



**FOOD PROCESSING EQUIPMENT
DESIGN AND CLEANABILITY**



**FLAIR-FLOW EUROPE
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F-FE 377A/00**

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FOOD PROCESSING EQUIPMENT DESIGN AND CLEANABILITY

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PREFACE

The acronym **RE:TU:ER** was coined by the FLAIR-FLOW dissemination team to denote 'ready-to-use European research' and resulted in a series of **RE:TU:ER** workshops across Europe. The **RE:TU:ER** workshops are aimed at food SMEs, and especially at the small and very small companies. The goal is to bring results from EU-supported food research projects to food SMEs Europe-wide, in an easily understood form, thereby facilitating application and use of the results both in the short and long term. Each workshop carries a series of handouts and these have been collated into five technical manuals with the following titles:

1. Ready-to-use fruit and vegetables
[ISBN 1 84170 106 8]
2. Food processing equipment design and cleanability
[ISBN 1 84170 107 6]
3. Managing the cold chain for quality and safety
[ISBN 1 84170 108 4]
4. Microbial control in the meat industry
[ISBN 1 84170 109 2]
5. Freshness, quality and safety in seafoods
[ISBN 1 84170 110 6]

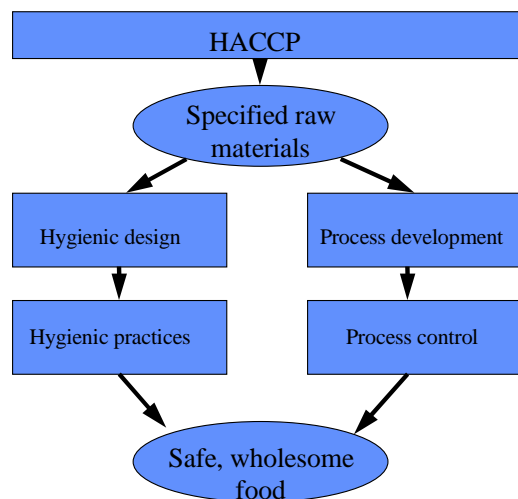
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Why should I be concerned with the hygienic design and cleanliness of food production equipment?

The schematic diagram below shows that the production of safe, wholesome foods, the major concern of the food industry, stems from a thorough risk assessment. Indeed this is now a legal requirement. The diagram also shows that given specified raw materials, there are four major 'building blocks' that govern the way the factory is operated to ensure that the safe, wholesome food goal is realised.



Risk assessment encompasses identifying the hazards that may affect the quality or safety of the food product and controlling them at all stages of the process such that their risk to product contamination is minimised. In the food industry this is commonly referred to as Hazard Analysis Critical Control Point (HACCP).

Such hazards are usually described as;

- *Biological*, e.g. bacteria, yeasts, moulds
- *Chemical*. e.g. cleaning chemicals, lubricating fluids
- *Physical*, e.g. glass, insects, pests, metal, dust

A hazard analysis should be undertaken at the earliest opportunity in the process of food production and if possible, before the design and construction of the processing facility.

Of the four building blocks illustrated in the schematic diagram, this presentation deals with hygienic design. and hygienic practices. Along with these two blocks, the design of a suitable process to kill or control relevant microorganisms, together with a suitable process control system (usually involving a quality system e.g. ISO9000 and HACCP) are equally important.

Hygienic design is concerned with:-

- factory siting and construction
- design of the building structure
- selection of surface finishes
- segregation of work areas to control hazards
- flow of raw materials and product
- movement and control of people
- design and installation of the process equipment
- design and installation of services (air, water, steam, electrics etc.).

Hygienic practices are concerned with:-

- processes that return the processing environment to its original condition. These are usually referred to as cleaning and disinfection or sanitation programmes.
- practices that keep the building and equipment in efficient operation. These are referred to as the maintenance programme.
- practices that relate to the control of cross-contamination during manufacture, usually related to people, surfaces, the air and the

segregation of raw and cooked product. Such control is generally referred to as Good Manufacturing Practice (GMP)

This technical manual is concerned with the hygienic design of food processing equipment and their sanitation programmes.

- ***Hygienic design and practices are thus two of the key factors in producing safe and wholesome foods***

Food processing equipment that is designed hygienically has three key advantages:-

- ***Food quality***

Good hygienic design maintains product in the main product flow. This ensures that product is not 'held-up' within the equipment where it could deteriorate and affect product quality on rejoining the main product flow. Or, for example in flavourings manufacture, one batch could not cross-contaminate a subsequent batch to give sensory problems.

- ***Food safety***

Good hygienic design prevents the contamination of the product with substances that would adversely affect the health of the consumer. Such contamination could be microbiological (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) and physical (e.g. glass).

- ***Cost reduction***

Good hygienic design reduces the time required for an item of equipment to be cleaned. This reduction of cleaning time is significant over the lifetime of the equipment such that hygienically designed equipment which may initially be more expensive (compared to similarly performing poorly designed equipment), will be more cost effective in the long term. In addition, reduced down time for cleaning may lead to the opportunity for increased production.

Of these three factors, safety is the most important to the food consumer. There have been many examples of product recalls, lost production, and indeed site closure, due to contamination arising from poorly designed equipment. Physical foreign body contaminants, such as pieces of plastic, affect the wholesomeness of food but rarely receive media attention. Physical contaminants of a more serious nature e.g. glass

fragments or caustic CIP fluids, however, are much more serious. Perhaps of the most concern are pathogenic microorganisms such as *Listeria* or *Escherichia coli* O157:H7, which may be harboured in equipment and then subsequently grow during production and contaminate the product.

How do I define the purpose for which the chosen equipment will be used?

Food processing equipment has traditionally been designed and built to be suitable for purpose. For example, a mixer for raw meat has rarely been designed to the same hygienic level as a slicer of cooked meats. Similarly, aseptic fillers have usually been designed to a much higher hygiene standard than can filling machines. The reason for this has been related to the risk of a hazard being transferred from the equipment to the product produced and thus the consumer.

The degree of risk from eating foodstuffs is dependent to a large extent on how that product has been processed, its degree of preservation and what further cooking steps (if any) the consumer has to perform prior to consumption. For example, a stable preserved product e.g. canned or dried goods, or one which requires thorough cooking prior to consumption, is less likely to confer a microbiological risk than a ready-to-eat chilled food. All of the above food products may, however, convey similar risks in terms of non microbiological hazards, i.e. physical hazards (e.g. glass, plastic) or chemical hazards (e.g. lubricating fluids, cleaning chemicals, pesticides).

- ***Both the designer and the user of the equipment have a responsibility to assess the risks to the product consumer arising from any hazards within the equipment.***

The designer and manufacturer of the equipment needs to:-

- identify the process for which the machine is intended,
- identify the relevant hazards associated with the products produced,
- design methods/measures which can eliminate hazards or reduce their risk,

- identify any other hazards introduced by the methods used to reduce the hazard under analysis,
- verify the effectiveness of the hazard elimination or risk reduction,
- describe any residual risks and any additional precautions necessary for the machine's safe use.

To help equipment manufacturers meet this challenge, and thus both control the risk of transfer of a hazard to a food product during manufacture and produce the equipment in a cost effective manner, food manufacturers should enter a dialogue with equipment manufacturers to consider the following:-

- *The intended use of the equipment.* Will the equipment be used for one specific purpose only, for which the hazards are readily identifiable, or could the machine be used for a wide range of products in many industries (e.g. a pump)?
- *The product type to be processed.* Will the product be already contaminated (e.g. a raw material) or will it be 'preserved' or 'aseptic'?
- *The degree of further product processing:* Will the product processed by the equipment subsequently undergo a further process which functions as a hazard elimination step (e.g. a heat treatment) or is the process for which the machine is intended the final process?
- *The degree of cleaning and/or inspection.* Is the equipment to be cleaned and/or inspected after every use, routinely during the day, every day or every week etc.?
- *The use of the machine.* Is the equipment likely to be well maintained or used infrequently, is it designed for high or continuous use or is it liable to abuse?

What level of hygienic design should I be looking for to control or eliminate these risks?

After a risk assessment has been made, it is possible to assign the suitability of an item of equipment to one of three basic categories for intended use. These can be described as:-

1. equipment that satisfies the minimum requirements to make it safe for its intended purpose. This may involve the control of single hazards, e.g. the equipment contains no glass.
2. equipment that satisfies all the current best practice hygienic design criteria and is thus fit for the production of most foods, though it needs to be dismantled prior to cleaning.
3. equipment that satisfies all the current best practice hygienic design criteria and can be cleaned without dismantling.
4. equipment that satisfies all the current best practice hygienic design criteria and is designed for a specific heat or chemical decontamination treatment.
5. equipment that satisfies all the current best practice hygienic design criteria, is also designed for a specific heat or chemical decontamination treatment and will prevent ingress of microorganisms. Such equipment would be suitable, for example, for the production of aseptic foods.

Whilst it is acceptable (though not necessarily cost effective) to use equipment designed for a higher hygienic requirement for a lower risk product, it is unlikely to be acceptable to use equipment designed for a lower risk category of food products for higher risk or aseptic products.

Does the equipment need to meet any legal requirements or is there any guidance on required hygienic design standards?

There are relatively few international hygienic equipment design standards and these are predominantly dairy based concerning pipelines and vessels (Anon 1973, 1974, 1976, 1980, 1983a, 1983b).

In the EC, the Council Directive on the approximation of the laws of Member States relating to machinery (89/392/EEC) was published on the 14th June 1989 and was subsequently updated by 98/37/EC. The Directive includes a short section dealing with hygiene and design requirements which states that machinery intended for the preparation and processing of foods must be designed and constructed so as to avoid health risks and consists of seven hygiene rules that must be observed. These rules are concerned with the suitability and cleanability of materials in contact with food; surface finish and design features such as joints, absence of ridges and crevices; avoidance of the use of fasteners,

e.g. screws and rivets; the design of internal angles and corners; drainage of residues from equipment surfaces; dead spaces and voids, and lastly bearings and shaft seals. The Directive requires that all machinery sold within the EC after January 1995 shall meet these basic standards and be marked accordingly to show compliance (the 'CE' mark).

