

3-A Sanitary Standards for Crossflow Membrane Modules, Number 45-02

*Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)*

Adopted November 16, 2003

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Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Crossflow Membrane Modules. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (3-A SSI), the United States Public Health Service (USPHS), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: trugh@3-a.org.

A SCOPE

A1 These standards cover the sanitary aspects of crossflow membrane modules for use with ultrafiltration, diafiltration, microfiltration and reverse osmosis systems for processing milk and milk products.

A2 In order to conform to these 3-A Sanitary Standards, membrane modules shall conform to the following design, material, and fabrication criteria.¹

B DEFINITIONS

B1 General

B1.1 *Product*: Shall mean milk, milk products or their fractions which are fractionated, concentrated or otherwise processed in this equipment and are to be used for human food. Either or both permeate or retentate are products.

B1.2 *Feed*: Shall mean that portion of the product that is about to enter the element. It may include recycled permeate, concentrate or retentate.

B1.3 *Permeate*: Shall mean that portion of the product which has passed through the membrane during processing.

B1.4 *Retentate*: Shall mean that portion of the product which does not pass through the membrane during processing.

B1.5 *Concentrate*: Shall mean that portion of the retentate that has left the system for disposition as final product or for recycling.

B1.6 *Membrane*: Shall mean a selectively permeable barrier which can separate a multi-component stream into fractions. This membrane may be polymeric, organic, inorganic or mineral.

B1.6.1 *Asymmetric Membrane*: Shall mean a membrane with an integral graded structure having a relatively consolidated surface skin underlain by a progressively more open spongy base.

B1.6.2 *Composite Membrane*: Shall mean a membrane which consists of several superimposed chemically or physically different layers. (Usually a composite membrane has a thin active

surface membrane of one material affixed to an asymmetric supporting membrane of another material.)

B1.7 *Membrane Support Material*: Shall mean porous material used for supporting the membrane.

B1.8 *Feed Channel Spacer*: Shall mean the open mesh screen used to maintain spacing between the membranes in elements and to define the channels through which retentate flows.

B1.9 *Permeate Carrier*: Shall mean the porous material used for conducting permeate away from the membrane to a collection point in the membrane element. The permeate carrier may be identical with the membrane support material.

B1.10 *Bypass Flow Restrictor*: Shall mean a device to direct feed material through the membrane elements' retentate flow channels while allowing a controlled amount to bypass these channels.

B1.11 *Module*: Shall mean that part of the membrane equipment that contains the membrane elements, element connectors, and external shrouds or housing. The module interfaces with the system pipelines carrying products to and from it.

B1.11.1 *Boundaries*: The boundaries of the membrane module are defined as the connections between:

- The feed manifold and the feed line(s) to the module.
- The retentate collection manifold and the retentate line(s) from the membrane module.
- The permeate collection manifold and the permeate line(s) from the membrane module.

B1.12 *Membrane Element*: Shall mean that part of the module which contains the membrane and is replaceable. (The element may be identical with the module and may contain the membrane support material and the permeate carrier.) There are six configurations of elements. These are:

- Tubular
- Spiral wound
- Plate and frame
- Parallel leaf
- Hollow fiber
- Monolithic ceramic

In these different configurations, the membrane support material may be part of the replaceable element or part of the module structure.

B1.13 *External Shroud*: Shall mean the impermeable shell which forms the exterior structure of the

¹ Use current revisions or editions of all referenced documents cited herein.

module. It may provide mechanical strength to resist internal operating pressure and may serve as a permeate collection vessel except for spiral modules where it serves as a feed conduit.

B1.14 *Membrane Element Seal(s)*: Shall mean that part of the module which is designed to prevent flow between the feed and retentate channel spaces and the permeate space.

B1.15 *Feed Channel Space*: Shall mean that flow channel within the module where product is introduced to the membrane element(s) for the purpose of concentration, fractionation or otherwise processed.

B1.16 *Retentate Channel Space*: Shall mean that flow channel within the module where products that do not flow through the membrane are discharged from the membrane element(s).

B1.17 *Permeate Channel Space*: Shall mean that part of the module where the permeate is collected as it flows from the membrane element(s).

