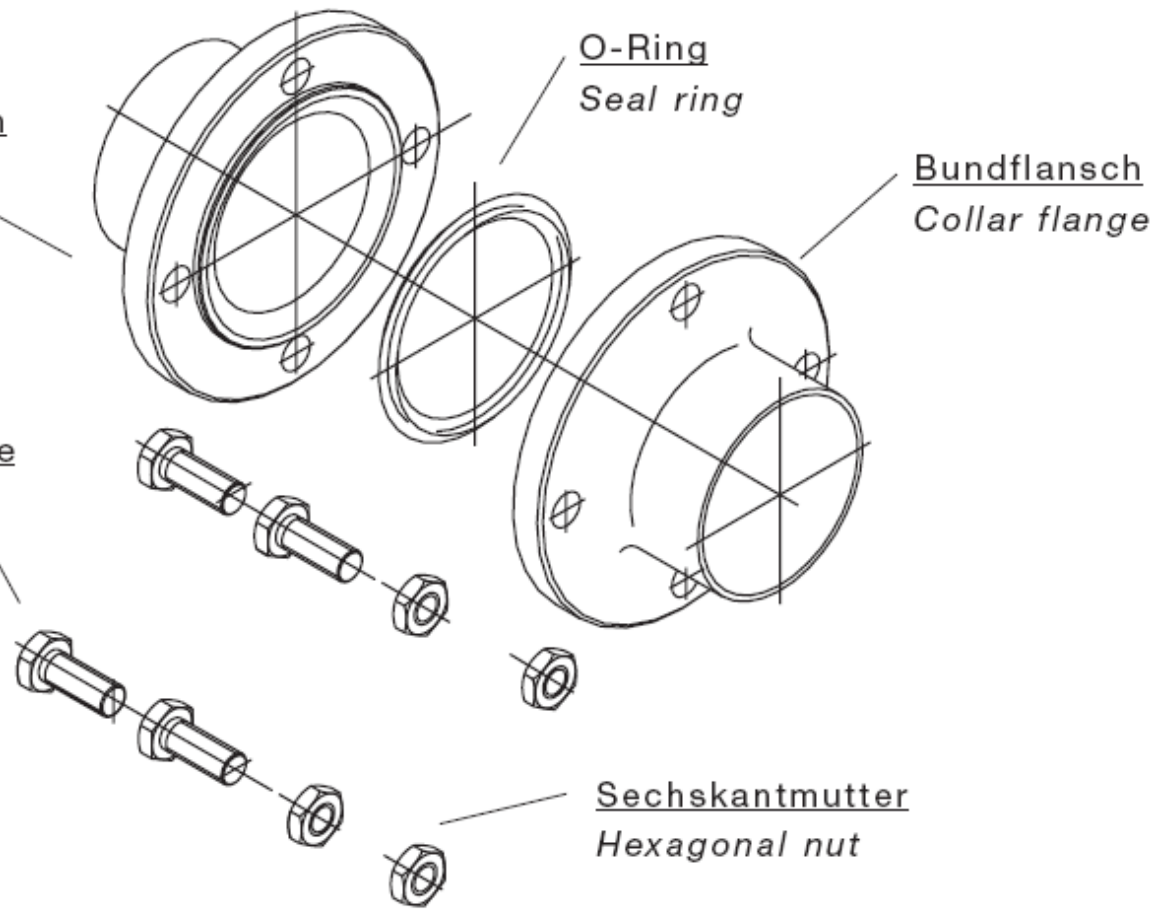
Potrúbné systémy – DIN 11864-2



Nutflansch
Nut flange



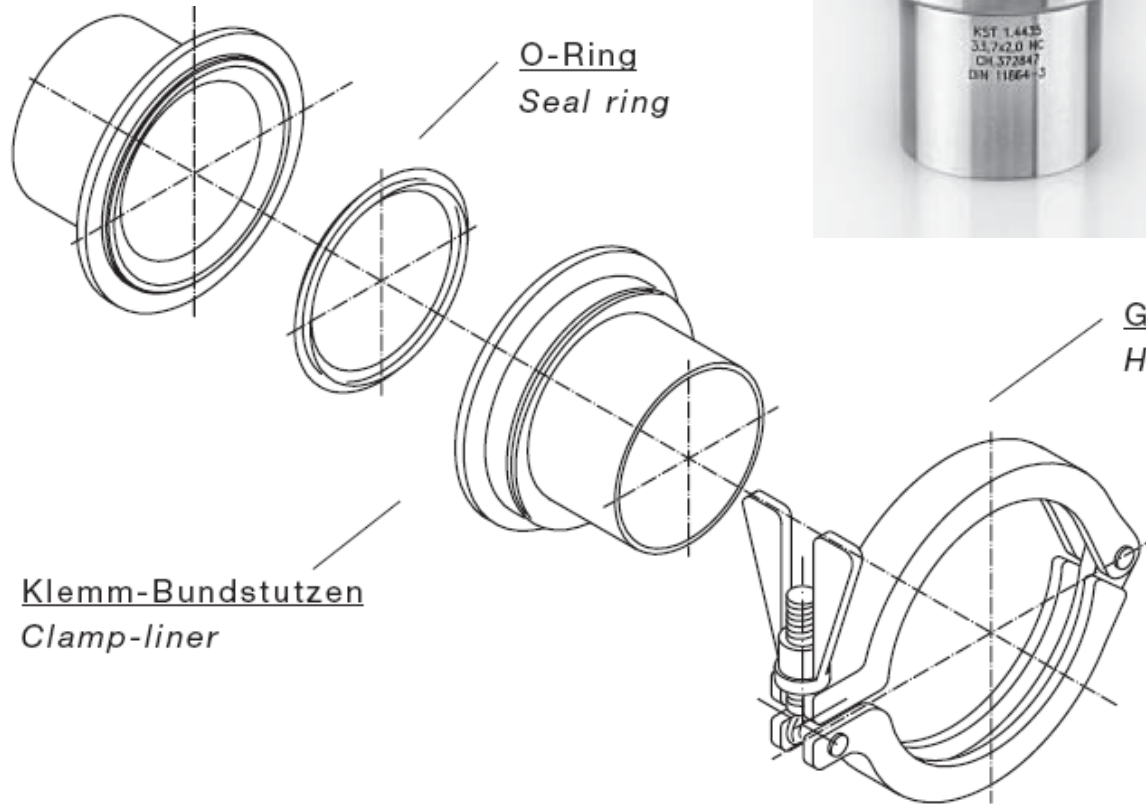
Sechskantschraube
Hexagonal bolt



Hygienic Design

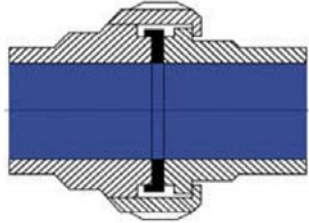
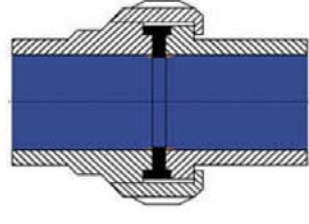
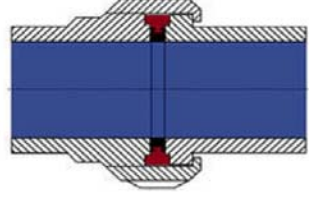
Potrúbné systémy – DIN 11864-3

Klemm-Nutstutzen
Clamp-nut



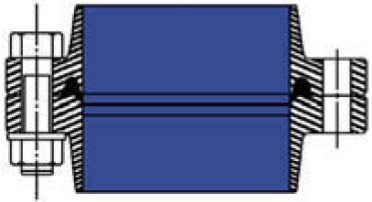
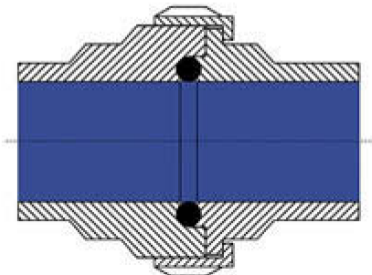
Hygienic Design

Potrúbné systémy

Type	Hygiene Characteristics	Application
<p>IDF coupling ISO 2853 with L-gasket</p> 	<p>When the coupling is correctly fitted and assembled, a smooth continuous bore and internal surface without crevice is obtained, so that cleaning may be performed without any problems.</p>	<p>This coupling is recommended for applications where CIP is normally practiced. Widely used for pasteurized circuits where dismantling is infrequent.</p>
<p>IDF coupling ISO 2853 with non-standard T-shaped gasket</p> 	<p>When properly made up, the joint is crevice free and has a smooth bore, flush with the pipe walls. If overtightened, the gasket may expand into the bore of the pipe, which creates a step where product can become trapped. Unless the nut is tightened correctly, the coupling will not be bacteria tight.</p>	<p>Most suitable for permanent or semi-permanent installations that are going to be cleaned in-place. If the seal material is suitable, then it can be sterilized.</p>
<p>IDF coupling ISO 2853 with metal-backed T-shaped gasket</p> 	<p>By supporting the seal with a stainless steel ring, both axial stop and centering can be achieved, allowing the connection to meet the requirements of hygienic design. The rubber is specifically shaped to give a flush interior joint when the union is tightened.</p>	<p>Most suitable for permanent or semi-permanent installations that are going to be cleaned in-place. If the seal material is suitable, then it can be sterilized.</p>