- ***All food processing equipment sold in the EU must show the 'CE' mark and comply with the safety and hygiene aspects of 98/37/EC***

In addition to these hygiene rules, Section 2.1 contains a requirement that machinery manufacturers must indicate the recommended products (chemicals) and methods for cleaning, disinfecting and rinsing both open equipment (e.g. a conveyor) and closed equipment (e.g. pipelines, valves and pumps) where clean-in-place (CIP) procedures need to be used.

The Commission turned to the European Standards Organisation (CEN) to produce standards as one means of interpreting this Directive and Technical Committee CEN/TC 153 is concerned with the hygiene specifications of food processing machinery. A European "C" level Standard EN 1672-2 "Food processing machinery-Safety and hygiene requirements-Basic concepts-Part 2; Hygiene requirements" has recently been adopted. In addition to this, a number of Working Groups of CEN/TC 153 are producing specific standards on bakery, meat, catering, edible oils, vending and dispensing, pasta, bulk milk coolers, cereal processing and dairy equipment.

It is impossible to provide hygienic design guidelines for all individual food processing equipment. The approach of the CEN/TC 153 was, therefore, to define the basic hygienic design requirements and these can be presented under two headings, Food contact (broken down into eleven subsections) and Non-food contact areas. These are described and interpreted below. Illustrative figures have been taken from CCFRA texts.

- ***Food contact area***
- ***Materials of construction***

Materials used for product contact must have adequate strength over a wide temperature range, a reasonable life; be non-toxic, non-tainting, non-absorbent; be resistant to cracking, chipping, flaking corrosion and abrasion, prevent penetration of unwanted matter under intended use and be easily cleaned and capable of being shaped.

Stainless steel usually meets all these requirements and there are various grades of stainless steel which are selected for their particular properties to meet operational requirements, e.g. Type 316 which contains molybdenum is used where improved corrosion resistance is necessary.

Elastomers and other polymers should retain their surface and conformational characteristics when exposed to the conditions encountered in production, cleaning and decontamination.

- ***Surface finish***

Product contact surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned and disinfected. For closed equipment (that used for liquid handling and usually cleaned-in-place CIP) a surface finish of $0.8\mu\text{mR}_a$ is recommended, with higher R_a values being acceptable if they can be shown to be cleanable (see Verification section). Surfaces will deteriorate with age and wear (abrasion) such that cleaning will become more difficult (Holah and Thorpe 1990).

- ***Joints***

Permanent joints, such as those that are welded or bonded, should be smooth and continuous and free from resses, gaps or crevices. Dismountable joints, such as screwed pipe couplings (Figure 1) must be crevice-free and provide a smooth continuous surface on the product side [Note: Figures 1 to 10 are given on pages 38 to 47 for convenience]. Flanged joints (Figure 2) must be located with each other and be sealed with a gasket because, although metal/metal joints can be made leak-tight, they may still permit the ingress of microorganisms.

- ***Fasteners***

Exposed screw threads, nuts, bolts, screws and rivets (Figure 3) must be avoided wherever possible in product contact areas. When unavoidable for technical reasons, alternative methods of fastening can be used (Figure 4) where the washer used has a rubber compressible insert to form a bacteria-tight seal.

- ***Drainage***

All pipelines and equipment surfaces should be self draining because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product (Figure 5). Care should be undertaken with the installation of equipment such that its drainability is not impaired.

- Internal angles and corners

These should be well radiused, wherever possible, to facilitate cleaning (Figure 6).

- Dead spaces

As well as ensuring that there are no dead spaces in the design of equipment, care must be taken that they are not introduced during installation. If dead spaces are unavoidable for technical reasons, they should be readily accessible for draining/cleaning as necessary.

- Bearings and shaft seals

Bearings should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants, unless they are edible, or possible failure of the bearings due to the ingress of the product (Figure 7). Shaft seals must be of such design so as to be easily cleaned and if not product lubricated, then the lubricant must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it is important that there is a groove completely through the bore of the bush, from top to bottom to permit the passage of cleaning fluid.

- Instrumentation

Instruments must be constructed from appropriate materials and if they contain a transmitting fluid, such as in a bourdon tube pressure gauge, then the fluid must be approved for food contact. Many instruments themselves are hygienic but often they are installed unhygienically (Figure 8).

- Doors, covers and panels

Doors, covers and panels should be designed so that they prevent the entry of and/or prevent the accumulation of soil. Where appropriate they

should be sloped to an outside edge and should be easily removed to facilitate cleaning.

- Controls

Controls, particularly those that are repeatedly touched by food handlers to allow process operation, should be designed to prevent the ingress of contamination and should be easily cleanable (Figure 9). Pathogenic microorganisms have been known to harbour in switches and be transferred to product every time they are operated.

- *Non-food contact area*

Equipment should be designed and constructed to prevent the retention of moisture, ingress and harbourage of pests and accumulation of soils. The design should facilitate inspection, servicing, maintenance, cleaning and where necessary, disinfection.

Surfaces should be made of corrosion resistant materials or should be treated (coated or painted) so as to be corrosion resistant. Equipment supports should be designed such that no water or soil can remain on or within their structure. Insulation materials should be properly mounted and sealed to prevent the ingress of contamination.

How do I know that the equipment meets my requirements and is cleanable?

The hygienic design of food processing equipment may need to be verified for a number of reasons. These include

- During equipment development, e.g. to examine a new configuration or concept.
- After design, to demonstrate compliance with relevant legislation e.g. 98/37/EC.
- As a quality assurance technique during equipment manufacture.
- As part of a 'sign-off' procedure after installation at a customer's site.
- As part of the normal selection procedure by the customer.

Verification methods at a simple level involve the examination of 2 or 3 dimensional drawings of the equipment, an examination of the equipment itself (including dismantling), and verification of the suitability of surface material. In Europe, for many pieces of open processing equipment this would probably be the limit of verification required to comply with 98/37/EC and thus enable attachment of a 'CE' mark. For more complex equipment, particularly closed processing equipment, however, cleanability tests may be necessary.

An EU Fourth Framework funded programme 'Test method development for the practical assessment of food processing equipment cleanability' (Contract Number AIR 1-CT92-0091) was undertaken by the participants shown in Annex 1 between January 1993 and March 1996. The aim of this project was to develop test protocols, on a practical basis, to assess the cleanability of equipment intended for food production.

Initial work within the programme concentrated on developing test conditions of materials, microorganism and organic soils, soil application methods and cleaning protocols that could be standardised amongst the participants. Stainless steel AISI 316 L was selected as the material on which to develop and compare methods. In later trials, comparative work was undertaken on silicone, two conveyor belt materials (2M 2964 FDA and 2M 1333 FDA) and Polysulfon. The following microorganisms were chosen for trial work as they were known to attach well to surfaces, could be detected after cleaning trials and were relatively safe for controlled aerosol dispersal during spray cleaning; *Pseudomonas fragi* ATCC 4973, *Photobacterium leiognathi* ATCC 33469, *Bacillus thuringiensis* ATCC 10792 and *Bacillus stearothermophilus* NIZO C953. Three organic soils were subsequently chosen for comparative studies as they were shown to be readily made, stable, easy to apply and relatively detectable after cleaning; 'Campden' soil, a mixture of milk, starch and oil; a margarine based soil for use in the assessment of moderately sized closed equipment; and a soured milk based soil for use in the EHEDG Cleanability Test Method (see Bibliography, Document 2) for small sized closed equipment

Initial work demonstrated that it was possible to cover small open test objects by spraying microbial and organic soils with hand held commercial compressed air driven sprayers. Uniformity of spraying was increased by the use of a repeat coating, if possible in a different spray direction, and a second spray of nutrient medium for microbial soils helped prevent viability loss on the surface. Soiling of larger size open test items by these methods may be difficult and, at best, time consuming. For equipment of large size it may be appropriate to first identify areas that could be potentially difficult to clean and soil and assess these areas only. For

instance, it is unlikely that flat easily accessible surfaces would be difficult to clean but fastenings, corners and areas of poor drainage could well be.

Closed equipment of all sizes was easily and consistently soiled by circulation of the organic and microbial soils. A cleaning protocol consisting of detergent foaming for 20 min followed by spraying with potable water at 250 psi for 5 sec with the spray lance approximately 20 cm from the surface at an angle of 90° was established as being suitable for open surfaces. Cleaning protocols for closed surfaces were engineered to provide a fixed flowrate (1.5 m/s) and variable detergent concentrations, temperature and contact times to allow some residual retention of soils as required for comparative analysis. Typically, cleaning of closed surfaces was based on a three stage process; a rinse with cold water (10-15°C) for 1 min followed by circulation of a 1.0% (w/v) mild detergent solution (Lever Industrial PD332) for 10 min at 63°C with a final rinse with cold water (10 - 15°C) for 1 min.

Once conditions had been standardised, development of techniques to detect soil residues after cleaning, could be undertaken. Techniques assessed included an apparatus designed to remove microorganisms from surfaces using ultrasound, traditional microbiological swabbing and ATP hygiene testing systems, Direct Epifluorescent Microscopy (DEM) and visual and image analysis measurements of stains remaining after cleaning. After a period of development, however, Participants in the programme agreed that five techniques were the most promising in terms of detecting residues after cleaning, and that further work should concentrate on the repeatability and reproducibility of these methods. These were:-

- a) Application of *P. fragi* to open surfaces by spraying, with detection by TVC, ATP or DEM/DEFT as appropriate.

Overnight cultures of *P. fragi* were resuspended in phosphate buffer and sprayed onto test surfaces using a small compressed air based sprayer (Merck) with spraying in a zig zag pattern to give even coverage. The surfaces or equipment were allowed to dry for 15 min and then sprayed with growth media (0.1% bacteriological peptone, 0.07% yeast extract) prior to cleaning. After cleaning, surfaces were swabbed and the swabs processed traditionally or the swab resuspension fluid was assessed by DEFT.

