

Page M. Inspection of Membrane Processing Operations. (Form DA - 151 - 10)

These guidelines are to be used for the inspection of all membrane processing systems. However, recommendations concerning the salty whey should be listed under the appropriate item on Page W on the report. Also, additional Inspection guidance for salty whey membrane processing is provided on Page W.

Processing

Item M1– Room Construction (58.126).

See the guidelines for Item A1 – Room Construction.

A separate room for membrane processing is not required. Membrane processing may be conducted in any processing area where the equipment can be installed in such a fashion as to permit proper operation and cleaning of all the equipment and facilities in the room. Membrane processing may be in the same room as pasteurization, cheese making, whey processing, etc.

Item M2 – Lighting & Ventilation (58.126d, e).

See the guidelines for Item A2 – Lighting & Ventilation.

Item M3 – Pumps, Pipelines, & Valves (58.128, 58.146a).

See the guidelines for Item A3 – Pumps, Pipelines, & Valves.

Item M4 – Separator (58.128e).

See the guidelines for Item B4 – Separator.

Item M5 – HTST Sealed _____ at _____ sec, _____ °F (58.128, 58.809).

See the guidelines for Item B5 – HTST Sealed _____ at _____ sec, _____ °F.

Products emanating from membrane processing systems shall be pasteurized at a suitable location to destroy pathogenic organisms and safeguard the public health. The pasteurization

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step may be prior to or following the membrane processing equipment. The location is at the option of the processor. Regardless of the location, pasteurization shall be accomplished at the processing plant. If pasteurization is not conducted in timed and sealed equipment recommend the INELIGIBLE status be assigned (category A deficiency).

Plant management should be advised that some regulatory and inspection agencies require the pasteurization step always be located prior to membrane processing. They may wish to consider this aspect when modifying their system.

Item M6 – HTST Equipment (58.128 58.809).

See the guidelines for Item B6 – HTST or Vat Pasteurizer.

Item M7 – Product Cooler (58.128i, j, k).

See the guidelines for Item A27 – Product Cooler. See the guidelines for Item A38 – Water Supplies & Handling if nonpotable heat exchange media is used.

If products are membrane processed within two hours, special cooling may not be required. However, if products are held for longer periods or if the specific process requires cooling, product coolers prior to processing or storage shall be present.

If products are held for longer than two hours and no coolers are provided, or if not cooled to below 45°F recommend that product coolers be provided. When products are being run continuously, an alternative is to provide dual tanks that can be alternately used and cleaned.

Item M8 – Storage Tank(s) (58.128d).

See the guidelines for Item W30 – Storage Tank(s). When used as the surge (feed) tank(s) for the system see the guidelines for Item M14 – Surge Tank.

When products other than whey are being processed the requirements are the same. The product shall be cooled to below 45°F or heated to above 145°F, or two tanks shall be provided and alternated so that they are cleaned and sanitized after approximately 4 hours of use. In-out storage of products between these temperatures is not acceptable.

Item M9 – Housekeeping (58.126e, 58.127f, 58.146d).

See the guidelines for Item A7 – Housekeeping.

Membrane Processing

Item M11 – Room Construction (58.126).

See the guidelines for Items A1 and M1 – Room Construction.

Item M12 – Lighting & Ventilation (58.126d, e).

See the guidelines for Item A2 – Lighting & Ventilation.

Item M13 – Pumps, Pipelines, & Valves (58.128, 58.146a).

See the guidelines for Item A3 – Pumps, Pipelines, & Valves.

Butterfly valves have commonly been used on membrane processing systems. Recommend replacement with valves that meet the 3-A Sanitary Standards when unsatisfactory conditions are observed or when the valves are included in a CIP system without daily disassembly and hand cleaning.

All membrane systems operate at elevated pressures. UF systems operate in the 30– 300 PSI range whereas RO systems operate at pressures of 600 PSI and above. Therefore, all systems utilize a pressure regulator valve.

When bladder style pulsation dampeners are used in conjunction with high pressure systems, ensure that all of the pressure has been released from both sides of the bladder before asking that the dampener be disassembled for inspection. For safety, request that the air line be disconnected.