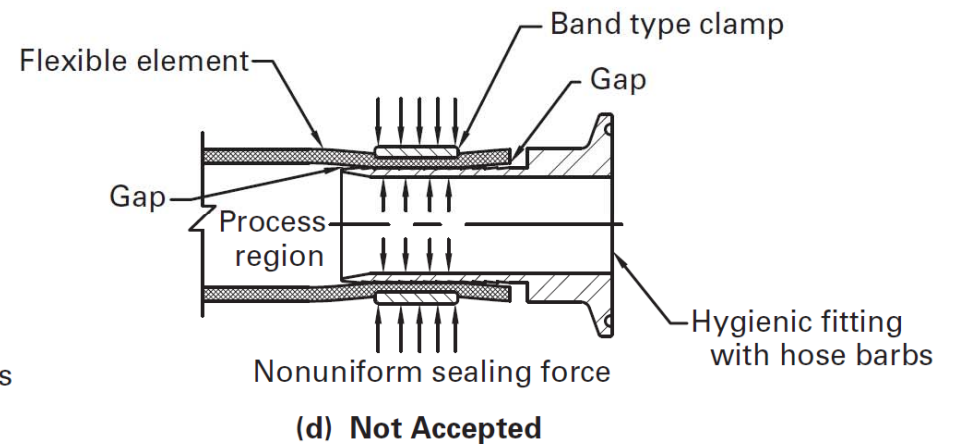
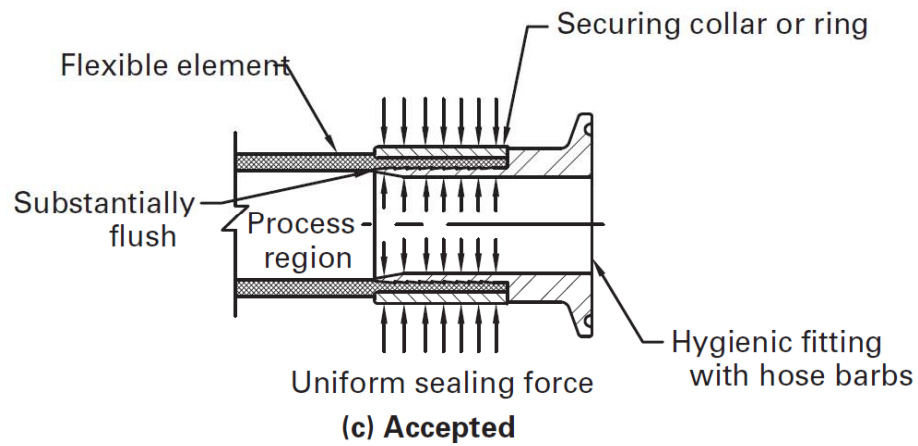
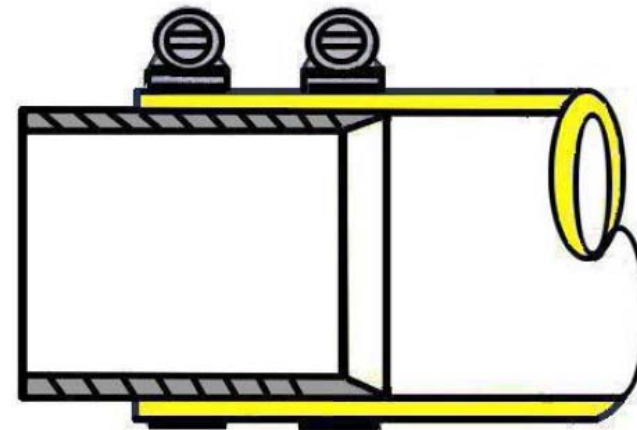
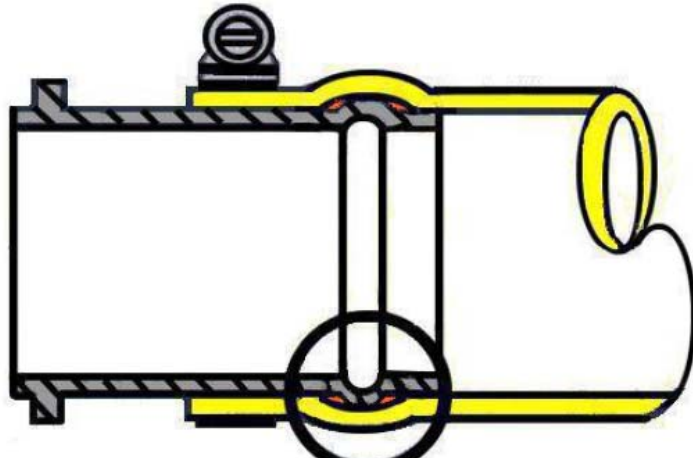
Hygienic Design

Potravné systémy

Type	Hygiene Characteristics	Application
<p>Varivent® flange coupling</p> 	<p>Varivent® flange coupling ensures a smooth transition, free of dead space. It complies with EHEDG and 3-A design criteria.</p>	<p>Successfully tested for CIP-ability. Suitable for aseptic processes.</p>
<p>Neumo Bioconnect®</p> 	<p>The seal is almost completely encapsulated. The highest press-on power is found at the transitions to wetted areas, preventing dirt and germs from penetrating into the sealing space behind the sealing element. Dead volume is minimized. Complies with EHEDG and 3-A design criteria. Successfully tested for CIP-ability.</p>	<p>Optimal for aseptic operations because it has been successfully tested for CIP-ability, steam sterilizability and bacteria tightness.</p>

