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Before The
State of Wisconsin
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

In the Matter of the Application for Approval of Health Care Plumbing Appliances, Mar Cor Purification, Inc., Applicant

FINAL DECISION AND ORDER
DO96213
Order No. _____

Division of Legal Services and Compliance Case No. 18 COM 190

The State of Wisconsin, Department of Safety and Professional Services, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, make the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Department of Safety and Professional Services.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated at Madison, Wisconsin on the 7th day of June, 2019.

Aloysius Rohmeyer

Aloysius Rohmeyer
Chief Legal Counsel
Department of Safety and Professional Services

Before The
State of Wisconsin
DIVISION OF HEARINGS AND APPEALS

In the Matter of the Application for Approval of Health Care Plumbing Appliances, Mar Cor Purification, Inc.,	DHA Case No. SPS-18-0049 DLSC Case No. 18 COM 190

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

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PROCEDURAL HISTORY

This proceeding was initiated when Mar Cor Purification, Inc. ("Applicant") filed an appeal of an October 30, 2018 decision of the Department and Safety and Professional Services ("Department") denying Applicant's applications for approval of two health care plumbing products, the WRO 300/H Dialysis Water System and CWP 100/100H Reverse Osmosis Systems. The Department served and filed a formal Notice of Hearing on November 27, 2018. The Notice stated that the issue presented for consideration at hearing was whether the Department's denial of the applications for approval as health care plumbing appliances of the products was reasonable under Wis. Stat. § 101.02(6)(e) and Wis. Admin. Code § SPS 384.01.

The undersigned administrative law judge conducted a telephone prehearing conference with the parties on December 13, 2018, at which time witness list and proposed exhibit exchange deadlines were established and a hearing was scheduled. The hearing took place on February 14, 2019. Applicant presented the testimony of Greg Reny, Applicant's Vice President of Global Marketing & Business Development; Wes Byrne, an Independent Consultant who has consulted for Applicant; Jim Curtis, an Independent Consultant and dialysis technician; and John Rickert, Applicant's Former Vice President of Sales. The Department presented the testimony of Glen Schlueter, Plumbing Product Reviewer for the Department's Division of Industry Services, Bureau of Technical Services. Applicant's exhibits 100-114 were received, as were the Department's exhibits 1, 2 and 4-9. The parties submitted post-hearing briefs, with the last brief filed on April 5, 2019.

FINDINGS OF FACT

Application and Denial

1. Applicant Mar Cor Purification, Inc. is a leading manufacturer of medical water filtration equipment used for hemodialysis. Applicant has been in this business since the 1980s. (Reny Hearing Testimony)

2. In the fall of 2017, Applicant submitted applications for approval for two health care plumbing appliances, the WRO 300/H Dialysis Water System ("WRO 300/H") and the CWP 100/100H Reverse Osmosis System ("CWP 100"). (Exs. 4 and 5)

3. On October 30, 2018, the Department denied the applications for approval for the CWP 100 and WRO 300/H. In addition to stating that the designs presented a risk of patient injury, the Department identified five provisions in the Wisconsin Administrative Code's "Plumbing Code" (Wis. Admin. Code chs. SPS 381-387) which it claims Applicant's products violated: Wis. Admin. Code §§ SPS 382.41(3), SPS 382.10(1)(g), SPS 384.15, SPS 384.20(1)(e), and SPS 384.20(4)(b)3. (Ex. 104; Schlueter Hearing Testimony)

4. On or about November 21, 2018, Applicant filed a petition for hearing on the reasonableness of the Department's denial of the applications for approval for the CWP 100 and WRO 300/H.

The Products

5. The CWP 100 is referred to as a "central" water purification system, supplying purified water for use in hemodialysis at an entire kidney dialysis clinic. The WRO 300/H is a portable device designed to supply purified water to a single dialysis patient at a time, often in a hospital or home setting. (Exs. 100, 101; Reny Hearing Testimony)

6. Both devices are reverse osmosis ("RO") systems. Since the 1980s, RO systems have been widely used in hemodialysis water treatment systems. These systems are hooked up to the city water supply. There is a backflow preventer installed at the point that the city's water supply system connects with the water treatment system. These backflow prevention devices are installed by local certified plumbers per local codes and are placed in front of the complete water treatment system. The backflow preventer and air gaps installed at all drain points prevent backflow of wastewater. (Ex. 111; Byrne and Rickert Hearing Testimony)