When a recirculation line is provided that continuously takes some finished product back to the surge tank or the first stage in a multistage system, recommend the INELIGIBLE status until the flow pattern is corrected (if the product is pasteurized prior to the membrane system this deficiency can be assigned to category B). Although this line is needed during start up, shut down, and the CIP cycle, it is not necessary to use such a loop during normal production, which increases average residence time significantly. Finished product concentration can be controlled by other means, such as control of the product in-feed and removal from the system.

During the survey, verify that no product is recirculated during production. The plant can disconnect the line or use a divert valve that is programmed to bypass the system during production. Contact the National Field Office if other methods are used. In addition, these lines, when used, shall be close-coupled to the balance tank or removed during production. If removed, the line shall be kept as short as possible and be hand washed prior to reconnecting and reuse (see the guidelines for Item M17–Product Processing Temperature).

Item M14 – Surge Tank (58.128d).

The surge tank is generally the beginning of the membrane processing system. The “system” shall meet the criteria in the *3-A Accepted Practices for The Sanitary Construction, Installation, and Cleaning of Cross Flow Membrane Processing Systems for Milk and Milk Products, Number 610-*. As appropriate, follow these 3-A criteria for the evaluation of subsequent component parts of the system.

Typically the temperature in the surge tank will be between 45°F and 145°F. At this temperature bacterial problems develop in the foam in the tank. Therefore, two tanks shall be provided and alternated so that they are cleaned and sanitized after approximately 4 hours of use. In-out storage of products between these temperatures is not acceptable.

When storage tanks are used as the surge (feed) tanks, see the guidelines for Item M8 – Storage Tank(s).

Some membrane manufacturers supply an integrated system that includes a single small balance tank at the beginning. This is acceptable provided that it meets the requirements of Section F.1 of the *3-A Accepted Practices for the Sanitary Construction, Installation Testing and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems, Number 603-07*. The main points to check during a routine survey are:

1. the average residence time shall be less than 4 minutes (i.e., a small tank such as those used for HTST balance tanks). Membrane systems that require a much larger flow during the CIP cycle can have a dual level control to maintain an average residence time of less than 4 minutes during production.
2. the inlet effectively minimizes the development of foam (e.g., an inlet that enters below the level of the product in the tank or a “gooseneck”).
3. the contents drain to the outlet before the outlet is uncovered.

Systems with a balance tank that develops a thick layer of foam, or with an average residence time of greater than 4 minutes during production, are not acceptable.

Note:

A single, small balance tank cannot replace the two storage (surge) tanks that are required when the processing temperature is between 45°F and 145°F.

The design of the float assembly shall be easy to disassemble without the need for special tools or the use of nuts and bolts, cotter pins, snap rings or similar hard to remove fastening devices. Inspect the surge tank and level control parts for sanitation and condition. If the tank has a mechanical float control assembly, take it apart for inspection. The tank shall be provided with

covers, which shall be in place during operation and be easily removable for cleaning or designed to clean in place.

All inlets into the surge tank shall be stainless steel and of sanitary construction. Black iron, copper, and threaded fittings for water are not acceptable. Water lines shall be installed in accordance with local plumbing codes, with an effective backflow preventer or an air gap equal to at least two pipe diameters, to protect the potable water supply. Steam shall comply with the criteria of the *3-A Accepted Practices for a Method of Producing Steam of Culinary Quality, Number 609-*. Steam inlets shall comply with the *3-A Sanitary Standards for Steam Injection Heaters for Milk and Milk Products, Number 61-*. The steam injector can be the check valve required by the Accepted Practice. Therefore, the steam line can be threaded into the injector. Have the injectors dismantled and check for sanitary construction and cleanup of the interior.

Item M15 – Prefilter(s) (58.128a).

See the guidelines for Item A3 – Pumps, Pipelines, & Valves.

Item M16 – High Pressure Pump (58.128, 58.219).

When a piston type high pressure pump is used, follow the appropriate guidance of Item D19 – High Pressure Pump.