B1.18 *Permeate Connector*: Shall mean that part of the module used for making a sanitary connection to the permeate collection line or manifold at the boundary of the module.

B1.19 *Feed Connector*: Shall mean that part of the module used for making a sanitary connection to the feed line(s) or manifold at the boundary of the module.

B1.20 *Retentate Connector*: Shall mean that part of the module used for making a sanitary connection to the retentate line(s) or manifold at the boundary of the module.

B1.21 *Cross Flow*: Shall mean the retentate flows in a direction parallel to the membrane surface.

B1.22 *Through Flow*: Shall mean entrance of fluid at one end of a passage and its removal at the opposite end so that the flowing fluid passes without dead areas through the intervening space.

B1.23 *System*: Shall mean all mechanical hardware, pumps, pipelines, instrumentation and the membrane module(s).

B1.24 *Membrane Process Equipment*: Shall mean equipment in which products are fractionated, concentrated or otherwise processed by a membrane.

B1.25 *Manifold*: Shall mean that part of the system to which connections are made to bring product, permeate, or cleaning solution to and from the module.

B2 SURFACES

B2.1 *Product Contact Surface*: Shall mean all surfaces that are exposed to the product or any of its fractions (whether feed, concentrate, retentate, or permeate) and surfaces from which liquid may drain, drop, or be drawn into the products.

B2.2 *Nonproduct Contact Surface*: Shall mean all other exposed surfaces.

B3 CLEANING

B3.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall denote cleaning, solely by circulation and/or flowing chemical and/or enzyme cleaning solutions and water rinses onto, over, and/or through the surfaces to be cleaned, by mechanical means.

B4 TUBULAR MODULE

B4.1 *Tubular Module*: Shall mean a module whose membrane elements carry retentate in individual, separated, rigid tubes of about 0.2 inch or larger inside diameter. These tubes may be single or multiple elements within an external shroud. (See Appendix F1)

B4.2 *"U" Bend*: Shall mean that device attached to the end of a tubular element used to reverse the direction of retentate flow and direct it into another tubular element.

B4.3 *Ferrule*: Shall mean the fitting(s) attached to the end of a tubular element used for making sanitary connection to a "U" Bend or manifold.

B4.4 *Membrane Array*: Shall mean a parallel array of one or more hollow single tubular or multi-channel tubular membrane elements contained within the module's external shroud.

B4.5 *Header*: Shall mean the device at the end of a multitubular element that holds the tubes in fixed array and into which they are sealed. Headers may be potted or cast in place, molded, or machined.

- B4.6 *Grommet*: Shall mean the elastomeric part used to seal tubes into headers. It acts as a membrane element seal.
- B4.7 *Expander*: Shall mean that device which when inserted into the end of the tube expands it against the grommet and the grommet against the tube sheet to effect a seal.
- B4.8 *Membrane Element Support Tube*: Shall mean that part of the module which closely supports the membrane element. This tube may be made of a porous composite or stainless steel.
- B4.9 *Module End Plate*: Shall mean part of a multi-tube into which the membrane element support tubes are fitted. (Single tube elements may have an individual connector like a ferrule.)
- B4.10 *Header Cap*: Shall mean that device fitted to the end of a module, used to direct the flow-path of the feed and retentate through the tubular membrane elements in the module. The header cap may:
- Direct the flow-path through all the tubular elements in parallel; or
 - Connect all the tubular elements in series by means of internally-molded U-bends; or
 - Separate the flow into two or more parallel paths each consisting of two or more tubular elements connected in series by means of internally-molded U-bends.
- B4.11 *Supported Metallic Oxide Membrane Module*: Shall mean a tubular module whose elements are formed from a rigid porous support on which has been deposited a metallic oxide coating to form the membrane. (See Appendix F1.3)
- B4.11.1 *End Tubular Plate*: Shall mean the drilled plate which holds the membrane elements in position and provides the surface to support and seal the membrane element gasket and counter plate.
- B4.11.2 *Counter Plate*: Shall mean the bored plate used to compress the membrane element gasket and to conduct retentate flows to the inlet of membrane elements.
- B4.11.3 *Inner Spacer*: Shall mean the device used to hold the membrane elements in the correct position in the interior of the module.

