

Lompoc Artificial Kidney Center, LLC
127 West Pine Avenue
Lompoc, California 93436
Telephone: 805-740-2000

Tikan Singh
Utilities Director
City of Lompoc
Lompoc California

October 1, 2018
By Hand

Dear Mr. Singh:

We are writing to you today to address your concerns over the water softening process at the Lompoc Artificial Kidney Center, LLC (LAKC) located at 127 West Pine Avenue here in Lompoc.

This facility is an outpatient dialysis clinic serving some of Lompoc's sickest patients. The patients treated here have End Stage Kidney Disease in need of renal replacement therapy. Most of the patients have multiple co-morbidities which include hypertension, diabetes, congestive heart failure, peripheral vascular disease and chronic anemia.

Outpatient dialysis clinics are very highly regulated and operate under the highest standards as dictated by the Centers for Medicare & Medicaid Services and by the California Department of Health Services, Licensing and Certification Division. The regulations governing outpatient dialysis facilities are spelled out in detail in the Code of Federal Regulations (CFR). 42 CFR Parts 405,410, 413 et al: Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule.

One of the provisions detailed in the CFR includes water quality for dialysis centers. These regulations call for essentially pure water which is free of ionic and organic contamination which meets or exceeds AAMI standards. This water is then used to prepare the special electrolyte solution which is used to "clean" the patient's blood during the dialysis procedure.

To achieve the level of water quality dictated by the regulations requires that the "feed water" from any municipality needs to pass through a number of steps using an FDA approved water treatment system. This FDA approved medical device first treats the water by passing it through a water softener and then carbon tanks with a required amount of bed contact time, with the last step being an advanced FDA approved reverse osmosis system.

As you are well aware, all water softeners work in an identical manner using an ion exchange resin which exchanges either sodium or potassium ions for other positive ions in the feed water which are usually calcium and magnesium. With continued use, the resin's sodium reserves are depleted requiring "regeneration". The regeneration process requires that the resin be rinsed with a concentrated sodium chloride solution to restore the resin's effectiveness. (Potassium chloride is not used in dialysis centers because it is highly toxic and potentially lethal to dialysis patients).

This entire process is accomplished "in house" for safety reasons by not using "commercial" exchange tanks which are regenerated off site. A dialysis center has no control over where any commercial exchange tank has been previously and has no way of knowing if those tanks contain any industrial contaminants which are potentially harmful to our chronically ill patients.

At LAKC, the amount of sodium chloride used for regeneration is adjusted on a regular basis based on the hardness of the feed water we receive from the city. We have a water softener system with a total of 5 cubic feet of resin. (Note that this water softener is used only for dialysis purposes, not for the building's water.) Regeneration has to be performed when there are no patients on dialysis for patient safety reasons.

Each cubic foot of resin needs between 12 to 15 lbs of salt (NaCl) for each regeneration cycle (60 to 75 lbs or 27.3 to 34 kg) Monday to Saturday. During that cycle, the sodium is taken up by the resin and the previously scavenged cations are released.

The sodium problem of concern to the water department has little to do with the regeneration process where the sodium is taken up by the resin. The sodium of concern is released in the softening process no matter what kind of tank is used or where it was regenerated.

To put this sodium process in perspective using the higher regeneration amount of 34 kg of NaCl/day one needs to keep in mind that on an average day water usage at LAKC approaches 11,000 gallons or 41,635 liters.

Thirty four kilograms of sodium chloride translates into approximately 590,000 mEq of sodium (or chloride). If this is dispersed in 42,000 liters, we are looking at a discharge sodium (or chloride) concentration of 14 mEq/liter which is a trivial concentration.

In contrast, the average American consumes a diet containing about 3,400mg (148 mEq) of sodium most of which will be excreted in approximately 2 liters of urine on a daily basis. The sodium concentration in that daily urine output would then be about 74 mEq per liter. This is many many times the concentration of what the water softener produces.

As a conclusion, we feel that the water softening process at the Lompoc Artificial Kidney Center, LLC poses no risk to Lompoc's waste water treatment processes or its equipment. Further, the regulations do not address medical water softening devices.

We strongly feel that this medical device should be exempt from the local water softening regulations.

We would be happy to sit down with you to discuss this further if that is necessary.

Sincerely,



Thomas R. Allyn, MD, FACP
CEO



Bindu M. Kamal, MD
Medical Director

CC: California Department of Health Services, Licensing and Certification Division