

3-A Sanitary Standard for Crossflow Membrane Modules, Number 45-03

Standards Developing Organizations

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Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

3-A Sanitary Standards Inc. (SSI), its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Appendix illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Appendix illustrations are non-normative.

Metric conversions are provided for convenience and are not intended to be mandatory.

The Appendix is an advisory or informative section unless specifically cited in the Materials or Fabrication Section as requiring conformance.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Crossflow Membrane Modules.

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, and regulatory agencies, and by other SDOs to assure that adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

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

It is our intent to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome at any time for consideration by 3-A SSI. Please forward comments to: 3-A SSI, 6888 Elm Street, Suite 2D, McLean, VA 22101-3829, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

- A1 This 3-A Sanitary Standard covers the sanitary aspects of crossflow membrane modules for use with ultrafiltration, diafiltration, microfiltration, nanofiltration and reverse osmosis systems. Product enters the feed connector and exits the retentate connector and the permeate connector.
- A2 To conform to this 3-A Sanitary Standard, membrane modules shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as appropriate, and the current revisions or editions of all referenced documents cited herein.

B NORMATIVE REFERENCES

- B1 The following listed 3-A Sanitary Standards, 3-A Accepted Practices and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document unless necessary to describe special considerations.

B2 3-A Sanitary Standards**Doc. No. Title (3-A Sanitary Standard for:)**

00-	General Requirements
33-	Metal Tubing
62-	Hose Assemblies
63-	Sanitary Fittings
74-	Sensors and Sensor Fittings and Connections
88-	Machine Leveling Feet and Supports

B3 3-A Accepted Practices**Doc. No. Title (3-A Accepted Practice for:)**

605-	Permanently Installed Product and Solution Pipelines and Cleaning Systems
610-	Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems

C DEFINITIONS

For the purpose of this Standard, the most current approved version of the *3-A Sanitary Standard for General Requirements, 00-* shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications or exclusions.

- C1 *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.
- C2 *Bypass Flow Restrictor:* A device to direct feed material through the membrane elements' retentate flow channels while allowing a controlled amount to bypass these channels.
- C3 *Concentrate:* That portion of the retentate that has left the system for disposition as final product or for recycling.
- C4 *Cross Flow:* The retentate flows in a direction parallel to the membrane surface.
- C5 *External Shroud:* The impermeable shell which forms the exterior structure of the 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.
- C6 *Feed:* That portion of the product that is about to enter the element. It may include recycled permeate, concentrate or retentate.
- C7 *Feed Channel Space:* That flow channel within the module where product is introduced to the membrane element(s) for the purpose of concentration, fractionation or otherwise processed.
- C8 *Feed Channel Spacer:* The open mesh screen used to maintain spacing between the membranes in elements and to define the channels through which retentate flows.
- C9 *Feed Connector:* That part of the module used for making a sanitary connection to the feed line(s) or manifold at the boundary of the module.
- C10 *Manifold:* That part of the system to which connections are made to bring product, permeate, or cleaning solution to and from the module.
- C11 *Membrane:* A selectively permeable barrier which can separate a multi-component stream into fractions. This membrane may be polymeric, organic, inorganic or mineral.
- C11.1 *Asymmetric Membrane:* A membrane with an integral graded structure having a relatively consolidated surface skin underlain by a progressively more open spongy base.

- C11.2 *Composite Membrane:* 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.)
- C12 *Membrane Element:* 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.
- C13 *Membrane Element Seal(s):* That part of the module which is designed to prevent flow between the feed and retentate channel spaces and the permeate space.
- C14 *Membrane Process Equipment:* Equipment in which products are fractionated, concentrated or otherwise processed by a membrane.
- C15 *Membrane Support Material:* Porous material used for supporting the membrane.
- C16 *Module:* 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.
- C17 *Permeate:* That portion of the product which has passed through the membrane during processing.
- C18 *Permeate Carrier:* 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.
- C19 *Permeate Channel Space:* That part of the module where the permeate is collected as it flows from the membrane element(s).
- C20 *Permeate Connector:* That part of the module used for making a sanitary connection to the permeate collection line or manifold at the boundary of the module.
- C21 *Product Contact Surface:* 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.
- C22 *Retentate:* That portion of the product which does not pass through the membrane during processing.

- C23 *Retentate Channel Space:* That flow channel within the module where products that do not flow through the membrane are discharged from the membrane element(s).
- C24 *Retentate Connector:* That part of the module used for making a sanitary connection to the retentate line(s) or manifold at the boundary of the module.
- C25 *System:* All mechanical hardware, pumps, pipelines, instrumentation and the membrane module(s).
- C26 *Through Flow:* The 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.

Tubular Module

- C27 *Counter Plate:* The bored plate used to compress the membrane element gasket and to conduct retentate flows to the inlet of membrane elements.
- C28 *End Tubular Plate:* 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.
- C29 *Expander:* 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.
- C30 *Ferrule:* The fitting(s) attached to the end of a tubular element used for making sanitary connection to a "U" Bend or manifold.
- C31 *Grommet:* The elastomeric part used to seal tubes into headers. It acts as a membrane element seal.
- C32 *Header:* The device at the end of a multi-tubular 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.
- C33 *Header Cap:* 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:
- a. Direct the flow-path through all the tubular elements in parallel; or
 - b. Connect all the tubular elements in series by means of internally-molded U-bends; or
 - c. 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.
- C34 *Inner Spacer:* The device used to hold the membrane elements in the correct position in the interior of the module.
- C35 *Membrane Array:* A parallel array of one or more hollow single tubular or multi-channel tubular membrane elements contained within the module's external shroud.
- C36 *Membrane Element Support Tube:* That part of the module which closely supports the membrane element. This tube may be made of a porous composite or stainless steel.