7. After the backflow preventer is a pre-treatment system, consisting of a series of sediment filters, carbon tanks and softeners to remove various chemicals, including chlorine. (Ex. 111; Byrne and Curtis Hearing Testimony)

8. After the pre-treatment process, water enters the RO system itself. The pre-treated water, called "feed water," enters the RO and is routed through a series of membranes, or RO Elements. A portion of the water is diffused through the membrane and becomes permeate or "product water." This is represented by the green line coming out of the membranes and running "to clinic" as illustrated in Exhibit 112. (Ex. 112; Byrne Hearing Testimony)

9. There are a series of sensors and alarms on this route to the clinic that, among other things, monitor and check the quality of the water. If the water is not of the quality necessary for hemodialysis, the system will shut down or the product water will be flushed to the drain. (Ex. 111; Byrne and Curtis Hearing Testimony)

10. The water that does not diffuse through the membrane on a particular pass is shown on Ex. 112 by the red line coming out of the second membrane. The red line is referred to as "reject water" because it did not diffuse through the membranes. In both the CWP 100 and the WRO 300/H systems, a portion of the reject water goes down the drain, while another portion is recycled into the feed water stream, at approximately Point 71 on Exhibit 112. Wes Byrne, an expert in the area of reverse osmosis systems, including design and performance, testified that the movement of water through the recycling feature is not caused by back flow, back siphonage or back pressure. The Department's Plumbing Product Reviewer Glen Schlueter testified that there was a cross connection between Point 71 and Point 41 as shown on Exhibit 12 because there is a connection between the drain and the potable water supply. (Ex. 112; Byrne and Schlueter Hearing Testimony)

11. Applicant witnesses Byrne, Curtis and Rickert testified that the portion of reject water that is returned to the system is best referred to as "process water" or "concentrate recycle" and the portion of the reject water that is discharged to the drain is considered "waste." (Byrne, Curtis and Rickert Hearing Testimony)

12. Department witness Schlueter testified that any water exiting the second membrane is "waste," although he initially testified that "waste" included the water going from one membrane to the next. (Schlueter Hearing Testimony)

13. The reject water which gets recycled into the feed water has the same particle concentrate as the reject water which gets routed to the drain. (Byrne Hearing Testimony)

14. Once the reject water combines with the feed water stream, it again passes through the membranes, producing additional product water. This recycling allows higher velocities across the membrane surface, which creates agitation and helps reduce membrane fouling and also allows for lower overall water usage by producing a much higher percentage of product water (referred to as "recovery"). (Ex. 112; Byrne Hearing Testimony)

15. An RO system without the recycling feature uses approximately three times more water than systems that do have that feature, an average of 169 gallons more water per treatment of a single dialysis patient. Based on 5,837 hemodialysis patients in Wisconsin as of December 31, 2017, this additional water usage would amount to 153,977,727 gallons of additional water used in Wisconsin per year. The estimated cost of this additional water usage is $1.2 million, which would be borne by clinics, hospitals or individual patients if used at home. (Ex. 113; Curtis Hearing Testimony)

16. Both the CWP 100 and the WRO 300/H are Class II medical devices. The CWP 100 received its 510(k) clearance from the Food and Drug Administration ("FDA") in 1998. The WRO 300/H received 510(k) clearance from the FDA in 2010. The 510(k) clearance process was an arduous, several-year process. (Reny Hearing Testimony)

17. Since being cleared by the FDA, both the CWP 100 and WRO 300/H have been sold throughout the United States and millions of procedures have been performed using these devices. According to research conducted by Applicant's witness, Jim Curtis, there have been no reported incidents of membrane failure or patient injuries due to the recycle feature. (Reny and Curtis Hearing Testimony)

18. Department witness Schlueter testified that Applicant's products could be as safe as other products the Department has approved. (Schlueter Hearing Testimony)

19. There are federal standards which apply to the design of water purification equipment intended specifically for hemodialysis. These standards were developed by the Renal Disease and Detoxification Committee of the Association for the Advancement of Medical Instrumentation ("AAMI"). This Committee included representatives of the FDA, the Centers for Disease Control and Prevention, physicians, nurses, providers, researchers and other industry experts. Applicant's witnesses Jim Curtis and John Rickert are AAMI Renal Disease Detoxification Committee members. The standards are set forth in ANSI/AAMI 23500, ANSI/AAMI 26722 and ANSI/RD52, and cover the design of water purification equipment for hemodialysis as well as the ultimate water quality standards specific for this application. RD52 specifically recognizes the inclusion of a recycling feature which "allows higher velocities across

the membrane surface, which may help reduce membrane fouling, as well as allowing higher overall use of water." (Exs. 110, p. 64; 106, 107, 108; Curtis and Rickert Hearing Testimony)