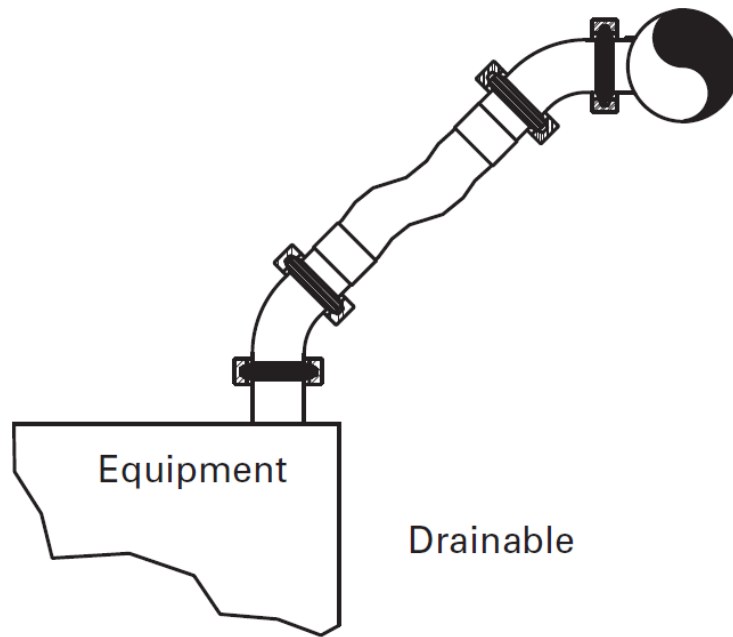
Hygienic Design

Potrubné systémy - hadice

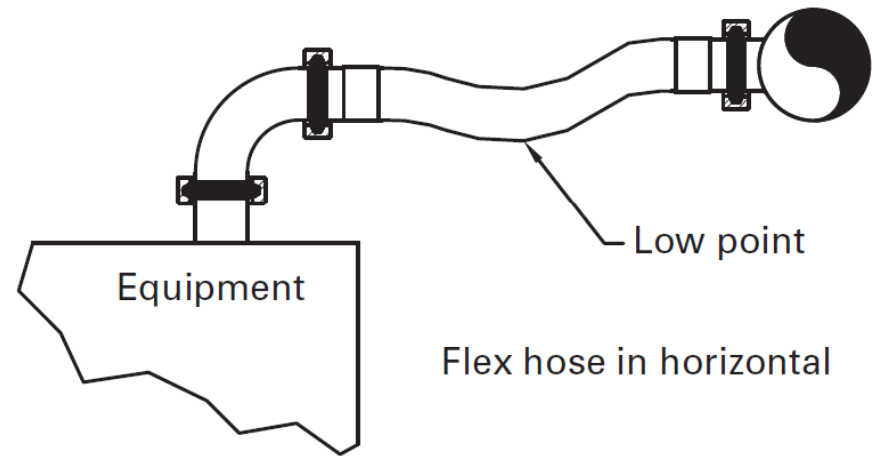


Hygienic Design

Potrubné systémy - hadice



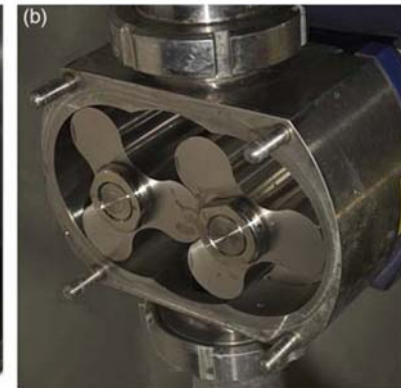
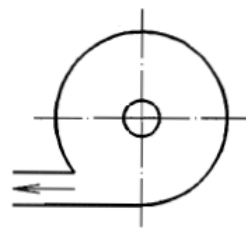
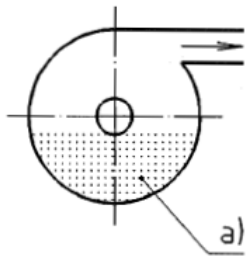
(a) Accepted