B5 Spiral Wound Module

- B5.1 *Spiral Wound Module*: Shall mean a module whose element is formed of leaves of membrane, membrane support, feed channel spacer, and permeate carrier wound in spiral fashion around a central permeate collection tube. (See Appendix F2)
- B5.2 *Anti-Telescope Device (ATD)*: Shall mean a support for spiral type elements to prevent their layers from sliding past each other when the element is in operation.
- B5.3 *Element Connector or Interconnector*: Shall mean the device used within modules to connect together membrane elements. In some embodiments, the element connector may be incorporated into the anti-telescoping device.
- B5.4 *Permeate Collection Tube*: Shall mean a perforated tube usually centrally located in a spiral membrane element into which permeate is conducted from the permeate carrier. The permeate collection tube conducts permeate out of the element.
- B5.5 *Connector/Interconnector Seals*: Shall mean the device for forming a seal between the module connector and the permeate collection tube.
- B5.6 *End Cap*: Shall mean the cover at the end of the external shroud which connects with the permeate collection tube.
- B5.7 *Glue Seams*: Shall mean the areas at each edge of a leaf to which adhesive is applied to bind the materials together and form a seal. (Note that each leaf generally has two end glue seams and one axial glue seam so named because of their relative locations in the finished element.)
- B5.8 *Leaf*: Shall mean the sandwich of membrane, membrane support material, permeate carrier and feed channel spacer that are multiply laid up and wound around the permeate collection tube to form a spiral element.
- B5.9 *Fold Line*: Shall mean the location adjacent to the permeate tube at which the membrane is bent 180° back upon itself for insertion into the spiral wound membrane element.
- B5.10 *Crease Protection Materials*: Shall mean materials applied to the fold area, on either side of the membrane to prevent leakage of feed into the

permeate in the event of damage to the membrane.

- B5.11 *Stitching Material*: Shall mean thread used to sew and attach adjacent leaves of the permeate carrier material to maintain leaf spacing during fabrication.

B6 **Plate and Frame Module**

- B6.1 *Plate and Frame Module*: Shall mean a module formed of multiple sandwiches of flat membrane elements held together by an external supporting frame. (See Appendix F3)

- B6.2 *Module of Plate and Frame Design*: Shall mean that part of the membrane processing system that contains the membrane elements of plate and frame design. The module consists of:
- Membrane elements.
 - Supporting frame.
 - Permeate collection manifold.
- The module interfaces with the system pipelines carrying product to and from it.

- B6.3 *Membrane Support Plate*: Shall mean that part of the membrane element which provides mechanical support for the membrane. The membrane support plate receives the permeate from the membranes and delivers it to the permeate collection manifold.

- B6.4 *Lock Rings*: Shall mean that part of the membrane element which can hold the membrane support plate and the two attached membranes together and form a barrier between the permeate and the retentate.

- B6.5 *Spacer Plate*: Shall mean that part of the membrane element which provides the necessary space to create the circulation channels across the membrane. The spacer plate separates two adjacent membrane support plates with membranes and lock rings.

- B6.6 *Section Plate*: Shall mean that part of the membrane element that makes it possible to divide the module into sections.

- B6.7 *Supporting Frames*: Shall mean that part of the module which internally or externally holds all the membrane elements within the module pressed together and provides the necessary support. The supporting frame consists of:
- End flanges.
 - Connecting bolt(s).

- Supporting legs.

- B6.7.1 *End Flanges*: Shall mean those parts of the supporting frame which hold together all the membrane elements within the module and provide the inlet connection from the feed line(s) to the module and the outlet connection from the module to the retentate line(s). The end flanges may include a flow distributing ring.

- B6.7.2 *Connecting Bolt(s)*: Shall mean that part(s) of the supporting frame which connects the end flanges and holds together the stack of membrane elements.

- B6.7.3 *Supporting Legs*: Shall mean that part of the supporting frame which provides means for support of the whole module.

- B6.8 *Permeate Collection Manifold*: Shall mean that part of the membrane module that receives the permeate from the membrane element. The manifold can be an integral part of the membrane element or be connected to this by flexible hose.

