

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/29/2009  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>052885</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>C</b> <b>02/06/2009</b>
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NAME OF PROVIDER OR SUPPLIER  <b>FMC DIALYSIS SERVICES OF PARADISE</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>6919 PARADISE VALLEY ROAD</b> <b>SAN DIEGO, CA 92139</b>
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>Surveyor: 17130 The following reflects the findings of the California Department of Public Health, Licensing and Certification Program during the investigation of complaint #CA00174860. The investigation was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility.</p> <p>Representing the Department: Linda Mosel, HFEN</p> <p>Glossary of Abbreviations:</p> <p>CDPH            California Department of Public Health CM                Clinic Manager mg/L             Milligram per liter</p>	V 000		
V 196	<p>494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE</p> <p>6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line</p>	V 196		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 196	<p>Continued From page 1</p> <p>monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].</p> <p>Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 17130 Based on interview and record review, the facility failed to ensure that Staff Member A documented the level of total chlorine in the water used for dialysis when the maximum allowable level was exceeded.</p> <p>Findings:</p> <p>On 1/15/09 at 4:09 P.M., an unannounced visit was made to the facility in response to a complaint filed with the CDPH related to water quality.</p> <p>During an interview on 1/15/09 at 4:10 P.M., the CM stated that the facility used two carbon tanks (#1, #2) to remove chlorine from water used for dialysis. According to the CM, on 1/2/09, there was a "breakthrough" of total chlorine that was above the "maximum allowable" level.</p> <p>The Association for the Advancement of Medical Instrumentation (AAMI ) Guidelines (RD52:2004) for Dialysate for Hemodialysis specified that the "maximum allowable" total chlorine levels must be less than 0.1 mg/L. Excess chlorine in dialysis</p>	V 196			

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V 196	<p>Continued From page 2</p> <p>water can destroy red blood cells. Patients exposed to water containing chlorine will be injured and could die.</p> <p>During an interview on 1/15/09 at 4:30 P.M., the Chief Water Technician stated that on 1/2/09 at 7:30 A.M. routine testing of total chlorine in the water from carbon tank #1 showed "breakthrough" greater than 0.1mg/L. Immediately, staff tested Tank #2. The level of chlorine was less than 0.1mg/L. Dialysis treatments continued using Tank #2 to remove the chlorine. Tank #1 was removed for repairs. At 8:45 A.M. the same day, Tank #2 showed chlorine "breakthrough" of 0.23mg/L, an amount greater than two times the maximum allowable limit. At this time, the staff discontinued dialysis treatments and removed patients from the machines.</p> <p>On 1/15/09, the Total Chlorine Log for January 2009 was reviewed. The log showed a breakthrough of chlorine from Tank #1 on 1/2/09 at 7:30 A.M. There was no documentation of the breakthrough at 8:45A.M. from Tank #2.</p> <p>On 1/15/09, the facility policy on Chlorine Testing of the Water Treatment System was reviewed. The purpose of the policy was "To provide guidance for the performance of testing for the presence and absence of chlorine in the water. The policy specified that "documentation" was one of the actions taken when results were above the maximum allowable limits.</p> <p>During an interview on 1/15/09 at 5:50 P.M., Staff Member A stated he tested Tank #2 for chlorine but that he did not document the level of chlorine breakthrough.</p>	V 196			

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V 196	Continued From page 3  During an interview on 1/15/09 at 5:55 P.M., the Chief Water Technician stated that staff should have documented the level of the breakthrough.	V 196			