Often the high pressures required for membrane processes can be obtained by special centrifugal type pumps. Two primary methods are used to achieve the pressures required, two or more standard centrifugal pumps in series, and multistage centrifugal pumps. When connected in series, the discharge of one standard centrifugal pump is connected directly to the intake of the next pump to obtain the desired pressures. Multistage pumps accomplish the same pressures within a single pump housing. The pumps used in either configuration shall meet the criteria of the *3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02-*. See the guidelines for Item A3 – Pumps, Pipelines, & Valves.

Disassemble and check the pumps for sanitation and condition. Pumps shall be specifically designed for CIP applications or be disassembled for daily hand cleaning. Carefully check multistage pumps for ease of disassembly and cleaning between the various stages.

Note:

Piston style high pressure pumps (homogenizers) are not suitable for CIP applications.

Item M17 – Product Processing Temperature (58.810a).

Unless processed within 2 hours, the product shall be cooled to 45°F or less or heated to 145°F or higher. Some whey products are exempt from this requirement, see the guidelines for Item

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W9 – Whey Heating or Cooling. Salty whey shall be cooled to 45°F or less or heated to 125°F or higher and processed at a minimum of 125°F. There is no heating or cooling requirement for acid whey with a pH of 4.6 or below or titratable acidity of .40 or above (whey from cottage cheese, cream cheese, etc.).

It is common practice to operate dairy membrane systems continuously at warm temperatures because of the higher flux rates that can be obtained. When processed promptly, these temperatures should not be criticized provided the system is designed and sized to provide as short a residence time as possible for the product being processed. Do not criticize interstage recirculation loops in multistage systems. Such recirculation loops are necessary to achieve the required cross-flow velocity at the surface of the membranes to prevent fouling. See the guidelines for Item M13 – Pumps, Pipelines, & Valves.

Do not criticize recirculation loops for batch processing systems. These systems utilize full recirculation of all product back to the batch tank over a period of several hours in order to achieve the desired final concentration. Batch systems generally require very long residence times. Therefore, bacterial control measures are required. Do not criticize the use of safe and suitable pH adjustment chemicals or the addition of benzoyl or hydrogen peroxide in batch systems as processing aids.

Item M18 – Membrane Modules (58.128 a, o).

All membranes shall comply with the criteria of the *3-A Sanitary Standards for Cross-flow Membrane Modules, Number 45-*. Refer to this standard for component part descriptions and diagrams of construction of the various types of membrane modules.

Membrane modules can be classified by pore size. Three types are common in the dairy industry, reverse osmosis (RO) (water removal), nanofiltration (NF) (salt and water removal), and ultrafiltration (UF) (lactose, salt, and water removal leaving concentrated protein). In addition, membrane systems can be classified by the configuration of the modules. These configurations include tubular, spiral wound, plate and frame, parallel leaf, hollow fiber, and ceramic. All these configurations are generally designed similar to a plate type heat exchanger. Product flow is directed into a series of “passes.” The flow will proceed through a group of membrane surfaces (the modules) and then be directed to the next grouping of surfaces. This is most clearly demonstrated on the plate and frame styles but is also used in other styles by arranging the manifold piping.

General Instructions for Selecting a Membrane for Inspection.

All evaluations of membrane surface cleanability may result in damage to the membrane module. Fortunately, some membrane module designs can be inspected without destroying the membrane. Ceramic, plate and frame, and parallel leaf are resistant to damage. However, in the case of the spiral wound and tubular membranes, some will require cutting in order to inspect the internal permeate transport materials.

A. Plants with a Single Membrane System.

When selecting membrane modules for examination, refer to the membrane log (see the guidelines for Item M28 – Membrane Module Log) and select from among the membrane modules at the end of each “pass” that have been in service for the longest period. These lower flow areas have a greater potential for inadequate cleaning. Pay special attention to the final stages of multistage systems as these areas have the highest product concentrations and associated, potential cleaning problems.