- C37 *Module End Plate*: 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.)
- C38 *Supported Metallic Oxide Membrane Module*: 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 6.4)
- C39 *Tubular Module*: 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 6.1)
- C40 *"U" Bend*: 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.

Spiral Wound Module

- C41 *Anti-Telescope Device (ATD)*: A support for spiral type elements to prevent their layers from sliding past each other when the element is in operation.
- C42 *Connector/Interconnector Seals*: The device for forming a seal between the module connector and the permeate collection tube.
- C43 *Crease Protection Materials*: 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.
- C44 *Element Connector or Interconnector*: The device used within modules to connect together membrane elements. In some embodiments, the element connector may be incorporated into the anti-telescoping device.
- C45 *End Cap*: The cover at the end of the external shroud which connects with the permeate collection tube.
- C46 *Fold Line*: 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.
- C47 *Glue Seams*: 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.)
- C48 *Leaf*: 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.
- C49 *Permeate Collection Tube*: 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.

- C50 *Spiral Wound Module:* 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 6.5)
- C51 *Stitching Material:* Thread used to sew and attach adjacent leaves of the permeate carrier material to maintain leaf spacing during fabrication.

Plate and Frame Module

- C52 *Connecting Bolt(s):* That part(s) of the supporting frame which connects the end flanges and holds together the stack of membrane elements.
- C53 *End Flanges:* 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.
- C54 *Lock Rings:* 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.
- C55 *Membrane Support Plate:* 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.
- C56 *Module of Plate and Frame Design:* That part of the membrane processing system that contains the membrane elements of plate and frame design. The module consists of:
- a. Membrane elements.
 - b. Supporting frame.
 - c. Permeate collection manifold.

The module interfaces with the system pipelines carrying product to and from it.

- C57 *Permeate Collection Manifold:* 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.
- C58 *Plate and Frame Module:* A module formed of multiple sandwiches of flat membrane elements held together by an external supporting frame. (See Appendix 6.6)
- C59 *Section Plate:* That part of the membrane element that makes it possible to divide the module into sections.
- C60 *Spacer Plate:* 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.

- C61 *Supporting Frames:* 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.
- C62 *Supporting Legs:* That part of the supporting frame which provides means for support of the whole module.

Parallel Leaf Module

- C63 *Membrane Cartridge:* A multiple of membrane elements joined to form a unit to be inserted into a membrane housing.
- C64 *Membrane Element Retaining Clamp:* 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.
- C65 *Parallel Leaf Module:* A module formed of multiple membrane elements whose membrane has been permanently bonded to a rigid support plate. (See Appendix 6.7)
- C66 *Permeate Fitting:* A device for communicating permeate from the membrane cartridge to the permeate tubing. It may hold and seal the membrane cartridge in situ.

Hollow Fiber Module

- C67 *Hollow Fiber Module:* 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, 6.8)
- C67.1 A module of hollow fiber design shall consist of the following components:
- Membrane cartridge.
 - Process manifold adapter assembly.
 - Permeate adapter assembly.
- C68 *Membrane Cartridge:* 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.

- C69 *Membrane Sheath*: That part of the membrane cartridge which provides mechanical support to the hollow fiber membrane elements.
- C70 *Permeate Adapter Assembly*: 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.
- C71 *Process Manifold Adapter Assembly*: 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.
- C72 *Tube Sheet*: The thermoset adhesive compound that is used to seal the hollow fiber membrane elements into the membrane housing.

Monolithic Ceramic Module

- C73 *Ceramic Bond*: The joining of ceramic materials by heat to produce fusion or sintering between particles.
- C74 *Ceramic Membrane Support*: 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.
- C75 *Membrane Element Array*: A parallel array of one or more single tubes or multichannel membrane elements contained within the module shroud.
- C76 *Membrane Element Fixed Retainer*: A retainer which is a part of the shroud.
- C77 *Membrane Element Removable Retainer*: 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.
- C78 *Membrane Element Retainer*: That part of the module which is designed to retain in place the membrane element seals and membrane element(s).
- C79 *Monolithic Ceramic Module*: 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 6.9)
- C80 *Uniform Transmembrane Pressure System*: 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.

D MATERIALS

The most current approved version of the *3-A Sanitary Standard for General Requirements, 00-* shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modification or exclusions.

D1 Product Contact Surfaces (Refer to *3-A Sanitary Standard for General Requirements, 00-*)**D1.1 Metals** (Refer to *3-A Sanitary Standard for General Requirements, 00-*)**D1.2 Non-Metals** (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

D1.2.1 Fiberglass reinforced composites may be used for membrane element support tubes.

D1.2.2 Plastic (including fiberglass and composites), rubber, and rubber-like materials may be used for membrane module components, and when used, shall be in accordance with the *3-A Sanitary Standard for General Requirements, 00-*.

D1.2.3 Adhesives and potting materials may be used for bonding metals, rubber and rubber like materials, plastic materials, fiberglass composites, and carbon or ceramic seal components. When used, adhesives shall be in accordance with the *3-A Sanitary Standard for General Requirements, 00-*.

D1.2.4 Carbon and ceramic materials may be used for membrane components, and when used, shall be in accordance with the *3-A Sanitary Standard for General Requirements, 00-*, except that when used as membranes, these materials may be porous.

D1.2.5 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.

D1.2.5.1 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.

D2 Nonproduct Contact Surfaces (Refer to *3-A Sanitary Standard for General Requirements, 00-*)