- b) Application of *B. thuringiensis* to open surfaces by spraying and closed surfaces by circulation, with detection by TTC agar overlay.

Spores of *B. thuringiensis* were suspended in saline and sprayed onto surfaces by spraying with sweeping movements using a compressed air 'artist's brush' type paint sprayer or by filling the item of equipment with the spore suspension. Immediately after cleaning, surfaces were covered with molten nutrient agar containing 2,3,5-triphenyltetrazoliumchloride (TTC). The agar was incubated with the surface for a variable time period (up to 5 h) at 30°C and the agar was removed from the surface and incubated overnight. TTC salts, which are water soluble in the oxidized state are reduced to water insoluble formazans by cellular respiration. When growing using this TTC solid medium, colonies appeared red and small, offering an easier visualisation of the contaminated areas.

- c) The EHEDG small closed equipment test using *B. stearothermophilus* in a milk soil applied by circulation with detection by agar overlay

This method was based on 'A method for the assessment of in-place cleanability of food processing equipment', EHEDG Document No. 2.. In this method, the test item was filled with soured milk containing spores of *B. stearothermophilus*, pressurised to 5 bar, drained and dried. The test item was then cleaned, drained and dismantled in the laboratory. Test items were covered in agar as appropriate such that all product contact surfaces were wetted and incubated at 58°C. Spores remaining on the test item after cleaning may germinate and ferment the glucose in the agar to acidic end points. A pH sensitive dye in the agar recorded this fermentation with a change from purple to yellow such that yellow areas indicated microbial growth and thus spore presence.

- d) Application of a margarine soil to closed equipment with visual detection of β -carotene residues.

The test item was filled with a commercially available soft margarine, containing 80% fat with a viscosity of less than 60mPA.s at room temperature, and pressurised to 5 bar. After cleaning, the test section was removed from the test rig and the test item dismantled. All product contact surfaces of the test item were examined for the presence of residual soil by visual inspection and by swabbing the surface with a cotton wool tipped swab. The relative amount of residual soil was recorded on a relative number (RN) scale from 0-4 where 0 represented no visible yellow soil and 4 indicated soil being highly visible.

Tests (c) and (d) were used to interpret cleanability in two ways. Firstly, a reference pipe of known surface roughness was assembled together with the test item to allow a cleanability comparison. Three results for the test item

were possible - more cleanable, less cleanable and the same cleanability. Secondly, information could be recorded as to the precise location of any yellow area recorded. If, after several tests, yellow was recorded in the same area on each occasion, this was interpreted as a particularly difficult to clean, or unhygienic, area of the test item.

- e) Application of a starch, milk and oil (Campden) soil to open surfaces by spraying and closed surfaces by circulation with detection via calcium residues.

A soil was prepared containing 'Coldflo' modified starch, whole milk powder and vegetable oil and was 'spiked with calcium carbonate (final concentration 1.25M) and diluted 1:2 for spraying to excess onto equipment surfaces using a Merck TLC sprayer. After cleaning, surfaces were swabbed by sponges which were resuspended in nitric acid. Diluted samples were aspirated into a Perkin Elmer 3300 atomic absorption spectrophotometer using an air/acetylene flame at 422.7 nm and results were calculated as mg calcium/cm².

The selected techniques were further developed and examined for their repeatability and reproducibility. All participants using *P. fragi* as a test organism have found it to be easy to use and results are repeatable. Further work, however, needs to concentrate on the methods reproducibility, i.e. how to standardise the methodology and interpretation of it between partners, as the principles of the method (choice of organism, method of soiling, cleaning variables and detection methods) have all been individually established.

Ultimately, methods using spores, e.g. *B. thuringiensis*, will offer greater repeatability and reproducibility than vegetative bacterial-based tests as spores have high resistance to heat and chemicals as well strong adhesive properties. They are less susceptible, therefore, to viability loss within the soiling and cleaning process. This proved to be the case. Difficulties arise, however, particularly for open surfaces, with the detection of spores if an agar overlay technique is used on large pieces of equipment because it would be impractical to cover them totally with agar and it may be difficult to cover only areas of the equipment identified as likely to be unhygienic.

The assessment of 'Campden soil' removal by instrumental detection of calcium concentration was possible. This technique proved very easy to use and was repeatable. Its detection was dependent, however, on access to atomic absorption spectroscopy which imposes a cost limitation to its widespread use. Alternative calcium detection methods are available and it

may be possible for cheaper analyses to be undertaken. The calcium techniques simplicity, safety and repeatability makes it particularly suitable for routine use outside the laboratory, especially in areas in which microbiological testing would be impossible, and it is certainly recommended for future study.

The measurement of *P. fragi* by TVC has the largest range of detection in that cleaning can remove >5 log orders of the organism attached to surfaces. This range allows even small differences in the cleanability of surfaces to be detected, though such small differences may not be relevant practically. The detection of *B. thuringiensis* by TTC is limited by the ability to differentiate colonies on an agar surface; this probably covers a range of 1-100 colonies/cm² above which colonies become indistinguishable (i.e. 2 log orders). This range is sufficient to both determine cleanability differences by means of colony counts, or by visual assessment. In contrast to this, the difference between cleaned and control surfaces as measured by calcium is approximately 1 log order. This range makes an assessment of the cleanability very difficult but is sufficient to detect areas of poor cleanability at a gross scale within individual test items.

This difference in sensitivity, together with comparative test results, indicates that ultimately the microbiologically-based tests are more sensitive. What is not known at this stage of the TTC methods development is the ability of the agar to fully wet the surface and thus come in contact with all surface bound spores and subsequently what proportion of spores are removed by the agar and are thus enumerated. The ability of the agar to enter into surface irregularities e.g. crevices and remove any spores present will clearly influence the sensitivity of the technique, though results to date have shown the method to be the most sensitive of the five developed.

The detection of β -carotene in margarine soils is dependent on visual observation and automated colour recognition systems were found to be less sensitive than the human eye. In addition, techniques based on absorbance spectrophotometry after extraction of the β -carotene into hexane also proved less sensitive. As test results were thus recorded on an arbitrary (RN) scale, statistical analysis of repeatability studies by the RN scale is difficult. Visual comparison of results did, however, suggest that similar results were obtained. Further work is required on the quantification of the level of β -carotene remaining in margarine on the surfaces of large pieces of equipment after cleaning. If no suitable automated system can be found, appropriate colour charts to enhance the RN scoring system could be considered to allow reproducible results between partners.

Of all the cleanability test methods developed, most time was spent on the EHEDG (European Hygienic Equipment Design Group) based test for small equipment. Two participants initially took the published test, further developed it, and examined its repeatability. Agar removal was enhanced with an 'apple corer' device which removed a cylinder of agar of approximately 0.5 mm thick from the surface of the pipe which could then be rolled out over a gridded surface for colour assessment by enumerating the squares that were yellow. Glass colour comparators were made and distributed to the participants as training aids on colour interpretation. These led to increased operator yellow/purple perception and thus increased the repeatability of the method.

Run No.	Spore conc (cfu/ml)	Rinse 1 (cfu/ml)	Rinse 2 (cfu/ml)	%Yellow in reference	%Yellow in coupling gasket
1	8.9x10 ⁵	57	0	5.4	100
2	6.0x10 ⁵	50	0	7	100
3	9.9x10 ⁵	48	0	7.8	100

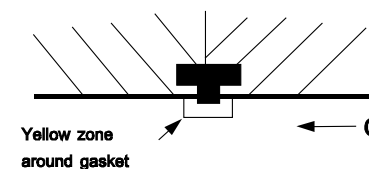


Figure 11 Repeatability of EHEDG small equipment test using a coupling. Run 1, 2 and 3 represent three different partners

The within-laboratory repeatability of the method suggested that the test was repeatable. The reproducibility of the test was demonstrated for two test items, a pipe with a step in it and a coupling with a protruding gasket. Three participants assessed the items and all three obtained the same results; a random distribution of yellow colour in the stepped pipe and yellow colour around the gasket in the coupling (Figure 11). (Note: Figures 1 to 10 are given on pages 38 to 47 for convenience). All participants thus concluded that the stepped pipe was as cleanable as the reference pipe and that the coupling was of poor hygienic design due to gasket protrusion.

The method has been accepted for accreditation to various countries National Standards (e.g. UKAS in the UK, DANAK in Denmark) and is currently being published as an updated version by the EHEDG. The method has been particularly successful and is used by many European liquid handling equipment manufacturers (e.g. pumps, valves, couplings, sensors) as a means of independently assessing equipment cleanability.

In addition to the test method for small equipment, the EHEDG have also published test methods on the assessment of pasteurizability (Document 4), sterilizability (Document 5) and degree of microbial ingress (Document 7) into specialised food processing equipment.

Is there any guidance on the installation of equipment

The potential for well designed and constructed equipment to be operated in a hygienic manner may be easily vitiated by inadequate attention to its location and installation. As a guide (modified from Thorpe and Barker, 1987), the following are useful and have been incorporated in a schematic diagram (Figure 10):-

- There should be sufficient height (200mm is recommended) to allow adequate access for inspection, cleaning and maintenance of the equipment and for the cleaning of floors.
- All parts of the equipment should be installed at a sufficient distance from walls, ceilings and adjacent equipment to allow easy access for inspection, cleaning and maintenance, especially if lifting is involved. A minimum distance of 1m is recommended though 2m is often seen as a more practical minimum.
- Ancillary equipment, control systems and services connected to the process equipment should be located so as to allow access for maintenance and cleaning.
- Supporting framework, wall mountings and legs should be kept to a minimum. They should be constructed from tubular or box section material which should be sealed to prevent ingress of water or soil. Angle or channel section material should not be used.
- Base plates used to support and fix equipment should have smooth, continuous and sloping surfaces to aid drainage. They should be coved at the floor junction. Alternatively, ball feet should be fitted.

- Pipework and valves should be supported independently of other equipment to reduce the chance of strain and damage to equipment, pipework and joints.
- Once installed, a series of maintenance measures should be put in place to ensure the required level of equipment hygiene is maintained for the equipment during its specified life.

How should I clean and disinfect my equipment to ensure that its hygienic status is preserved?