Select a minimum of 3 modules. Pay special attention to identified problem areas that have been observed on prior inspections. Visually inspect all surfaces available without damage or destruction of the three modules. If defects such as folds, irregular glue lines, holes, etc., are noted on one of the modules, select that module for further inspection. If no visible defects are noted, select one of the three at random for further destructive inspection. Record any deficiencies noted during the inspection of the module, no further action is required on the other modules from this system. When a plant has established a history of satisfactory cleaning and fabrication, destructive inspection of the modules can be reduced to one module every other survey. A visual inspection of 3 modules is still required each survey and any module with visible defects should be subjected to destructive inspection techniques.

B. Plants With Multiple Membrane Systems.

Following the guidelines for a single system above, select a minimum of 3 modules from each system.

When a plant with two systems has established a history of satisfactory cleaning and fabrication, destructive inspection of the modules can be reduced to not less than 1 module each survey. A module shall be selected from each system with an unsatisfactory history. When a satisfactory history has been established, select a module from alternating satisfactory systems for destructive inspection. However, be prepared to increase the number of modules if the following circumstances are encountered:

1. If the module scheduled to be cut is not clean.
2. If the module scheduled to be cut is found to have interior fabrication deficiencies that were undetectable during the visual, nondestructive examination.
3. If any of the modules from the system not scheduled to be cut appear to have fabrication deficiencies.
4. If flux rate tests indicate possible fouling of the membranes (see the guidelines for Item M27 – Flux Test Reports).

A module from another system shall be selected to be cut to determine whether the deficiency is isolated or involves more than the initial system.

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When the above circumstances are encountered in plants with three or more systems, a minimum of 2 membranes shall be cut. Select 3 modules from each system for visual inspection. However, only 2 modules need to be subjected to destructive inspection techniques. If both modules are satisfactory, the systems can be alternated on future surveys with the system not selected during this survey being 1 of the 2 selected during the next survey. Any system that does not have a satisfactory history shall have a membrane cut each survey until a satisfactory history is reestablished.

Example 1: (If the membrane systems are on a single Page M)

M18. — RO and UF modules satisfactory this survey.

These systems have a satisfactory history. During the next survey 3 modules shall be selected from each system. A minimum of one module shall be cut. The next survey should have a comment such as:

M18. — RO module satisfactory this survey, visual inspection of UF module was satisfactory.

Example 2: (If the membrane systems are each on a separate Page M)

(Page M for the UF system)

M18. — UF modules satisfactory last survey. Visual inspection was satisfactory this survey.

(Page M for the RO system)

M18. — RO modules satisfactory this survey

Because these systems have a satisfactory history, during the next survey 3 RO and 3 UF modules shall be selected for inspection and a UF module shall be cut.

Example 3: (If the membrane systems are each on a separate Page M)

(Page M for the UF system)

M18. — Provide modules that meet the 3-A Sanitary Standards. Numerous blisters with clear liquid noted on glue seams (C).

(Page M for the RO system)

M18. — Modules satisfactory this survey.

In this example, the UF system does not have a satisfactory history while the RO system has established a satisfactory history. Therefore, during the next survey 3 modules shall be selected from each system and a module from the UF system shall be cut.

Example 4: (If the membrane systems are each on a separate Page M)

(Page M for the UF system)

M18. — Provide modules that meet the 3-A Sanitary Standards. Holes in the membrane surface have been repaired with glue (C).

(Page M for the RO system)

M18. — Provide modules that meet the 3-A Sanitary Standards. Numerous blisters noted on glue seams (C).

In this example both systems have a fabrication deficiency, therefore, a module from each system shall be cut during the next survey to reestablish a satisfactory history. If the plant had an additional system with a satisfactory history, a module from it would not have to be cut.

General Guidelines for all Membrane Systems Concerning Cleaning Deficiencies.

Membrane systems are extremely difficult to clean. The basic design of the membranes results in their ability to capture soil and impurities from the water supply and cleaning compounds. It is important, therefore, to use extremely clean water to make cleaning solutions. The cleaning solution compounds for membrane system cleaning are usually specially formulated to specifications provided by the membrane manufacturer or by the company which provides cleaning expertise. The choice of cleaning compounds and cleaning temperatures are at the discretion of the plant and the membrane supplier.