20. The AAMI standards have been adopted by the Center for Medicare and Medicaid Services ("CMS"), which enforces the standards through federal regulations that are conditions for coverage. Because 85% of patients who receive kidney dialysis treatment are covered by CMS, compliance with these federal regulations, and thus, AAMI standards, is critical. (Curtis Hearing Testimony)

21. RO water purification systems with the recycling feature are widely used in kidney dialysis clinics throughout the country. Approximately 90% of dialysis facilities use ROs that recycle concentrate (reject water). Mr. Curtis testified that the last time he saw a system without recycle was in the 1980s, and he has been in hundreds of dialysis clinics since that time. (Reny and Curtis Hearing Testimony)

22. Wisconsin is the only jurisdiction in which the applicable regulatory agency has sought to disallow the proposed design. (Reny Hearing Testimony)

DISCUSSION

Burden of Proof

Applicant has the burden of proof to show that the Department was unreasonable in denying the applications. Wis. Stat. § 101.02(6)(e).[1]

Violations Alleged

The Department's denial letter was based on its assertion that Applicant's products violated five provisions of the Plumbing Code: Wis. Admin. Code §§ SPS 382.41(3), 382.10(1)(g), 384.15, 384.20(1)(e) and 384.20(4)(b)3. At hearing, the Department also alleged that the products violated Wis. Admin. Code § NR 811.50(16), a provision incorporated into the plumbing standards by Wis. Admin. Code § SPS 382.70(4)(a). These provisions are examined in turn.

[1] The Department argues that an agency's interpretation of its own administrative rules is entitled to controlling weight deference unless inconsistent with the language of the regulation or clearly erroneous. Applicant responds that, pursuant to the Wisconsin Supreme Court's decision in *Tetra Tech EC Inc. v. DOR*, 2018 WI 75, 382 Wis. 2d 496, 914 N.W.2d 21, an administrative agency's conclusions of law are provided no deference. With respect to Applicant's argument, I note that *Tetra Tech* and related cases appear to address the court's review of an agency's legal interpretation of statutes, not its own administrative rules. However, that issue need not be decided here as the deference advocated by the Department is rejected on other grounds, namely, that the authority the Department cites addresses a *court's* review of an administrative decision, not an administrative law judge's review of an agency's decision. *See also Wis. Dept. of Revenue v. Menasha Corp.*, 2008 WI 88, ¶ 62, 311 Wis. 2d 579, 754 N.W.2d 95 (Court holds that Wisconsin Tax Appeals Commission need not afford the Wisconsin Department of Revenue ("DOR") deference regarding DOR's interpretation of its own administrative rules, noting "the Commission reviews the DOR's decisions, and it is the Commission's decision, not the DOR's, that is appealed to the circuit court."). Thus, the appropriate standard is the reasonableness standard articulated in Wis. Stat. § 101.02(6)(e).

Wis. Admin. Code SPS 382.41(3)

Wisconsin Admin. Code § SPS 382.41(3), provides that "[w]ater supply systems and the connection of each plumbing fixture, piece of equipment, appliance or nonpotable water piping system shall be designed, installed and maintained in such a manner to prevent the contamination of water supplies by means of cross connections."

The design of Applicant's products does not violate this provision. First, in order to constitute a violation of this code provision, there must be a "cross connection." The Department argues that a cross connection exists at or around the Point 71 valve as shown on Exhibit 112, which is the point where a portion of the reject water (also referred to as process water or concentrate recycle) gets reintroduced or recycled into the feed water. The evidence and Plumbing Code definitions do not support the Department's position. A "cross connection" is defined by Wis. Admin. Code § SPS 381.01(65) as "a connection or potential connection between any part of a water supply system and another environment containing substances in a manner that, under any circumstances, would allow the substances to enter the water supply system by means of back siphonage or back pressure."