Food equipment manufacturers, the food producer and cleaning chemical suppliers all have a role to play in cleaning and disinfection (collectively known as sanitation).

- *The equipment manufacturer* must recommend typical routine procedures for cleaning, disinfection, rinsing and inspection for cleanliness, including indicating cleaning compounds that are acceptable/not acceptable based on, for instance, the chemical resistance of the materials of construction.
- *The food manufacturer's* responsibility is to determine the required degree of cleaning necessary and its frequency, devise a suitable sanitation programme and schedule and control and verify its overall performance.
- *The chemical supplier*, in consultation with the equipment supplier and food producer, should help recommend suitable cleaning and disinfection chemicals and methods for their application.
- ***Cleaning principles***

In the food processing industry sanitation is undertaken primarily to remove all undesirable material (food residues, microorganisms, foreign bodies and cleaning chemicals) from surfaces in an economical manner, to a level at which any residues remaining are of minimal risk to the quality or safety of the product. Such undesirable material, which may include food residues, microorganisms and foreign matter, is generally referred to as 'soil' and can be derived from normal production, spillages, line-jams, equipment maintenance, packaging or general environmental contamination (dust and dirt).

To complete a successful sanitation programme it is essential to understand the nature of the soil to be removed. The product residues are readily observed and may be characterised by their chemical composition e.g. carbohydrate, fat, protein or starch. In addition, different processing and/or environmental factors on the same product soil may lead to a variety of cleaning problems dependent primarily on moisture levels and temperature. Generally, the higher the product soil temperature and the longer the time period before the sanitation programme is initiated, i.e. the drier and more baked the soil becomes, and the more difficult it is to remove it.

Microorganisms can either be incorporated into the soil or can attach to surfaces and ultimately form layers or biofilms. Microbial numbers will increase in line with time for growth, temperature, nutrient supply, available water and presence of antimicrobial agents.

Sanitation programmes utilise a combination of the four major energy factors; mechanical or kinetic energy, chemical energy, temperature or thermal energy, time. The combinations of these four factors varies for each sanitation programme and generally, if the use of one energy source is restricted, this short-fall may be compensated for by increasing energy inputs from the other factors.

Mechanical or kinetic energy is used to physically remove soils and may include manual scraping, brushing and wiping, automated scrubbing (physical abrasion) and pressure jet washing (fluid abrasion). Of all four factors, physical abrasion is regarded as the most efficient in terms of energy transfer. In cleaning, chemical energy is used to break down soils to render them easier to remove, and to disperse and suspend them in solution to aid rinsability. In chemical disinfection, chemicals react with microorganisms remaining on surfaces after cleaning to reduce their viability or affect their growth rate. Cleaning and disinfection chemical effects increase with temperature linearly and approximately double for every 10°C rise. For fatty soils, temperatures above their melting point are used to break down and emulsify these deposits to aid removal. For cleaning processes using mechanical, chemical and thermal energies, generally the longer the time period employed, the more efficient the process.

- *Cleaning chemicals*

No one cleaning agent is able to perform all the functions necessary to facilitate a successful cleaning programme, so a cleaning solution, or detergent, is blended from a range of typical characteristic components selected from the following; water, surfactants, inorganic alkalis, inorganic and organic acids and sequestering agents. A general purpose food detergent could contain, therefore, a strong alkali to saponify fats, weaker alkali 'builders' or 'bulking' agents, surfactants to improve wetting, dispersion and rinsability and sequestrants to control hard water ions. The detergent should ideally be safe, non-tainting, non-corrosive, stable, and environmentally friendly. The choice of cleaning agent will depend on the soil to be removed and its solubility characteristics

Following cleaning, disinfection is undertaken to further reduce the surface population of viable microorganisms, via removal or destruction, and/or to prevent surface microbial growth during the inter-production period. Temperature is the best disinfectant as it penetrates into surfaces, is non-corrosive, is non-selective to microbial types, is easily measured and leaves no residue. However, for open surfaces, the use of hot water or steam is uneconomic, hazardous or impossible and reliance is, therefore, placed on chemical biocides. Whilst there are many chemicals with biocidal properties, many common disinfectants are not used in food applications because of safety or taint problems. Of the acceptable chemicals, the most commonly used products are: chlorine-releasing components, quaternary ammonium compounds, amphoteric and quaternary ammonium/ amphoteric mixtures.

The efficacy of disinfectants is generally controlled by five factors: interfering substances (primarily organic matter), pH, temperature, concentration and contact time. The efficiency of all disinfectants is reduced in the presence of organic matter, and it is therefore essential to remove all soil and chemical residues prior to disinfection. Disinfectants should only be used within the pH range as specified by the manufacturer and, in general, the higher the temperature the greater the disinfection. The manufacturer's in-use concentration must always be used as concentrations above this recommended level may not enhance biocidal effect and will be uneconomic whilst concentrations below this level may significantly reduce biocidal action. Sufficient contact time between the disinfectant and the microorganisms is perhaps the most important factor controlling biocidal efficiency; for disinfecting bacteria at least 5 minutes is required but more resistant organisms such as spores or moulds require repeated surface dosing to ensure extended contact times of 15–60 minutes.

- **Cleaning methodology**

Cleaning and disinfection can be undertaken manually using simple tools e.g. brushes or cloths, and this form of cleaning is simple (i.e. less susceptible to mechanical breakdown or error), well directed and cost effective for small areas. For larger areas, specialist equipment becomes necessary to rinse, dispense chemicals and/or provide mechanical energy. Chemicals may be applied as low pressure mists, foams or gels whilst mechanical energy is provided by high and low pressure water jets or electrically powered scrubbing brushes. Foams and gels are more viscous than mists; are not as prone to aerosol formation and thus allow the use of more concentrated detergents; are able to cope with higher levels of soils than misting; are well liked by operatives and management because of their consistent application of chemicals though in some cases rinsing of the surfaces can be a problem and large water volumes may be required. Alternatively, dismantled equipment and production utensils may undergo manual gross soil removal and then be cleaned and disinfected automatically in tray or tunnel washers.

Mists, foams and gels are removed from surfaces by low pressure hoses operating at mains water pressure or by high pressure/low volume systems. Pressure washing systems can be mobile units, in which water is typically pumped at pressures up to 100 bar through a 15 degree nozzle, wall mounted serving one or more outlets, or centralised where one unit may supply many outlets via a ring main. Water jets confer high mechanical energy, can be used on a wide range of equipment and environmental surfaces, are not limited to flat surfaces, will penetrate into surface irregularities and can mix and apply sanitation chemicals.

- **Sanitation programme**

The manipulation of cleaning and disinfection chemicals and methods is referred to as the sanitation programme. This is undertaken to be efficient with water and chemicals, to allow selected chemicals to be used under their optimum conditions, to be safe in operation to operatives, machinery and product, to be easily managed and to reduce manual labour and cleaning costs. In this way an adequate level of sanitation will be achieved, economically and with due regard to environmental pollution.

The principle stages involved in a typical sanitation programme are:

1. *Production periods.* Production staff should be encouraged to operate good housekeeping practices during production and leave their work stations in a

reasonable condition (soil left on process lines is wasted product!). The greater the degree of attention by production staff, the easier the job of the sanitation team and thus the quality and safety of the next batch.

2. *Preparation.* After production, in-process product and packaging materials should be removed, machinery should be switched off and electrical and other sensitive systems protected from water/chemical ingress. Equipment should be dismantled as far as is required and unwanted utensils/equipment removed. Dismantled equipment should be stored on racks, tables or soak tanks, not on the floor!
3. *Gross soil removal.* All loosely adhered or gross soil should be manually removed by brushing, scraping, shoveling or vacuum etc. Wherever possible soil should be picked up and placed in waste bins rather than washed to drains using hoses.
4. *Pre-rinse.* Surfaces should be rinsed, from the top downwards, with low pressure cold water to remove loosely adhered small debris. For fatty soils, hot water can be used but too high a temperature may coagulate proteins.
5. *Cleaning.* The application of a selection of cleaning chemicals, temperature and mechanical energy sources to remove adhered soils.
6. *Inter-rinse.* Soil detached and dispersed by cleaning operations, together with cleaning chemical residues, should be removed from surfaces by rinsing with low pressure cold water.
7. *Disinfection.* If necessary, dependent on the food product and process, chemical disinfectants (or occasionally heat) are applied to remove and/or reduce the viability of remaining microorganisms to a level of no significant risk.
8. *Post-rinse.* Disinfectant residues may be removed by rinsing away with low pressure cold water of known potable quality. Note: EU Directives state that rinsing is required within the milk and egg sectors but can be negated in other sectors providing the disinfectants are described by their manufactures as food safe and have no effect on food product quality or safety..
9. *Inter-production cycle conditions.* Procedures should be undertaken, to prevent the growth of microorganisms on product contact surfaces in the period up until the next production process starts. This may include drying of the equipment and screening it from other cleaning operations.

10. *Periodic practices.* Procedures should be undertaken, at given time periods e.g. weekly or monthly, to thoroughly clean equipment to a level beyond that undertaken daily. This normally involves additional equipment dismantling and/or the application of increased cleaning energy. Periodic practices also include the more infrequent cleaning tasks such as ceilings and overhead fittings.

- ***Sanitation schedule***

To minimise the risks of cross contamination within the sanitation programme, and thus ensure that all product contact surfaces within the food processing area have the minimal level of microbial and physical contamination prior to production commencing, a sanitation sequence should be established for each processing area. A sanitation sequence determines the order in which the product contact surfaces (equipment) and environmental surfaces (walls, floors, drains etc.) are sanitised such that once product contact surfaces are disinfected, they should not be recontaminated from cleaning aerosols. A typical sanitation sequence would be:

1. Remove gross soil from production equipment.
2. Remove gross soil from environmental surfaces.
3. Rinse down equipment and environmental surfaces (usually to a minimum of 2m in height for walls) in a 'top to bottom' manner and flush to drain.
4. Clean environmental surfaces. Usually in the order of drains, floors walls.
5. Rinse environmental surfaces, in the opposite order to cleaning.
6. Clean equipment.
7. Rinse equipment.
8. Disinfect equipment.
9. Rinse equipment.