Membrane systems do not lend themselves to manual cleaning operations. Therefore, an automated CIP system shall be provided to clean the membranes, manifold, permeate collection system and the retentate collection system. The CIP cycle shall be controlled automatically to regulate temperatures, times, cleaning solution addition and rinse sequences.

In addition, the plant shall provide and post for the operator a detailed cleaning procedure. The procedure shall include the manufacturers recommended cleaning compounds, times and temperatures to be used during cleaning and sanitizing of the membrane system.

Check the system to determine that the necessary controls are present and used. If it is found that the cleaning is dependent on the manual adjustment of times, temperatures or cleaning compound addition, Item M41 – CIP System(s) is unsatisfactory, recommend the APPROVED 3-MONTHS status (category B deficiency). Make the recommendation that automatic controls be provided and used to control cleaning. This should not be taken to preclude a manual titration of enzyme strength, pH, etc. to verify the automatic controls.

Membrane surfaces shall be clean. They shall be free of yellow or white slimy residues, milk or milk product residues, off odors such as sour, fermented, or yeasty, etc. (category A deficiencies) Even though the oldest membranes are selected for examination there shall be no allowances for observed defects. Regardless of their age, membranes in use are expected to be clean.

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During inspections of RO and UF installations a grayish to light brown or tan film has been observed on the membrane surfaces. They may originate from the water supply or the cleaning compounds. This film has been analyzed as an inorganic deposit consisting primarily of silicates. Although not as serious as organic soil, such mineral films should not be present on the membrane surfaces (category B deficiencies). They can be eliminated by alteration of the cleaning procedures or compounds. Even though there are not high bacterial levels in this film, it is our policy that the membranes are to be physically cleaned of all deposits during the CIP cycle.

When deposits are noted on RO and UF membrane systems during inspections, it is appropriate to recommend that the cleaning cycle be modified to eliminate the film deposits and to inform the plant that the manufacturer should assist them in making the necessary corrections.

When cleaning or rinsing problems are noted, describe them accurately and in detail so the plant can take effective corrective action and the deficiencies can be reevaluated during the next survey.

Inspection of Membrane Systems.

Following is inspection guidance for the various styles of membrane modules.

A. Tubular.

The inside diameter of membrane tubes shall be no smaller than 0.2 inches. Tubes may be either singular or installed in multiple groups within the membrane housing. The tubes may be inserted within a metal or plastic support tube or have the support material as an integral part of the tube.

Disassemble the membrane support housing. This will include some type of end cap or elbow arrangement. Check for product residues and deteriorated or improperly installed gaskets, O-rings, membrane retainers, etc. Using your flash light, look down the length of the membrane tube. Make appropriate recommendations if product residue, stains, discolorations, sediments, films, buckled or torn membranes, or other improper conditions are observed. Select and remove designated tubes from the housing and cut them lengthwise so that they may be opened flat to examine all surfaces. Check for the defects listed above as well as for blisters, or delamination of the membrane surfaces and improper cleaning of the membrane attachment areas. Smell the membranes for any off odors indicative of improper cleaning.

B. Spiral Wound.

These are the most popular type of dairy membrane modules in use. They are manufactured by a variety of companies. Check that the module meets the *3-A Sanitary Standards for Crossflow Membrane Modules, Number 45* - .

Disassemble the membrane support housing and remove the membrane modules. Check the end caps for proper design and construction, product residues, deteriorated or improperly installed gaskets, O-rings, anti-telescoping devices (ATD), interconnectors, and seals. As the membrane modules are removed, observe if the operating conditions have caused the rolled membranes to telescope (push out of alignment) or caused the outer shrouds to wrinkle or bunch up. Do not criticize minor telescoping or wrinkles. Wrinkles or bunched up shroud material that impede product or cleaning solution flow is unsatisfactory (category D). The permeate tube shall be free of rough cut edges, cracks, and burrs.

Check the condition of the interconnectors. Interconnectors may have the ATD as an integral part. Check for product residues on interior surfaces, cracks, torn or missing surfaces and deteriorated or missing O-rings.