B7 **Parallel Leaf Module**

- B7.1 *Parallel Leaf Module*: Shall mean a module formed of multiple membrane elements whose membrane has been permanently bonded to a rigid support plate. (See Appendix F.4)

- B7.2 *Membrane Cartridge*: Shall mean a multiple of membrane elements joined to form a unit to be inserted into a membrane housing.

- B7.3 *Permeate Fitting*: Shall mean a device for communicating permeate from the membrane cartridge to the permeate tubing. It may hold and seal the membrane cartridge in situ.

- B7.4 *Membrane Element Retaining Clamp*: Shall mean a device for holding together a multiple of membrane elements (membrane element stack). The retaining clamp consists of two rigid nonporous plates, one on each side of the membrane element stack, and a tie rod that holds the two rigid plates together.

B8 **Hollow Fiber Module**

- B8.1 *Hollow Fiber Module*: Shall mean a module whose membrane elements are formed of a multiplicity of flexible tubules generally less than 0.2 inches (5.1 mm) in inside diameter and potted

or otherwise bound together into a common header. (See Appendix, F5)

- B8.2 A module of hollow fiber design shall consist of the following components:
- Membrane cartridge.
 - Process manifold adapter assembly.
 - Permeate adapter assembly.

B8.3 *Membrane Cartridge*: Shall mean a parallel array of hollow fiber membrane elements which are housed in a plastic or metallic cartridge assembly and fixed at both ends via an adhesive tubesheet. The hollow fiber membrane element is a self-supporting structure. Therefore, in this configuration, the membrane element and support are an integral part of the membrane cartridge.

B8.4 *Process Manifold Adapter Assembly*: Shall mean that part of the membrane module that connects the membrane cartridge to the system pipelines that carry product to and from the cartridge. This assembly consists of a manifold adapter, V-band clamp and a gasket.

B8.5 *Permeate Adapter Assembly*: Shall mean that part of the membrane module that connects the permeate outlets of each membrane cartridge to the permeate collection manifold. This assembly consists of a permeate adapter, V-band clamp and gasket.

B8.6 *Membrane Sheath*: Shall mean that part of the membrane cartridge which provides mechanical support to the hollow fiber membrane elements.

B8.7 *Tube Sheet*: Shall mean the thermoset adhesive compound that is used to seal the hollow fiber membrane elements into the membrane housing.

B9 Monolithic Ceramic Modules

B9.1 *Monolithic Ceramic Module*: Shall mean a module that contains membrane elements wherein the membrane and the support are ceramic bonded structures which are in turn joined by ceramic bonds such that the joined membrane and support are monolithic in nature. (See Appendix F6)

B9.2 *Ceramic Bond*: Shall mean the joining of ceramic materials by heat to produce fusion or sintering between particles.

B9.3 *Ceramic Membrane Support*: Shall mean a ceramic porous base structure used to support a

thinner and finer more uniformly graded porous structure. A membrane element may contain one or more supports all joined by ceramic bonds.

B9.4 *Membrane Element Retainer*: Shall mean that part of the module which is designed to retain in place the membrane element seals and membrane element(s).

B9.5 *Membrane Element Fixed Retainer*: Shall mean a retainer which is a part of the shroud.

B9.6 *Membrane Element Removable Retainer*: Shall mean a retainer which is secured to the external shroud by mechanical means and may be removed for membrane element seal or membrane element cleaning or replacement.

B9.7 *Membrane Element Array*: Shall mean a parallel array of one or more single tubes or multichannel membrane elements contained within the module shroud.

B9.8 *Uniform Transmembrane Pressure System*: Shall mean process equipment including pumps, valves, flow meters, and pressure sensors used to monitor feed-to-retentate pressure drop and adjust permeate recirculation flow to create a corresponding permeate pressure drop, thereby maintaining a uniform pressure differential from feed side to permeate side of the membrane along the length of the module.

C MATERIALS

C1 Membrane product contact surfaces, membrane support material, permeate carrier material, stitching and crease protection materials, shall be constructed of materials meeting one of the following:

- Title 21, Part 177 of the Code of Federal Regulations, or
- Generally recognized as safe (GRAS Title 21, Part 182 of the Code of Federal Regulations) or affirmed (GRAS Title 21 Part 186 of the Code of Federal Regulations), or
- Otherwise be approved by the Food and Drug Administration for food contact.