- ***To help manage both the sanitation programme and schedule, written work instructions (usually developed jointly between the food manufacturer and the chemical supplier) should be provided as part of the factory quality system.*** These instructions should detail:

- Description of the area/room to be cleaned, with a sequence of events that leaves the food processing surfaces as free as possible of microbial contamination.
- Description of the equipment to be cleaned, procedures for dismantling and assembly, and the requirement for engineers.
- Description of the other surfaces within the area that require cleaning together with suitable cleaning frequencies
- A description, hazard code, in-use concentration, method of make up, storage conditions, location and amount to be used of all chemicals.
- Type, use of, set parameters (pressure, nozzle type etc.), maintenance and location of all sanitation equipment to be used.
- Full description of the cleaning process, its frequency and requirement for periodic measures.
- Staff requirements and their responsibilities.
- Key points for assessment of the control and performance verification of the sanitation programme and a description of evaluation procedures to be used.

What hygienic design training do I need?

The importance of hygienic design cannot be overstated. Regardless of the quality of the general design (fit for purpose) and execution of the sanitation programme, contamination will never be controlled unless the areas in which soils can accumulate are either avoided by good hygienic design or can be readily exposed for cleaning.

Both equipment designers and persons responsible for the selection of equipment, hopefully after a dialogue with engineers, microbiologists and production, must be familiar with the principles of hygienic design to ensure that suitable equipment is purchased. Further to this, persons responsible for the management of sanitation programmes, especially in 'high risk' food manufacturing areas, must also be familiar with basic hygienic design concepts to be sure that equipment is dismantled sufficiently so that surfaces are safe for food production. Similarly, anyone involved in the inspection of hygienic design from a regulatory

viewpoint must be specifically trained in this field to ensure that suitable equipment is being used. Hygienic design training should, therefore, be targeted at engineers during their higher education and at key food processing staff.

- ***Courses in hygienic design are available at CCFRA in the UK and through the EHEDG (see below)***

Where can I get further information?

Hygienic design advice can be obtained, in the form of 'guidelines' or legislative requirements, from a range of sources.

- ***In-house***

Many large international equipment manufacturers have engineers dedicated to hygienic design who are conversant with both internal and external knowledge bases. Similarly, large international food manufacturers have staff specialising in the selection of hygienic equipment and may have hygienic specifications to which equipment suppliers must comply. Many smaller equipment and food manufacturers, however, have no detailed knowledge of this area.

- ***Academic/research associations***

A relatively few academic texts have been published on hygienic design, though texts by Jowitt, Imholte and CCFRA are internationally recognised (Anon 1982b, 1983c, Jowitt 1980, Imholte 1984, Thorpe and Barker 1985, 1987, Timperley and Timperley 1993).

- ***Scientific/marketing trade associations***

Foremost amongst the trade associations that have produced hygienic guidelines specifically for their industry is the International Dairy Federation (Anon 1982a, 1987). Currently a group (B36 - Hygienic design of equipment used in dairy plants) is active and has published some general recommendations for the hygienic design of dairy equipment in IDF Bulletin 310, 1996.

- ***Equipment manufacturers/users/regulators consortia***

Within Europe and the USA, a number of organisations exist to foster consensus in hygienic design and the use of these organisations'

guidelines can have a quasi legal status. In 1989 an independent group, the European Hygienic Equipment Design Group (EHEDG) was formed; it consists of approximately 100 members who are equipment manufacturers, food processors, research organisations, or government representatives. The remit of the group is:

- to ensure that food products are processed hygienically and safely.
- to provide Standards Organisations with specialist views on hygienic aspects of equipment design.
- to ensure that in the future there will be no confusion whether and under which conditions equipment is microbiologically safe for the processing and packaging of food.
- to identify areas where knowledge of hygienic and aseptic design, needed to produce recommendations, is insufficient and to encourage research and development in such areas.

The EHEDG has produced 18 guidelines to date covering a range of hygienic design, verification and processing subjects (see Bibliography) as extended abstracts in the journal *Trends in Food Science and Technology* and in-full by CCFRA (in English), ASEPT (in French), Technical University of Munich (in German) and PAVO (in Dutch). Further information on the EHEDG can be obtained from the secretariat at the following address:

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In the USA, a number of guidelines in the form of third party approval schemes have been developed for the dairy industry (the 3-A standards) and food service equipment (the National Sanitation Foundation - NSF). The structure of these schemes is commendable in that representatives of equipment manufacturers, users and regulatory bodies are all involved in

the implementation of recommendations. In particular, the 3-A standards group has been producing hygienic design standards, particularly for the dairy industry in the USA, for over 50 years and regularly publishes its documents in the journal *Dairy, Food and Environmental Sanitation* (Gilmore 1996).

Harmonisation is currently being explored between the EHEDG, 3-A and NSF, and all three organisations will jointly publish hygienic guideline documentation in the future. Such co-operation will harmonise current national standards and guidelines to achieve technically equivalent hygienic design standards on a scientific and technical basis, and thus remove national or regional standards as non-tariff barriers to trade.

- ***International standards***

At an International level, a committee ISO/TC 199/WG 2 has been established to produce a "B" level standard on the hygienic aspects of machinery design relevant to any manufacturing sector in which hygiene is critical (e.g. food, biotechnology, pharmaceuticals). This standard will be the base standard to which all other, more detailed, manufacturing sector standards will relate. A draft standard ISO/DIS 14159, has been prepared and is currently being commented upon.

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ANNEX 1

TEST METHOD DEVELOPMENT FOR THE PRACTICAL ASSESSMENT OF FOOD PROCESSING EQUIPMENT CLEANABILITY

(CONTRACT NUMBER AIR 1-CT92-0091)
JANUARY 1993-MARCH 1996

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FIGURE 1: HYGENIC AND UNHYGENIC SCREWED PIPE COUPLINGS (DIN 11851)

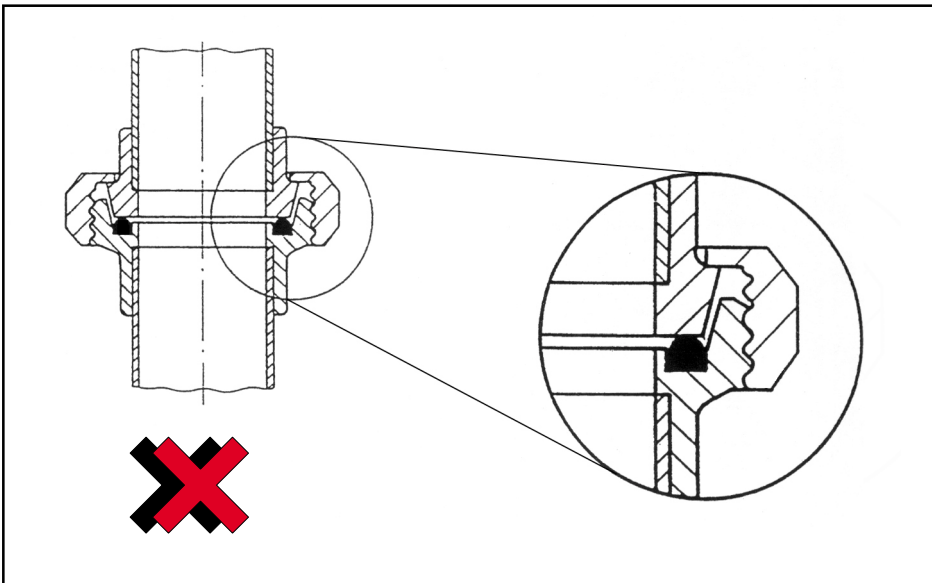
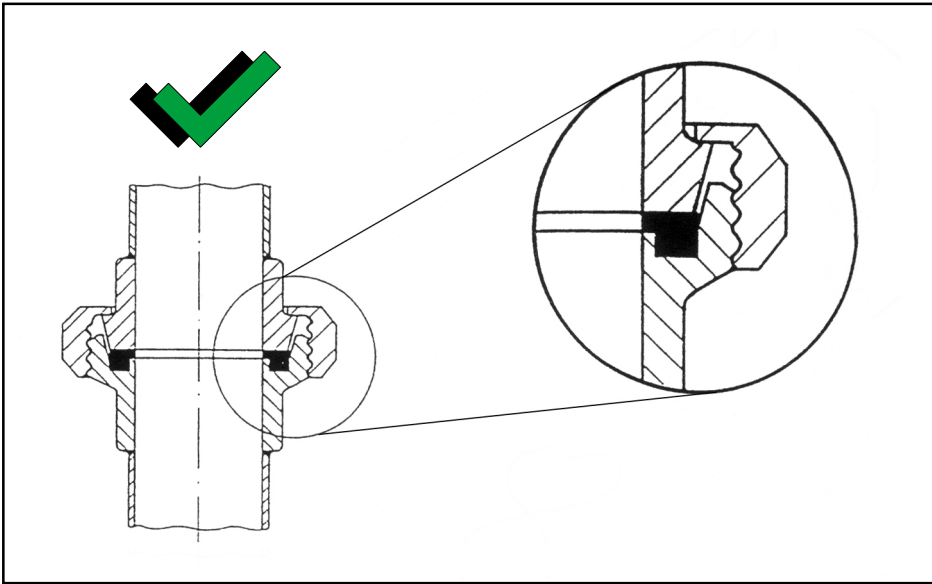