Take the selected membrane(s) to a flat table where they can be cut open. If there is an outer shroud, remove it and unroll the membrane leaves. Spiral wound membrane modules generally have more than one layer of membrane surfaces rolled into the spiral. Carefully check the membrane surfaces for product residues, sediments, films, and indications of improper cleaning or low flow areas, especially in the area of the permeate tube. Older membranes may crack or deteriorate as they are unwound. Do not criticize this unless there is evidence that the membrane failed while in its normal operating configuration (rolled). Evidence of deterioration prior to unrolling shall be considered a category C deficiency. Smell the surfaces for off odors indicative of improper cleaning.

When checking the workmanship of the modules look for the following items:

1. The glue lines attaching the membrane to the support and permeate transport material should be generally uniform and shall not create hooks, folds, recesses or other areas that will impede liquid or cleaning solution flow. Wide glue areas that are free of defects do not have sanitary significance and should not be criticized. They only reduce the module efficiency by reducing effective membrane surface area.

The glue lines shall be smooth, with no blistering, crevices or delamination. Blistering and other problems with the glue lines indicate that the membrane manufacturer experienced problems during production. Therefore, to give the plant time make the necessary corrections, blisters in the glue seams that contain only clear liquid should be noted on the report as a category C deficiency. However, blisters that contain discolored liquid or product shall be considered a category A deficiency.

2. Holes or defects in the membrane surface (except when located on a glue seam) decrease the efficiency of the module but have no sanitary significance. However, look for glue spots in the middle of the membrane sheet as small imperfections will sometimes be repaired in this manor. These repairs do have a sanitary significance because they create "shadow" that may restrict flow of CIP solutions. Therefore, defects that have been repaired by gluing the membrane material to the permeate carrier below, and holes in the membrane material on the glue seams, shall be noted on the report and assigned

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to category C. Repairs that cause the membrane surface or the permeate carrier material to be unclean shall be assigned to category A.

3. Check the area where the open weave membrane spacer materials ends near the crease in the membrane surfaces. These may be loose, glued, or fastened into place by various means.

If loose, they are to be as close as possible to the permeate collection tube at the center to avoid any dead flow areas created by two membrane surfaces touching each other. Check these areas carefully because the flow is sometimes restricted, which can create a hard to clean area.

If glued, check that the glue lines are properly applied and that they do not obstruct any of the permeate drain holes in the permeate tube.

Other methods of attachment may be acceptable, if you have any questions contact the National Field Office for assistance. Check the permeate tube for rough cut edges, cracks and for residue remaining from drilling the permeate drain holes.

4. The crease in the membrane material is usually strengthened with crease protection materials such as glue or tape.

If tape is used, check that the bond is continuous and tight across the entire length. Tape that has come loose should be assigned to category D. If product is present under the tape, assign the deficiency to category A.

5. Cut the membrane surfaces so the permeate surfaces and transport material can be examined. The permeate carrier material will end at the permeate tube. The 3-A Sanitary Standard allows the permeate carrier materials to be stitched together. It also allows these materials to be attached to the permeate tube by intermittent ultrasonic attachment (i.e., the permeate material will be melted to the tube at several points).

If any deficiencies are noted, but the membrane is clean, assign them to category D with a recommendation to provide modules that meet the 3-A Sanitary Standards.

C. Plate and Frame.

Plate and frame style membrane systems can be inspected using essentially the same techniques as a plate and frame heat exchanger. After the clamping bolts have been removed, the individual membrane elements can be separated and inspected.

As stated earlier, the product flow through these systems is based on a series of "passes." Carefully inspect the membrane elements located at the end of the "passes." They have the greatest potential for product residues or evidence of improper cleaning as the internal pressures and flow rates are lowest for these areas.

Check for product residue, debris, rust stains or any type of off color films or deposits on the membrane surfaces. Membrane material is transparent. Therefore, the white of the backing material is the predominant color of a clean membrane element surface. Pay particular attention to the edges of the elements, and along the ridges of the various flow channels. Inspect the permeate discharge ports and spacer plates.