Users may rely on vendor certification that proprietary materials meet these requirements.

C2 All product contact surfaces except those listed in C1 shall be:

- C2.1 Plastic or plastic-like materials conforming to applicable provisions of 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-, or
- C2.2 Stainless steel of the American Iron and Steel Institute (AISI) 300 series² or the corresponding Alloy Cast Institute (ACI)³ types. (See Appendix G.) or types which under conditions of intended use are at least as corrosion-resistant as stainless steel of the foregoing types and are non-toxic and non-absorbent, except that;
- C2.2.1 Rubber and rubber-like materials may be used for gaskets, seals, flexible product connectors, and O-rings.
- C2.2.2 Rubber and rubber-like materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.
- C2.2.3 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to conditions encountered in the environment of intended use in cleaning and bactericidal treatment.
- C2.2.4 Fiberglass reinforced composites may be used where required for strength such as for membrane element support tubes.
- C2.2.5 Adhesive and potting materials in product contact surfaces including edge contact shall meet the requirements of Title 21, Part 175.105 or part 175.300 of the Code of Federal Regulations and be inert under conditions of operation, cleaning and sanitizing.
- C2.2.6 Composite methods of construction may be used to produce elements with ceramic materials for supports different than the materials used for the membrane. Such composites shall retain the

ceramic bond properties between multiple supporting layers.

- C2.2.6.1 Ceramic materials selected shall be such that the membrane ceramic bonds attach the membrane to the support with sufficient mechanical integrity that it does not peel, chip or spall under processing or cleaning and sanitizing conditions.
- C3 All materials used shall be inert, nontoxic, insoluble in the product and in cleaning and sanitizing solutions. They shall be resistant to scratching, scoring, and distortion when exposed to the conditions of intended use and of cleaning and sanitizing.
- C4 Nonproduct surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. Nonproduct surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product and nonproduct contact surfaces shall not be painted.

D FABRICATION

D1 General

- D1.1 The module shall be constructed such that the element can be mechanically cleaned on both retentate and permeate sides.
- D1.2 Membrane elements designed and constructed to fit into a shroud shall be without dead spaces so that they and it can be mechanically cleaned by a through flow of cleaning and sanitizing solutions.
- D1.3 The design and fabrication of the membrane element seals and retainers shall take into consideration the combined effects of differential thermal expansions, between the shroud, if any, and the elements, hydraulic shock and thermal shock such that the membrane elements are free of excessive compressive or tensile forces. The membrane element seals or supports, as the case may be, shall be designed in such a manner as to firmly support the membrane elements but allow for elastic axial and lateral movements to prevent undue stress and strains which could lead to failure of the membrane.
- D1.4 The membrane shall be firmly attached to its support material or have sufficient mechanical integrity that it does not peel, spall or chip.

² The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, Table 2-1. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086.

³ Steel Founders' Society of America, Cast Metals Federation Bldg., 455 State St., Des Plaines, IL 60016.

D1.5 Grommets or seals against the membrane surface must be made against impermeable support materials or alternatively against porous materials that can be mechanically cleaned or demonstrated to be effectively sealed.

D1.6 Surfaces

D1.6.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form except those in the membrane element. (See Appendix H.)

D1.6.2 Permanent metallic joints in product contact surfaces shall be continuously welded, except that tubes may be expanded and rolled into tube sheets. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets free of imperfections such as pits, folds, and crevices. When tubes are expanded and rolled into tube sheets, the resulting joint shall be completely rigid and without pockets or crevices. Alternatively metallic joints, if used, shall be in accord with the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605-.

D1.6.3 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound, so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, the rubber and rubber-like material or plastic material does not separate from the base material to which it is bonded.

D1.6.4 Appurtenances having product contact surfaces shall be easily removable for cleaning and inspection, or shall be mechanically cleanable.

D1.6.5 Membrane modules shall be designed for chemical and mechanical cleaning and sanitizing of all product contact surfaces.

D1.6.6 There shall be no exposed threads on product contact surfaces.