Thus, a cross connection must be between any part of a "water supply system" and "another environment containing substances." The valve at Point 71 does not connect anything to the "water supply system," as that phrase is defined by the Plumbing Code. Pursuant to Wis. Admin. Code § SPS 381.01(284), "water supply system" means "the piping of a private water main, water service and water distribution system, fixture supply connectors, fittings, valves, and appurtenances through which water is conveyed to points of usage such as plumbing fixtures, plumbing appliances, water using equipment or other piping systems to be served."

According to this definition, a "water supply system" is the water service "conveyed *to points of usage*," such as plumbing fixtures, plumbing appliances, water using equipment or other piping systems to be served. In the case of the CWP 100 and WRO 300/H systems, the water supply system runs from the city service line up to the point of attachment to the products' water purification systems. The water purification system is the "point of usage" for purposes of Wis. Admin. Code § SPS 381.01(284), not Point 71 within the system. Thus, there is no support for the Department's position that the water supply system extends to all of the water within the RO systems themselves.

Second, because of the backflow preventers at the connection to the systems and the air gaps at the drain points in the systems, there is no possibility of substances from the environments within the RO systems entering the water supply system, as required to meet the definition of a cross connection.

Third, a cross connection means that substances from one environment have the potential to enter the water supply system "by means of back siphonage or back pressure." The terms "back siphonage" and "back pressure" are also defined by the Plumbing Code. "Back siphonage" means "the creation of a backflow as a result of negative pressure." Wis. Admin. Code § SPS 381.01(19). "Back pressure" means "a pressure greater than the supply pressure that may cause backflow." Wis. Admin. Code § SPS 381.01(17). Both of these definitions refer to the

term "backflow," which is defined by Wis. Admin. Code § SPS 381.01(16) as "the unwanted reverse flow of liquids, solids or gases."

Applicant argues that there is no "backflow," as that term is defined, because there is no "unwanted reverse flow" of any liquids solids or gases. Applicant asserts that the flow of liquids is exactly as designed and that the only possibility for any "unwanted reverse flow" would be if the liquids were able to enter the city's water supply system at the drain locations or at the point where the water supply systems meet the water using equipment. The Department makes no argument that unwanted reverse flow occurs at the drain locations; moreover, the undisputed evidence is that air gaps prevent that from happening. The evidence is also undisputed that the backflow preventers prevent unwanted reverse flow from the systems into the city's water supply system. The Department argues that a cross connection exists simply by virtue of the fact that it is at this point that the reject water with the highest concentration of particles is reintroduced (or recycled) into the feed water. In so arguing, however, the Department appears to ignore the fact that once reintroduced into the feed water, the combined liquid passes through the membranes an additional time – it does not go directly to the dialysis machines or patients for use.

In addition, the Department failed to produce any evidence that back siphonage or back pressure occurs at Point 71 or as a result of the recycling feature. Wes Byrne, an expert in RO technology, design, and performance, testified that there is no back pressure or back siphonage involved in the recycle feature of the products, as those terms are defined. In its brief, the Department argues that "it is scientifically impossible for the RO reject water to be reintroduced into the feed water stream without some sort of pressure or siphonage. . . . The RO reject water would either need to be at a higher pressure to be introduced into the feed water, thus creating pressure, or there would need to be a siphon action to introduce the reject water into the feed water, thus creating back siphonage." (Department Brief, p. 12.) The Department did not present any evidence for these assertions. This tribunal must rely on evidence for scientific principles or conclusions; it cannot rely on the Department's *ipse dixit* statements. Moreover, the Department disregards the Plumbing Code's definitions of back pressure and back siphonage, actually accusing Applicant of "sleight of hand" for "adding" the definition of "backflow" to its analysis, when the term "backflow" is explicitly incorporated into the Plumbing Code definitions of back pressure and back siphonage. (Department's Closing Brief, p. 13)

The Department's only attempt to incorporate the actual definitions of the terms back pressure or back siphonage is its statement that the term back pressure uses the word "may," *i.e.*, that "back pressure" is "a pressure greater than the supply pressure that *may* cause backflow." Wis. Admin. Code § SPS 381.01(17). However, the Department failed to produce any evidence that the recycle feature (Point 71) involves a "pressure greater than the supply pressure." Thus, even if a finding of backflow is not required for a finding of back pressure, the Department did not overcome the evidence presented by Applicant that no back pressure or back siphonage occurs as a result of the recycling feature.

Based on the foregoing, the design of the products did not violate Wis. Admin. Code § SPS 382.41(3).