D. Parallel Leaf.

This style, when used for dairy application, has stacks of membrane elements that are assembled in brick shaped groups which are then inserted into a square, stainless steel module housing. Each of these membrane cartridges has a permeate discharge connection. Prior to the inspection, designate the membrane cartridges to be inspected. In order to be inspected, membrane cartridges preceding the designated membrane cartridge will have to be removed from the module housing. This is similar to the removing of unselected spiral wound membranes modules in order to reach the module that was selected for inspection.

Once removed, the membrane cartridge can be disassembled to inspect the individual membrane elements and surfaces. Carefully check each membrane as it is removed from the module for product residue, debris, rust stains or any type of off color films or deposits on the membrane surfaces. Pay particular attention to the edges of the elements, and along the ridges of the various flow channels. Inspect the permeate discharge ports and spacer plates.

E. Hollow Fiber.

These modules do not allow for detailed inspection of the membrane surfaces. The membrane surface is on the interior of the hollow fibers which are usually sealed within a permanently bonded, transparent plastic housing. The bore of an individual hollow fiber is too small for visual inspection. You can, however, hold the module in front of a strong light source to observe if the tubules are plugged.

Check the modules for proper workmanship of the potting resin securing the fibers in place at the ends of the housing. The surfaces shall be smooth and be free of pits, bubbles, folds or crevices. Also, examine the module to determine if there is a product film or other residue visible inside the module housing. Carefully review cleaning and module flux records to determine if any significant variations or drop in flux rates have been recorded. Concentrate inspection on any modules which indicate reduced flow rates.

F. Ceramic

Monolithic ceramic membranes are extremely brittle and will shatter if subjected to sharp blows or other stresses. Care must be taken when handling and inspecting these elements. Generally these are designed similar to tubular membranes. The ceramic membrane may be a series of single tubes or a series of cast multi-tubes within a module housing. Gasketing or self-vulcanizing potting material can be removed in order to remove a membrane element for inspection.

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Using a flashlight, carefully inspect the interior surfaces for product residue, debris, rust stains or any type of off color films or deposits on the membrane surfaces. Pay particular attention to the ends of the elements.

Note:

The SFEC membrane is a black carbon matrix with a grayish, alumina oxide interior membrane surface. The light grey color is normal and not a residue film.

Inspect the permeate discharge ports, lines and the inside of the module housing after the membrane elements have been removed.

Item M19 – Diafiltration Water (58.127a).

Diafiltration is the process during which water is introduced into the concentrated product stream to facilitate the removal of the remaining water soluble components such as residual lactose and minerals.

All water used for diafiltration shall be from the potable plant supply or from a supply of plant process water that has been treated and approved according to the USDA guidelines for process water (see the guidelines for Item A38 – Water Supplies & Handling for the proper handling of process water). Untreated cow water or RO permeate is not acceptable for use as diafiltration water (category A deficiency).

Item M20 – Permeate Piping (58.128a, I, o).

As the permeate passes through the membrane surface, it is collected within the modules. From the modules, it is generally transported through a variety of small diameter plastic tubes or pipes to a manifold system. The manifold system may also be of plastic or it may be of stainless steel. Do not criticize the use of plastic for permeate collection integral with the modules and their permeate manifolds. Subsequent piping, however, shall be stainless steel using “3-A” sanitary connections or sanitary welds. The small diameter tubes may be slip on fittings, or held in place with clamps or special fittings. Screw driver type clamps are unacceptable. Remove several of the fittings or slip on tubes and examine for product residue or other evidence of improper cleaning.

Follow the appropriate inspection guidance for Item A3 – Pumps, Pipelines, & Valves for the larger diameter tubes, manifolds, valves, and pumps. If the fittings and tube sizes equal or exceed 1 inch in diameter, they shall comply with all applicable 3-A Sanitary Standards.

Flow meters shall comply with the *3-A Sanitary Standards for Flow Meters for Milk and Liquid Milk Products, Number 28- .*

Permeate lines are seldom found dirty. RO permeate is essentially water and UF permeate is essentially sugar water. Do not spend a lot of time inspecting these areas. Spot check several areas to confirm that the permeate system is clean.

Item M21 – Storage Tanks (58.128d).

See the guidelines for Items A28–Storage Tanks - Silo & A29–Storage Tanks - Horizontal.