D1.6.7 Nonproduct contact surfaces shall be smooth, free of pockets and crevices and be readily cleanable

and those to be coated shall be properly prepared for coating.

D1.6.8 When used, fiberglass shall be completely encapsulated with no exposed fibers with a polymeric coating meeting the requirements of Title 21, Section 175 or 177 of the Code of Federal Regulations.

D1.7 Connections

D1.7.1 Product connections to manifolds shall meet 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63- except that these connections shall be made in a sanitary manner with rigid and/or flexible connectors provided the materials conform to the applicable provisions of 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

D1.7.2 Flexible permeate tubes are permitted and shall have connections that are crevice free. Internal diameter may be selected to suit mechanical requirements.

D1.7.3 Hose clamps shall be easily disassembled and assembled.

D1.8 Gaskets and Seals

D1.8.1 Gaskets having a product contact surface shall be removable or permanently bonded to the surface. Any gasket groove or gasket retaining groove except in the bonded area shall be no deeper than its width and shall not exceed 1/4 inch (6.35 mm) in depth or be less than 1/4 inch (6.35 mm) wide except those for standard O-Rings smaller than 1/4 inch (6.35 mm).

D1.8.2 Grooves in gaskets shall be no deeper than their width and the minimum radius of any internal angle shall not be less than 1/8 inch (3.18 mm) unless the gasket is readily removable and reversible for cleaning.

D1.8.3 Gasket grooves or gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 inch (6.35 mm) in depth and, except those for standard O-rings smaller than 1/4 inch (6.35 mm), shall be at least 1/4 inch (6.35 mm) wide.

D1.8.4 Element seals that are potted, poured, or otherwise cast in place shall have joints that are

fully filled such that there are no voids pits or cavities.

- D1.8.5 Element seals of the grommet type shall be one piece construction and shall firmly fit the mating surfaces such that there are no crevices or voids.

D1.9 Radii

- D1.9.1 Internal angles on product contact surfaces shall have minimum radii of 1/16 inch (1.59 mm), except:

- D1.9.1.1 Gasket recesses and grooves in which all sharp corners shall be avoided.

- D1.9.1.2 The minimum radii in gasket grooves or gasket retaining grooves other than those for bonded gaskets or for standard 1/4 inch (6.35 mm) and smaller O-rings shall be not less than 1/8 inch (3.18 mm).

- D1.9.1.3 The minimum radii in grooves for standard 1/4 inch (6.35 mm) O-rings shall be not less than 3/32 inch (2.38 mm) and for standard 1/8 inch (3.18 mm) O-rings shall be not less than 1/32 inch (0.794 mm). In either case the internal product contact surface must be readily available for cleaning and inspection.

- D1.9.1.4 For essential functional reasons, smaller internal angles or radii may be used provided the product contact surfaces are demonstrated to be mechanically cleanable.

D2 Tubular Modules

- D2.1 The element shall fit into its shroud without dead spaces so that it can be completely mechanically cleaned by through flow of cleaning solutions or placed in the shroud so that the exterior can be flooded or sprayed with cleaning solution to achieve effective cleaning.

- D2.2 Ferrules that are potted, swaged or otherwise attached to tubes must have joints fully filled so that there are no voids.

D3 Spiral Wound Modules

- D3.1 Glue seams in spiral elements shall be free of indentations or protrusions that may interfere with cleaning and shall be of sufficiently uniform width not to impede permeate flow.

- D3.2 The cut surfaces of the element shall be completely within the glue area.

- D3.3 Elements shall be tightly wound and have interior flow channels that are uniform in height.

- D3.4 Elements shall be equipped with a bypassing flow restrictor to allow a portion of the feed stream to flow through the annulus between the element and its external shroud to eliminate an annular dead-end condition and to keep that area clean.

- D3.5 The membrane support material and the permeate carrier material are porous. Visual inspection of an element from time to time after cleaning shall be necessary to confirm that cleaning and sanitation are effective.

- D3.5.1 Permeate carrier material may be fixed in position with porous materials by stitching, intermittent ultrasonic attachment, or other methods, provided that the areas are open to the flow and penetration of cleaning solutions.