FIGURE 2: HYGENIC AND UNHYGENIC FLANGED JOINTS

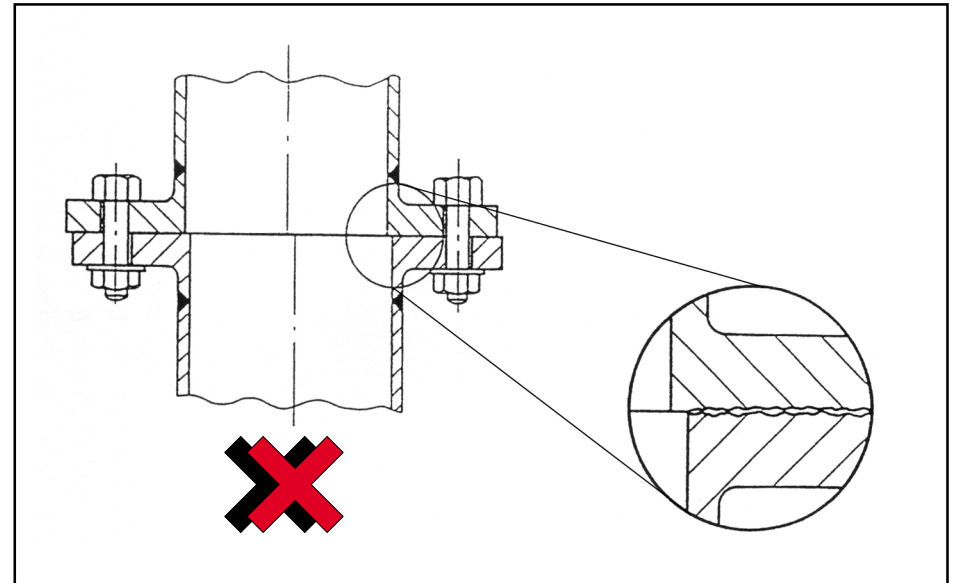
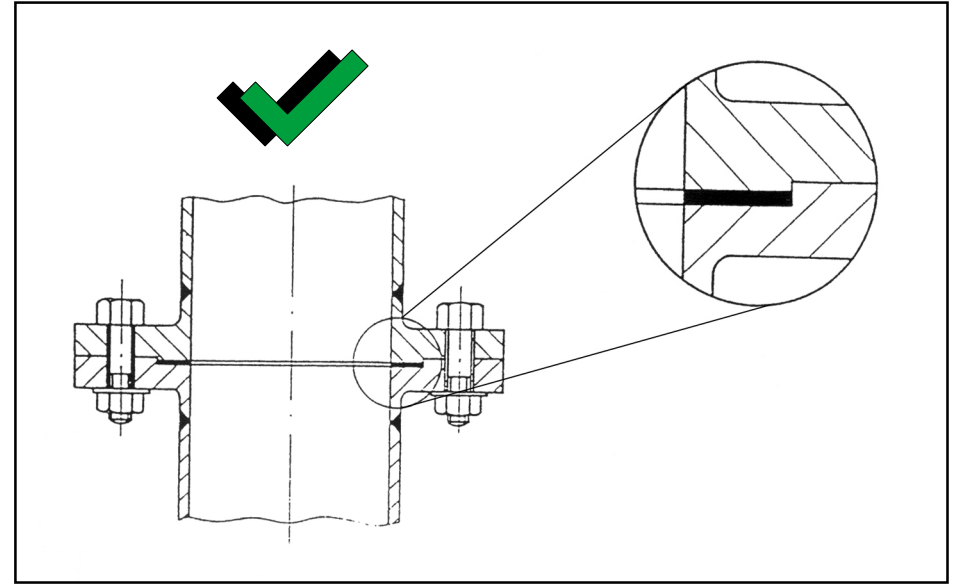