Item M22 – Housekeeping (58.126e, 58.127f, 58.146d).

See the guidelines for Item A7 – Housekeeping

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Records

Item M25 – Recording Charts (58.146a, 58.148).

Examine the recorder charts on file to see that they match the procedures for time and temperatures of the various cleaning cycle steps. If charts are not available, this item is unsatisfactory, recommend that charts be provided and retained on file for a period of three months.

If no provision is made for recording the cleaning cycle recommend the INELIGIBLE status.

Also check the recording charts for product storage tanks, and the processing system where specific temperatures are required. Make recommendations as appropriate.

Item M26 – Processing Log (58.148).

The plant shall maintain a daily processing log which details the daily operation. The log shall include at least the following items:

1. The date and hours of operation.
2. Operating pressures.
3. Stream temperatures.
4. Feed, retentate, concentrate and permeate flow rates.
5. Element replacement.
6. Unusual occurrences.
7. Operator's signature or initials.

Review the processing logs to see if they are properly maintained and complete. Be particularly alert to notations of unusual occurrences. Question plant management or the operators about the nature of the occurrence and the follow-up response made by the plant.

If no records are maintained, recommend they be implemented immediately and recommend the assignment of the APPROVED-3 MONTHS status (category B deficiency).

Item M27 – Flux Test Reports (58.148).

Flux tests are an important method to monitor the sanitary condition of the membrane modules. Flux is the rate of extraction of permeate measured in liters per square meter of membrane

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surface per hour. As membrane surfaces age or become fouled the flux rates decrease. This test is used to evaluate the effectiveness of the cleaning regimen.

Check that the plant is running daily flux rate tests or some other test to evaluate the membrane modules within the system. If wide variations in daily flux rates are observed, recommend that the cleaning system be reviewed and evaluated. A slight decrease in flux rates over time is normal as the membranes age and should not be criticized. Dramatic changes indicate a problem that should be investigated and resolved.

If no records are maintained, recommend they be implemented immediately and recommend the assignment of the APPROVED-3 MONTHS status (category B deficiency).

Item M28 – Membrane Module Log (58.148).

Most membrane modules in a spiral wound system bear a serial number. Other systems also identify individual membranes or membrane bundles or groupings. Check that the plant maintains a log of when the membranes were placed into service and their location in the system. This log is used when selecting membranes for inspection.

If no records are maintained, recommend that they be implemented immediately and recommend the assignment of the APPROVED-3 MONTHS status (category B deficiency).

Retentate and Permeate Handling

Item M31 – Room Construction (58.126).

See the guidelines for Item A1 – Room Construction.

Item M32 – Lighting & Ventilation (58.126d, e).

See the guidelines for Item A2 – Lighting & Ventilation.

Item M33 – Pumps, Pipelines, & Valves (58.128, 58.146a).

See the guidelines for Item A3 – Pumps, Pipelines, & Valves.

Item M34 – Retentate Storage (58.128d, 58.810).

See the guidelines for Items A28 – Storage Tanks - Silo & A29 – Storage Tanks - Horizontal and Item W9 – Whey Heating or Cooling for special considerations for the handling of whey, whey products, and whey fractions.

Item M35 – Permeate Storage (58.128d, 58.810).

See the guidelines for Items A28–Storage Tanks - Silo & A29–Storage Tanks - Horizontal

If the permeate is to be used as animal feed or disposal, check that the handling and storage do not adversely impact on the cleanliness of the plant or surroundings. Make recommendations as appropriate.

Item M36 – Permeate Use.

Have plant management declare the intended use of the permeate. Record the utilization on the report.

If it is intended for further processing as a human food and inspection is requested, complete the appropriate plant survey pages. If it is shipped to another facility for processing as human food, record the destination plant on the report.

If it is intended for animal feed or disposal, record the specific uses.

The RO permeate is essentially water and shall be handled and inspected under the same procedures as for evaporator cow water. See the guidelines for Item A38 – Water Supplies & Handling.

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Item M37 – Housekeeping (58.126e, 58.127f, 58.146d).

See the guidelines for Item A7 – Housekeeping.

General Items

See the guidelines for Page A – General Items

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