(b) Not Accepted

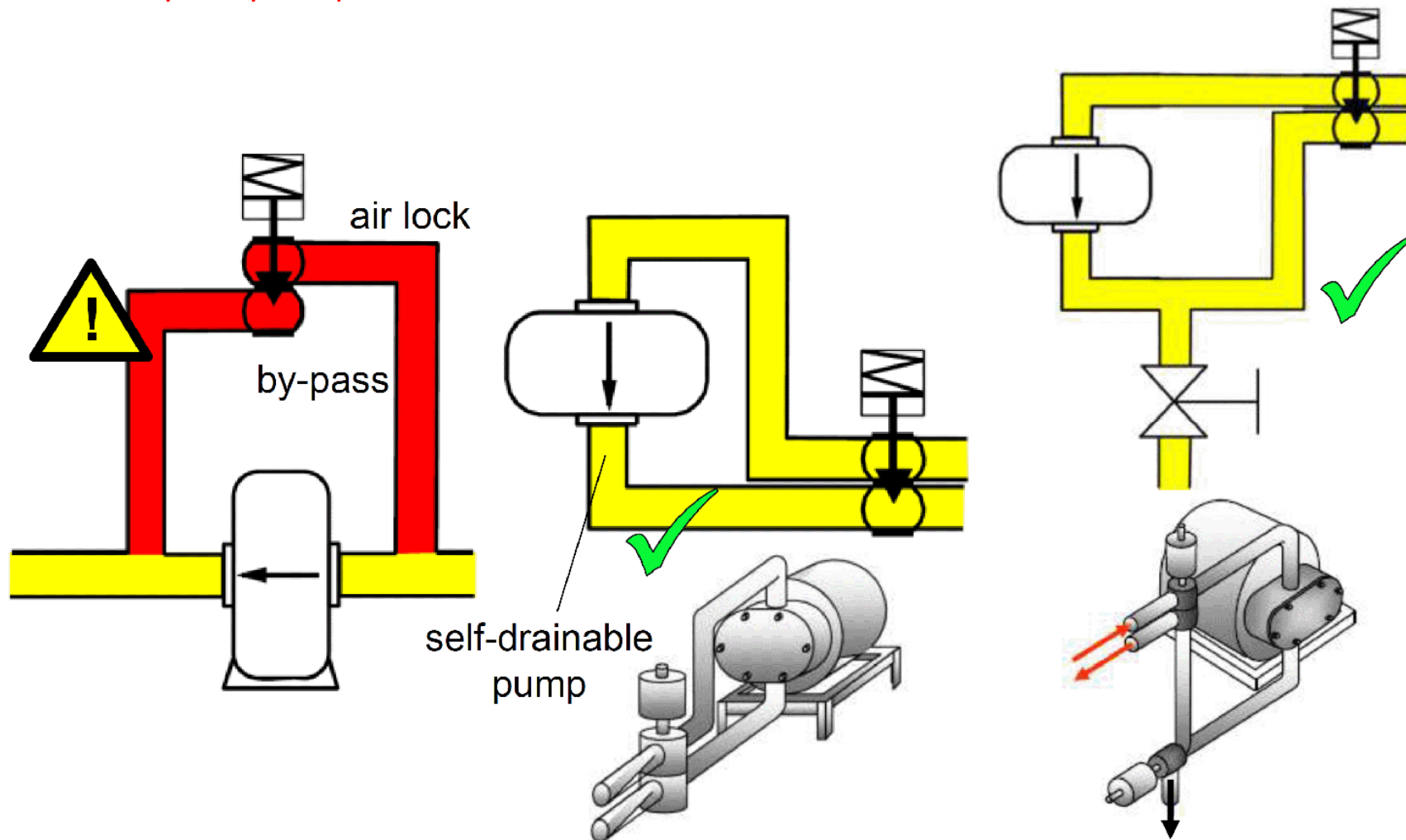
Hygienic Design

Potrúbné systémy - čerpadlo



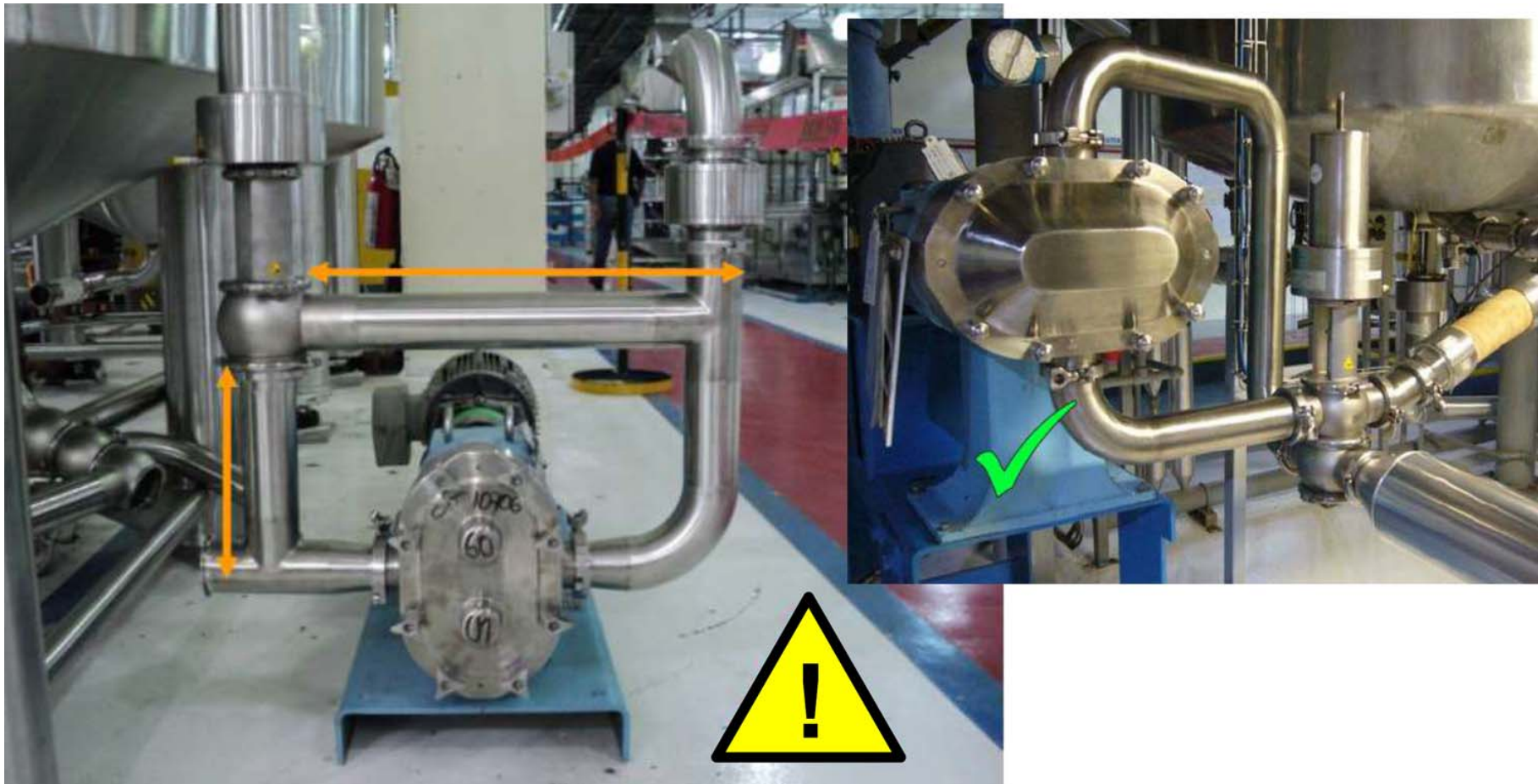