Wis. Admin. Code § SPS 382.10(1)(g)

Wisconsin Admin. Code § SPS 382.10(1)(g) states that "[p]roper protection shall be provided to prevent contamination of food, water, sterile goods and similar materials by backflow of wastewater."

As stated above, Applicant has shown that its products do not involve "backflow." Therefore, Applicant's products do not violate Wis. Admin. Code § SPS 382.10(1)(g). In addition, Applicant has established that "wastewater," as used in this provision, applies to the water going into the drain and not to the reject water that is recycled and will again pass through the membranes. Pursuant to Wis. Admin. Code § SPS 381.01(274), "waste" means "the discharge from any fixture, appliance, area or appurtenance." "The term "wastewater" refers to "clear water, storm water, domestic wastewater, industrial wastewater, sewage or any combination of these." Wis. Admin. Code § SPS 381.01(276). Applicant has established that only the reject water which is discharged to the drain is wastewater. [2] The portion of reject water which is recycled is not discharged from the products, as required to meet the definition of "waste," but is sent back to the membranes in order to extract additional product water for use in hemodialysis.

Accordingly, the design of Applicant's products did not violate Wis. Admin. Code § SPS 382.10(1)(g).

Wis. Admin. Code § SPS 384.15

Wisconsin Admin. Code § SPS 384.15 provides: "Health care plumbing appliances shall function and perform in accordance with the drain, vent, water supply and backflow protection requirements of ch. SPS 382."

As stated above, the Department has failed to refute Applicant's evidence that the recycling feature of these products involve no backflow as that term is defined by the Plumbing Code. The evidence further shows that the products comply with the drain, vent, and water supply protection requirements in Wis. Admin. Code ch. SPS 382. As a result, Applicant's products did not violate Wis. Admin. Code § SPS 384.15.

Wis. Admin. Code § SPS 384.20(1)(e)

Wisconsin Admin. Code § SPS 384.20(1)(e) provides that "[a]ll plumbing fixtures, appliances and equipment shall be designed and constructed to: . . . (e) Prevent nonpotable liquids, solids or gasses from being introduced into a potable water supply system through cross-connections." Applicant has shown that its products do not violate this provision because, as stated above, they do not involve cross connections.[3]

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[2] Witnesses Byrne, Curtis and Rickert testified that the portion of reject water that is returned to the system is best referred to as "process water" or "concentrate recycle," and the portion of the reject water that is discharged to the drain is considered "waste."

[3] The parties also argue about whether the water within the system is potable or nonpotable; however, because of the conclusion that the products do not involve cross connections, this issue need not be addressed.

Wis. Admin. Code § SPS 384.20(4)(b)3.

Wisconsin Admin. Code § SPS 384.20(4)(b)3. provides that "[t]he water supply pipes and fittings within every plumbing fixture shall be so installed as to prevent backflow."

As stated, it is undisputed that the systems in question include backflow preventers and air gaps, and there is no evidence to rebut Applicant's evidence that the recycle features do not involve backflow. As a result, the products do not violate Wis. Admin. Code § SPS 384.20(4)(b)3.

Wis. Admin. Code § NR 811.50(16) (as incorporated by Wis. Admin. Code § SPS 382.70(4)(a).

Although not cited in its denial letter, the Department also alleged at hearing that Applicant's products violated Wis. Admin. Code § NR 811.50(16), a provision incorporated into the plumbing standards by Wis. Admin. Code § SPS 382.70(4)(a).

Wisconsin Admin. Code § SPS 382.70(4)(a) provides, in relevant part, that "a plumbing system shall supply a quality of water at the outlet or at the termination of the plumbing system that meets or exceeds the minimum requirements as specified in Table 382.70-1." According to Table 382.70-1, water intended for medical use must comply with chs NR 811 and 812. Wisconsin Admin. Code § NR 811.50(16) provides:

> **NR 811.50 Filtration — membrane.** Membrane technologies have a wide range of applications from the use of lower pressure membranes for removal of surface water contaminants such as *Giardia Lamblia* and *Cryptosporidium* to the use of reverse osmosis for desalination, inorganic compound removal, and radionuclide removal. The following specific requirements shall be met: . . . (16) REJECT WATER. Reject volumes shall be evaluated in terms of the source availability and from the waste treatment availabilities. The amount of reject water from a unit may be reduced to a limited extent by increasing the feed pressure to the unit. Waste disposal from reverse osmosis or nanofiltration reject water shall discharge to a municipal sewer system, to waste treatment facilities, or to an evaporation pond.