- D3.6 Shrouds for spiral elements shall be fabricated of stainless steel or plastic. All joints shall be free from flaws and voids and flush with adjoining surfaces.

- D3.7 The anti-telescope device and module inter-connectors shall be designed in such a way that element surfaces can be mechanically cleaned and no dead-end areas are created.

- D3.8 Inter-connector seals shall be tight with no open crevices and shall be made against impervious surfaces.

- D3.9 Crease protection materials conforming to Sections C.1 or C.2.2.5 such as tape may be present at the fold lines.

- D3.10 Feed channel spacer material shall be located as close as practical to the fold line to promote flow through the fold line area.

D4 Plate and Frame Modules

- D4.1 Membrane surface shall be smooth, flat and devoid of wrinkles.

- D4.2 The membrane, support plates, and spacer plates shall be tightly stacked and have a uniform flow in the retentate flow channels.

D4.3 Elastomeric seals, locking rings and gaskets shall be a sanitary design with no open crevices and made against impervious surfaces or demonstrated to be effectively sealed.

D4.4 End-flange(s), spacer, section, and support plates, permeate manifolds, and lock rings shall be fabricated of stainless steel or plastic.

D4.5 The membrane support plates may be porous. Visual inspection of the plates from time to time, after cleaning, shall be necessary to ensure cleaning and sanitation procedures are effective.

D4.6 The permeate outlet shall be positioned in such a way that when assembled, air is not entrapped in the plate.

D5 **Parallel Leaf**

D5.1 The membrane (of the membrane element) shall be firmly attached to the membrane support plate with even and continuous leak-proof bonds of sufficient mechanical integrity to remain free of voids, peel backs or delaminations. The transition from protruding support plate surface to membrane surface shall be smooth.

D5.2 Membrane surface shall be smooth, flat and devoid of wrinkles.

D5.3 Membrane cartridges shall be tightly stacked and have uniform retentate flow channels.

D5.4 When bypassing flow restrictors are employed, they shall allow a portion of the feed stream to flow through the annulus between the membrane cartridge and the membrane housing to keep that area clean.

D5.5 Elastomeric seals and gaskets should be of sanitary design with no open crevices, and made against impervious surfaces, or alternatively, against porous materials that can be mechanically cleaned or demonstrated to be effectively sealed.

D5.6 Housings and membrane element retaining clamps shall be fabricated of stainless steel or plastic.

D5.7 The membrane support material and the membrane element permeate carrier material are porous. Visual inspection of an element from time to time, after cleaning, shall be necessary to assure cleaning and sanitation procedures are effective.

D6 **Hollow Fiber Modules**

D6.1 The manifold adapter assembly shall utilize sanitary type gasket designs and stainless steel clamps at both the membrane cartridge and system feedline interface connections.

D6.2 The permeate adapter assembly shall utilize sanitary type gasket designs and stainless steel clamps at both the cartridge permeate outlet and permeate collection manifold interface connections.

D6.3 The surface of the epoxy or thermoset adhesive tube sheet shall be smooth and free of pits, voids or crevices.

D6.4 Membrane cartridge housings shall be fabricated of plastic or stainless steel.

D7 **Monolithic Ceramic Modules**

D7.1 Ceramic membrane elements shall be a monolithic construction incorporating both the support and the membrane into a one-piece element resistant to delamination, peeling, chipping or spalling of the membrane.

D7.2 Plastic balls may be used to fill the permeate space when the module is used with a uniform transmembrane pressure system, provided that:

D7.2.1 The permeate space shall have inlet and outlet ports positioned adjacent to the feed and retentate ends of the module, respectively, to allow recirculation of permeate fluid through the space by means of a uniform transmembrane pressure system.

D7.2.2 Plastic balls shall be relatively free of geometrical imperfections, be of relatively uniform diameter, and be equal to or greater than 0.140 in. (3.50 mm).

D7.2.3 Plastic balls shall be readily removable for inspection.

E **INSTALLATION, OPERATION AND CLEANING**

E1 Membrane modules shall be installed, operated and mechanically cleaned in a membrane processing system meeting the requirements of the 3-A Accepted Practice for the Sanitary Construction, Installation, and Cleaning of Membrane Processing Systems for Milk and Milk Products, Number 610-.