Hygienic Design

Potrubné systémy - čerpadlo



Hygienic Design

Potrubné systémy - čerpadlo



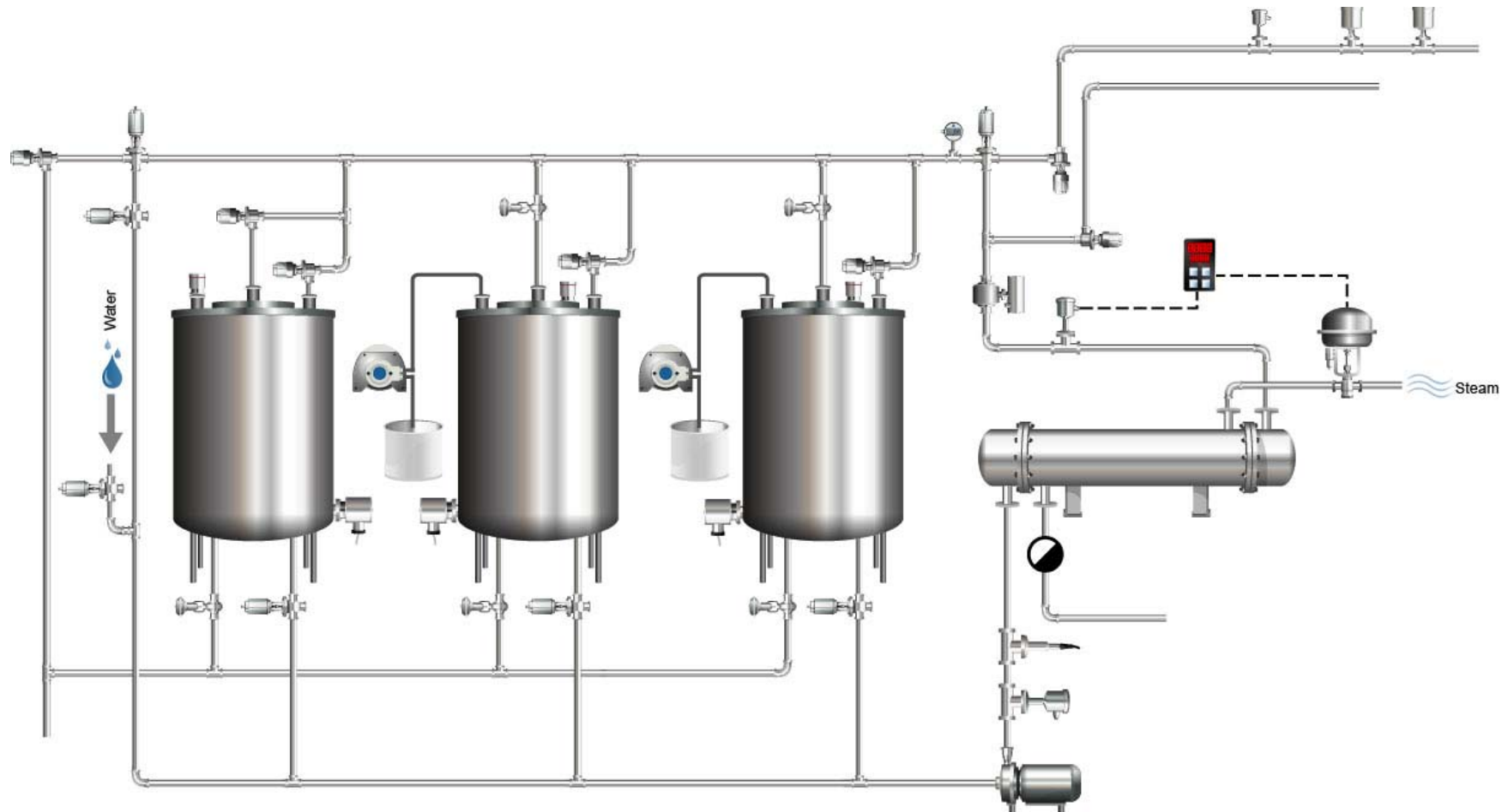