FIGURE 3: EXAMPLES OF UNHYGENIC FASTENERS. A = SOIL TRAP POINTS; B = METAL TO METAL; C = DEAD SPACES

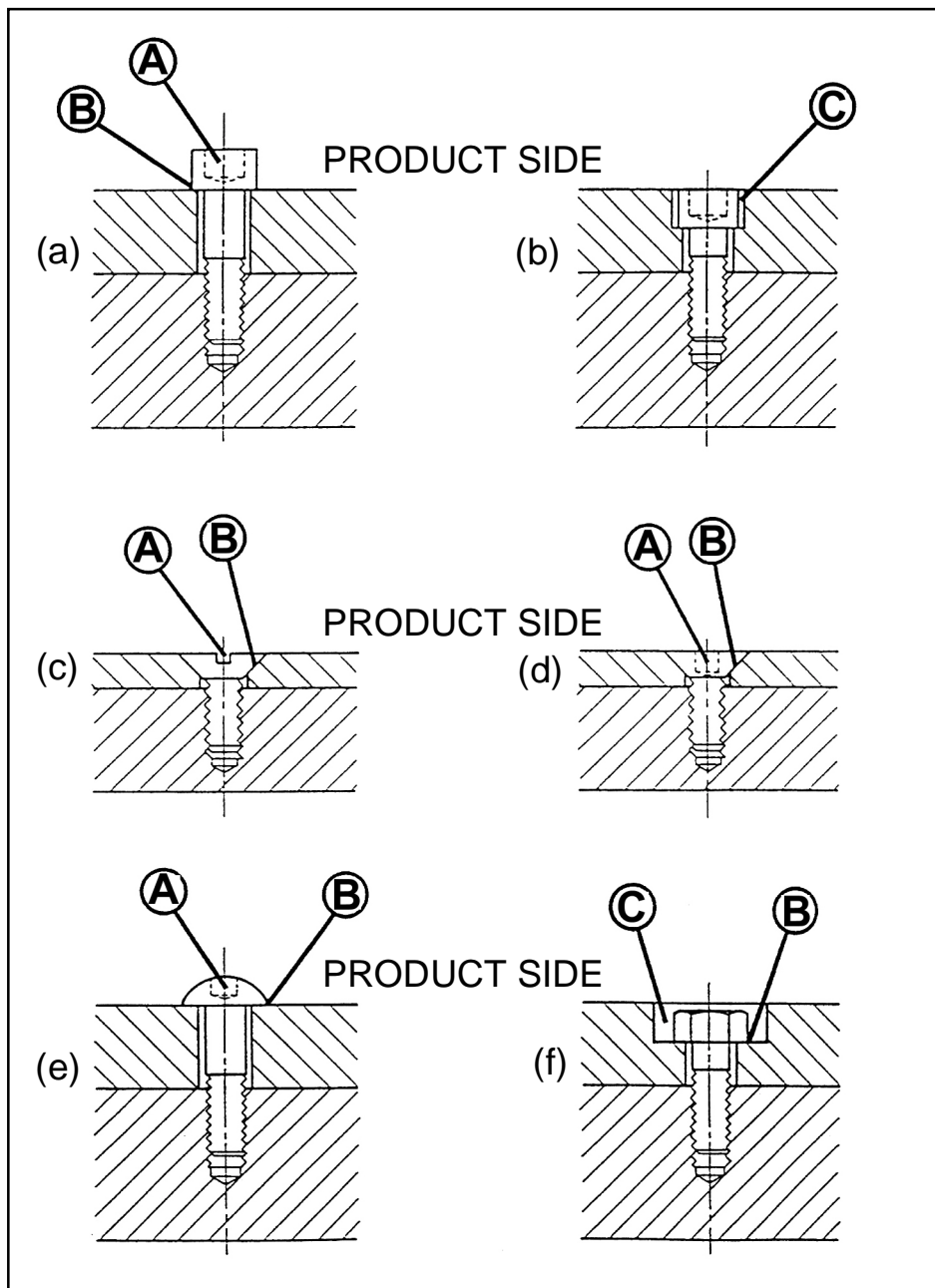


FIGURE 4: EXAMPLES OF HYGENIC FASTENERS

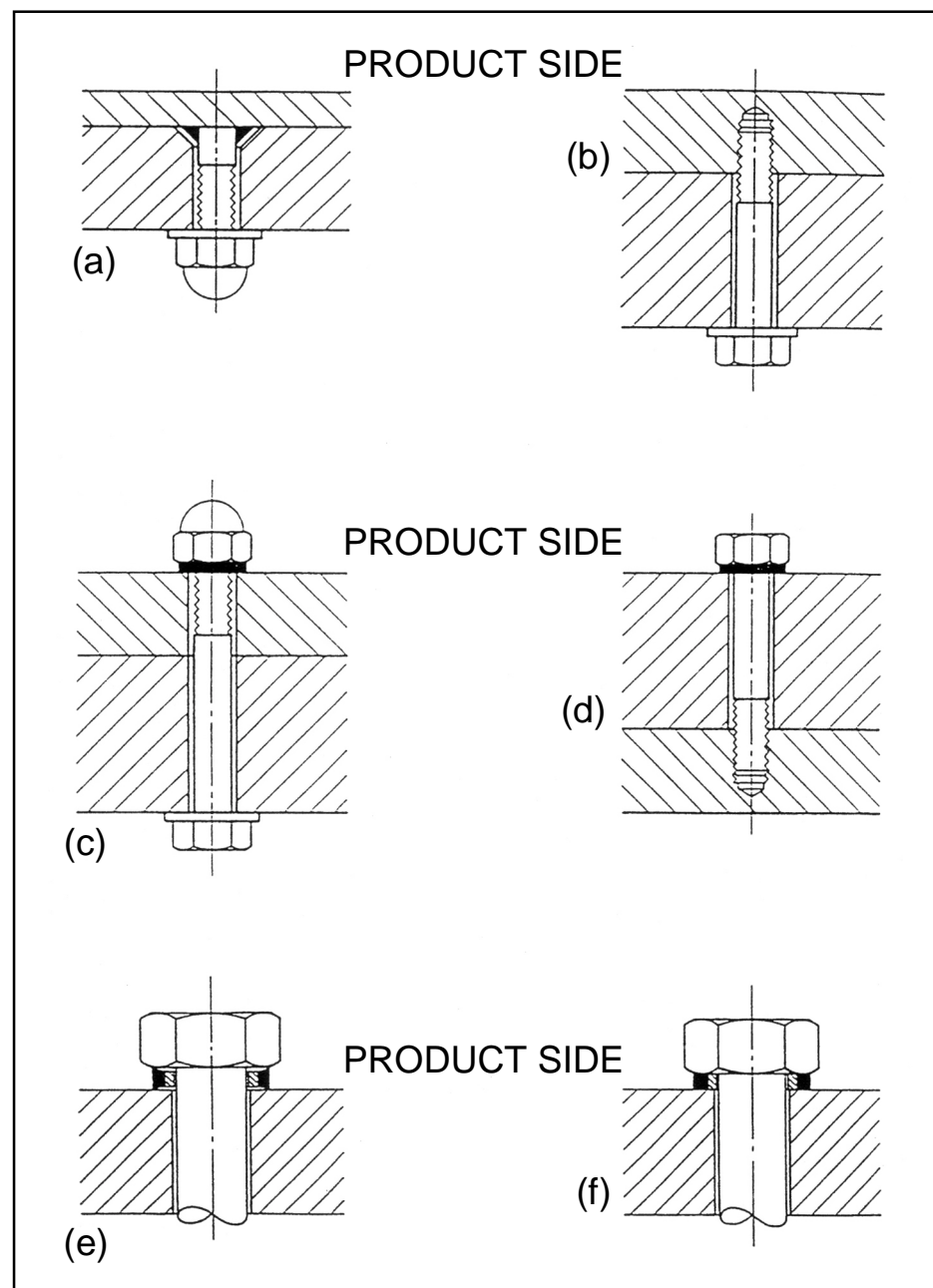


FIGURE 5: EQUIPMENT SHOULD BE SELF DRAINING OF PRODUCT AND CLEANING FLUIDS

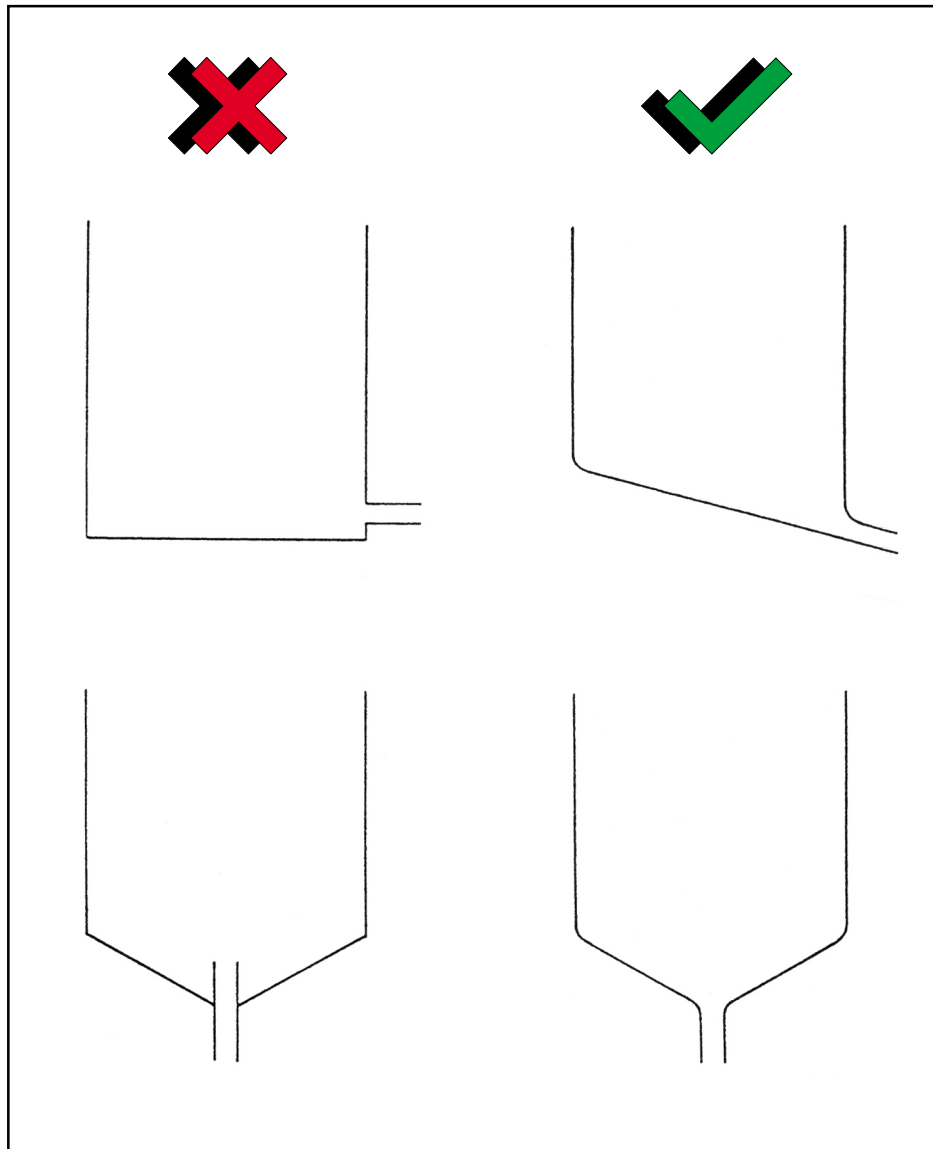


FIGURE 6: INTERNAL ANGLES AND CORNERS SHOULD BE RADIUSED TO FACILITATE CLEANING

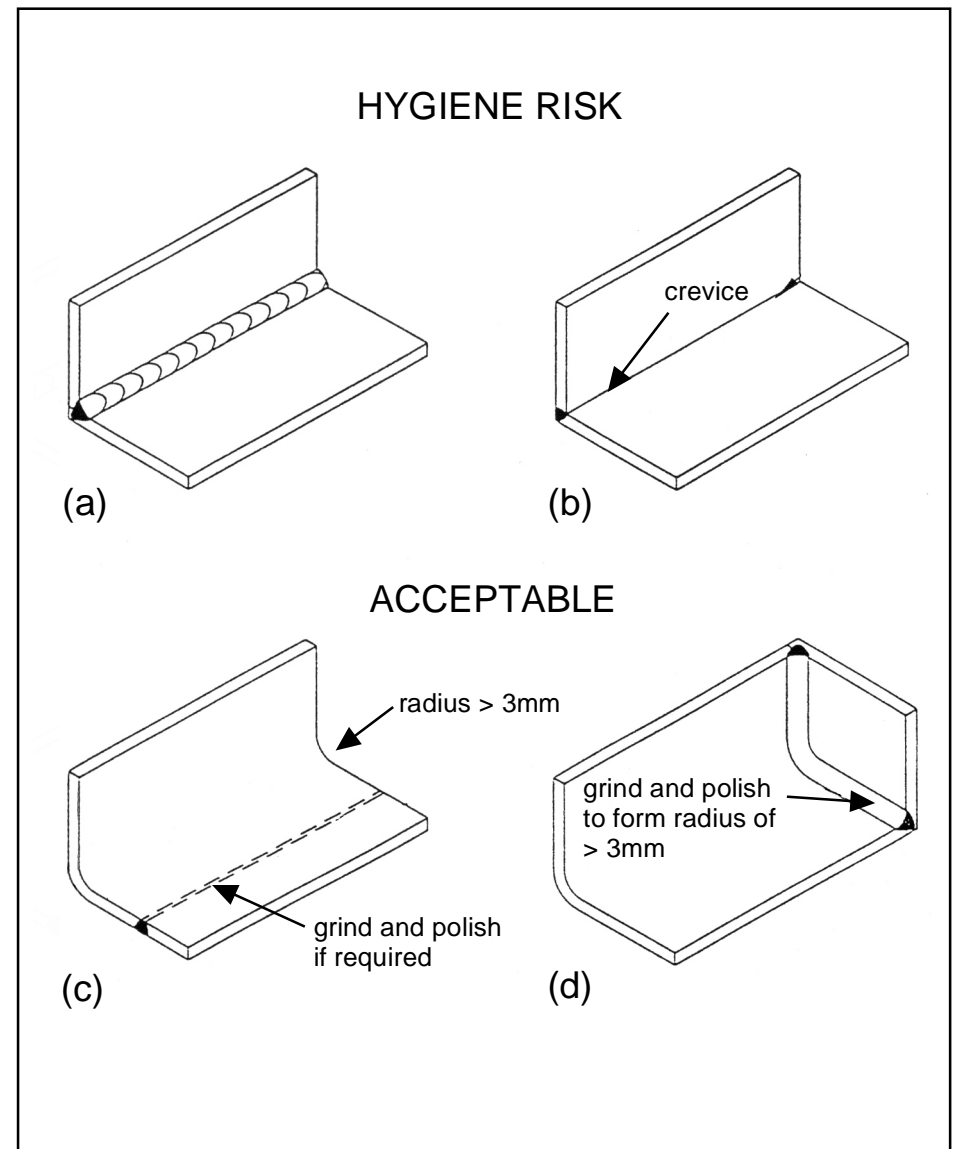