The Department alleges that Applicants' products violate the last sentence of this provision: "Waste disposal from reverse osmosis or nanofiltration reject water shall discharge to a municipal sewer system, to waste treatment facilities, or to an evaporation pond." Both the Applicant and the Department agree that, pursuant to this provision, the water which must discharge to the specified locations is "waste disposal from reverse osmosis . . . reject water." *See* Applicant's Closing Brief, p. 10; *see also* Department's Recommended Proposed Decision and Order, p. 6 ("Wis. Admin. Code § NR 811.50(16) clearly states that waste disposal from reverse osmosis reject water shall discharge to a municipal sewer system, to waste treatment facilities, or to an evaporation pond.") The parties' disagreement is over what constitutes "waste." As stated, the Department's position is that waste is the reject water which has passed

through all the membranes because it has the highest concentration of particles of all the water streams in the RO system. Therefore, according to the Department, under Wis. Admin. Code § NR 811.50(16), all of this reject water must go to the drain (which goes to the municipal sewer system), and none of it may be recycled. The Department emphasizes that there is no difference in terms of particle concentration between that portion of the reject water that goes to the drain and that which gets recycled into the system. However, as determined above, Applicant has shown that the RO reject water only becomes waste once it is discharged to the drain. It is at this point that it is no longer being used to create product water for use in hemodialysis. This interpretation is consistent with the definition of "waste" in the Plumbing Code which means the discharge from any fixture, appliance, area or appurtenance. As a result, Applicant's products do not violate Wis. Admin. Code §§ NR 811.50(16) or SPS 382.70(4)(a).

Because the design of the CWP 100 and WRO 300/H do not violate any of the provisions relied upon by the Department in denying Applicant's applications for approval, the Department's denial was unreasonable under Wis. Stat. § 101.02(6)(e).

CONCLUSIONS OF LAW

1. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § SPS 382.41(3) because: (1) the products contain no cross connection as that term is defined by Wis. Admin. Code § SPS 381.01(65); (2) the products do not create circumstances where substances could enter the "water supply system," as that phrase is defined by Wis. Admin. Code § SPS 381.01(284); and (3) the movement of substances within the recycle features is not caused by "back pressure" or "back siphonage," as those terms are defined by Wis. Admin. Code § SPS 381.01(17) and (19), respectively.

2. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § SPS 382.10(1)(g) because the products include backflow preventers and air gaps, and there was no evidence that the products could cause contamination of water by "backflow" of "wastewater," as those terms are defined by Wis. Admin. Code §§ SPS 381.01(16), 381.01(274), and 381.01(276).

3. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § SPS 384.15 because the products comply with the drain, vent, water supply and backflow requirements in Chapter SPS 382 of the Administrative Code.

4. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § SPS 384.20(1)(e) because the products contain no cross connection as defined by Wis. Admin. Code § SPS 381.01(65).

5. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § SPS 384.20(4)(b)3. due to the inclusion of a backflow preventer and air gaps, and because the recycle features do not involve backflow.

6. The design of the CWP 100 and WRO 300/H does not violate Wis. Admin. Code § NR 811.50(16) because only the portion of reject water that is discharged from the system

must be discharged to the municipal sewer system and there is no dispute that the portion of the reject water that is being discharged from these systems is sent directly to drain and into the municipal sewer.

7. Because the design of the CWP 100 and WRO 300/H did not violate the administrative code provisions relied upon by the Department in denying Applicant's applications for approval, the Department's denial was unreasonable under Wis. Stat. § 101.02(6)(e).[4]

ORDER

For the reasons set forth above, IT IS ORDERED that:

1. The Department's October 30, 2018 denial of Applicant's 2017 applications for approval of the CWP 100/100H Reverse Osmosis System and the WRO 300/H Dialysis Water System is withdrawn and the applications for approval of these products is GRANTED.

2. This Order is effective the date the Final Decision and Order is signed by the Department.

Dated at Madison, Wisconsin on May 9, 2019.

STATE OF WISCONSIN
DIVISION OF HEARINGS AND APPEALS
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By: _____
Jennifer E. Nashold
Administrative Law Judge

[4] In light of the conclusions in this case, this tribunal need not consider Applicant's additional argument that the Department's consistent interpretation of the Plumbing Code is invalid without promulgation of a rule.