Hygienic Design

Čistenie - CIP



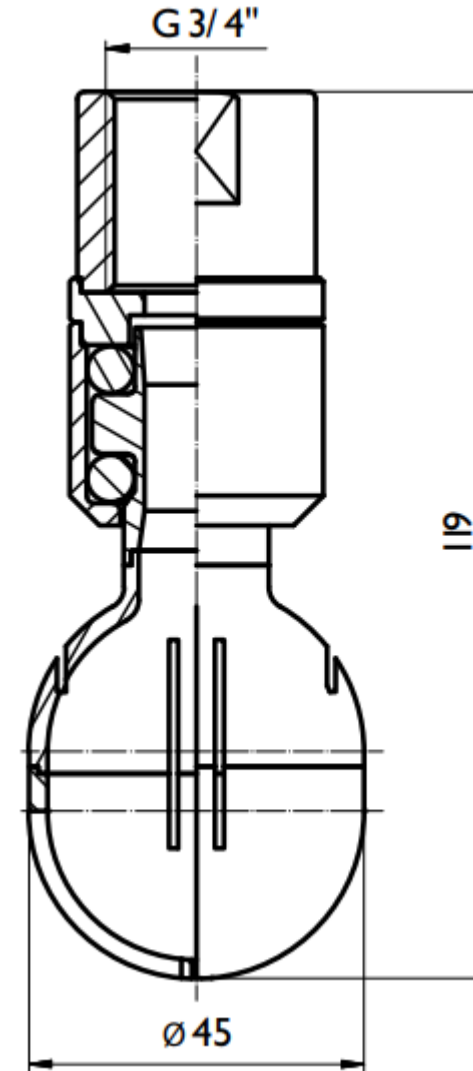
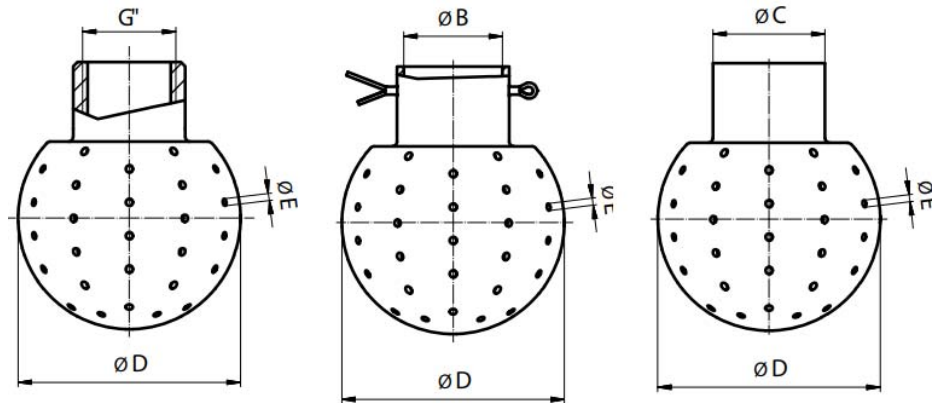
Hygienic Design