FIGURE 7: BEARINGS AND SHAFT SEALS TO INDICATE SEAL FAILURE AND OIL LEAKS

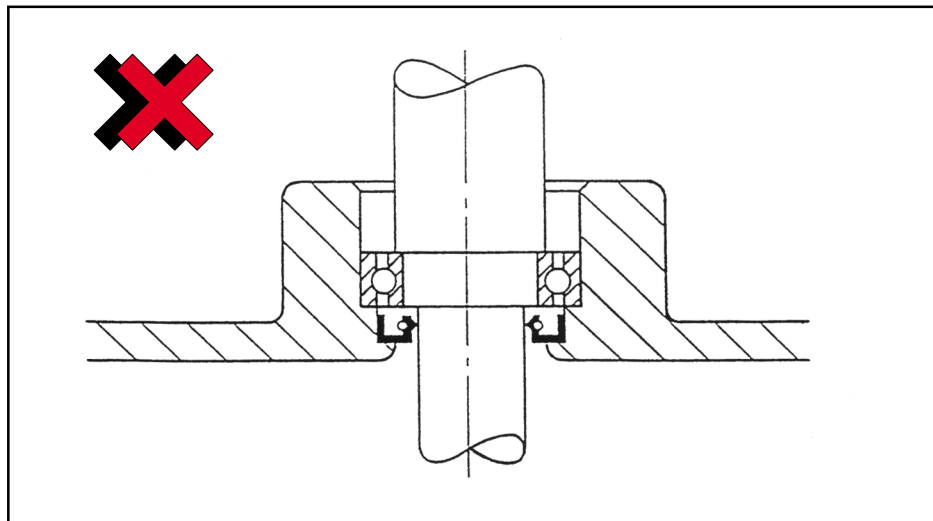
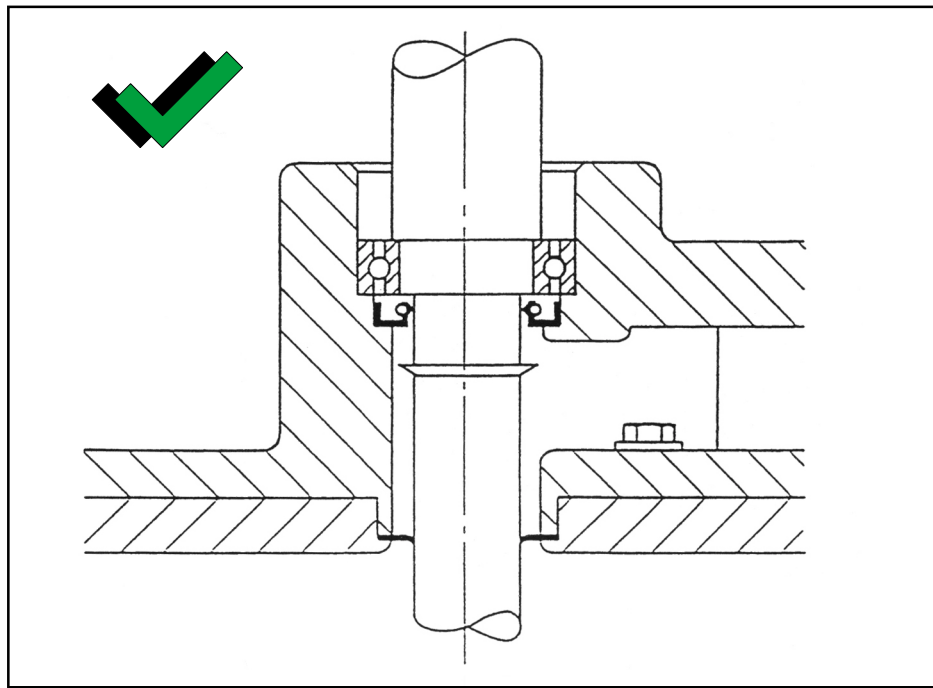


FIGURE 8: POOR POSITIONING OF INSTRUMENTATION TO CREATE DEAD LEGS

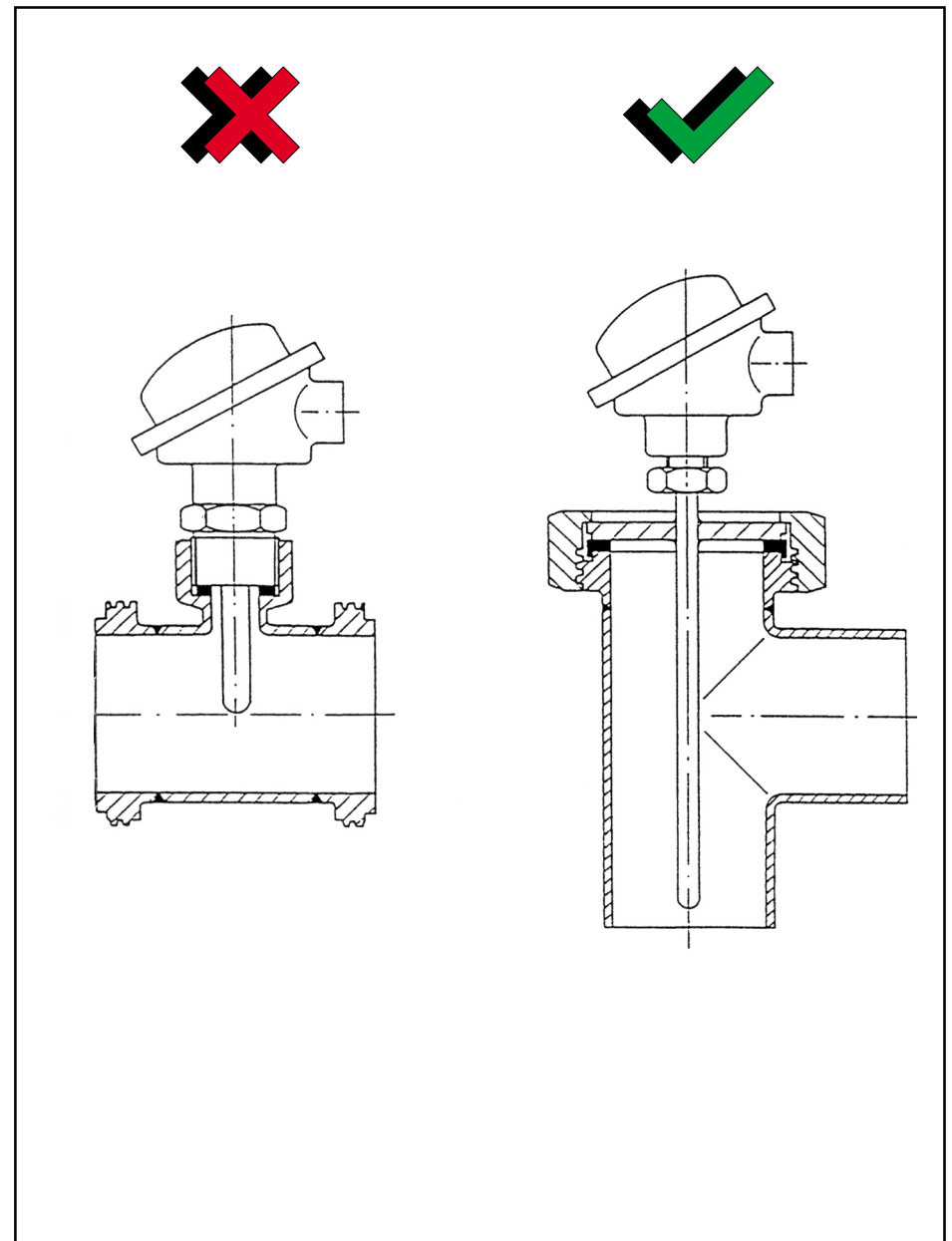


FIGURE 9: RUBBER CAPPED SWITCHES TO ALLOW EASY CLEANING

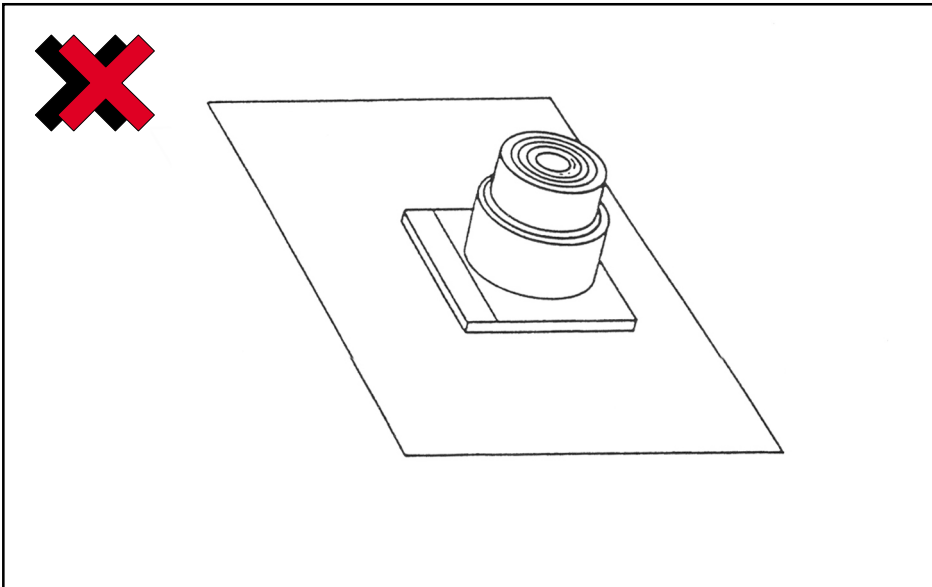
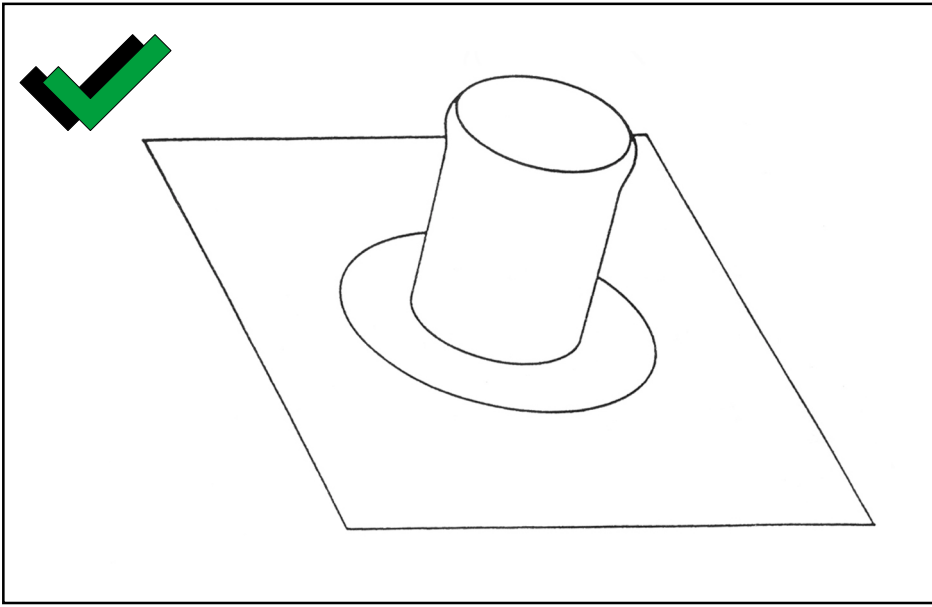


FIGURE 10: INSTALLATION OF EQUIPMENT TO PROVIDE EASE OF CLEANING AND SERVICING