Čistenie - CIP



Hygienic Design

Čistenie - CIP



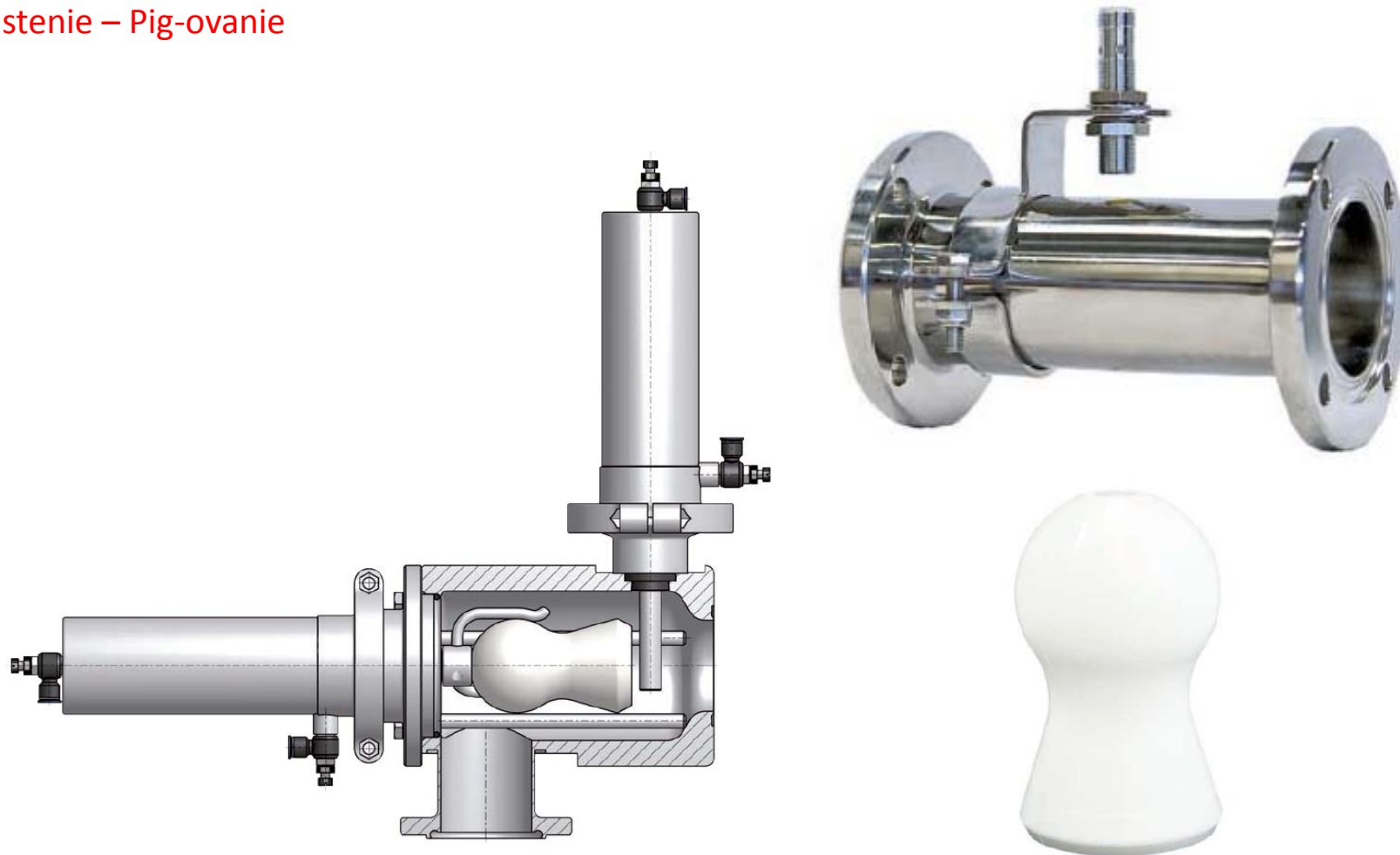
Hygienic Design

Čistenie - CIP



Hygienic Design

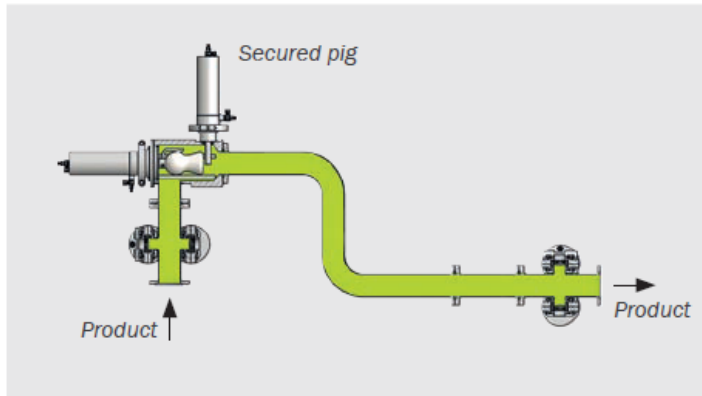
Čistenie – Pig-ovanie



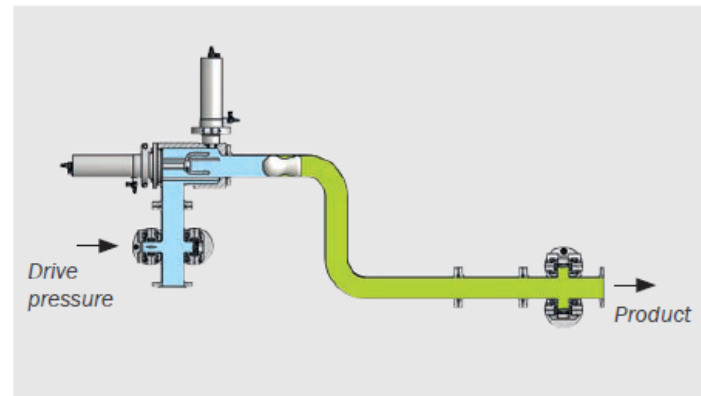
Hygienic Design

Čistenie – Pig-ovanie

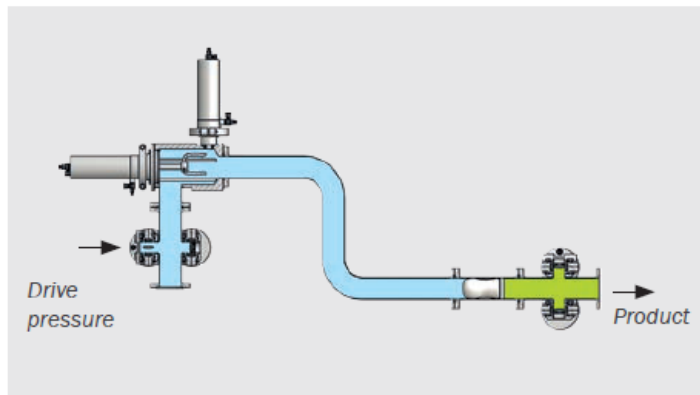
1. Product Cycle –
The pig is entirely streamed by the product.



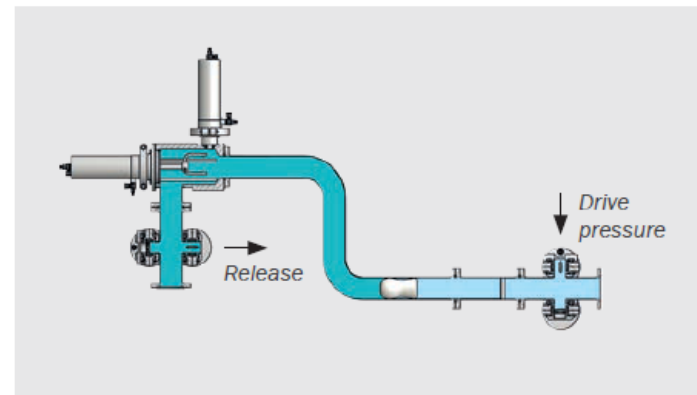
2. Pig Cycle –
The product is discharged from the pipework.



3. Receiving Cycle –
The pig is safely stopped by the receiving station.



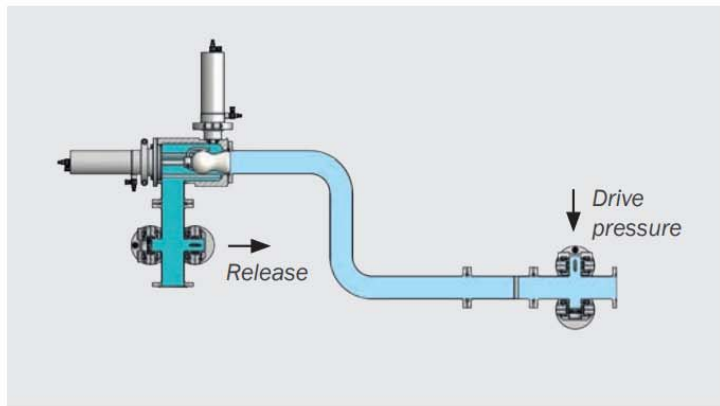
4. Returning Cycle –
The pig is returning.



Hygienic Design

Čistenie – Pig-ovanie

5. Capture Cycle –
The pig reaches its starting position.



6. Cleaning Cycle –
The pig is entirely streamed by CIP medium.

