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FDA Issues Alert on Hemodialysis Water Quality Systems

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Medical News Editor

The Food and Drug Administration (FDA) has sent a Safety Alert to hemodialysis personnel and water or dialysate service contractors informing them of a recent incident in which three hemodialysis patients died and several others were hospitalized after exposure to high levels of fluoride in the dialysate. In the recent incident described in the August 19, 1993, alert, the fluoride concentration in the dialysate was reported to be 15 to 25 parts per million (ppm). The American National Standards Institute (AAMI) standard identifies 0.2 ppm as the acceptable level of fluoride in dialysate.

The FDA has stated that "the recent incident underscores the need to continuously monitor the quality of water in hemodialysis systems." The FDA also urges personnel involved in providing hemodialysis to verify that the dialysis water is safe and that an adequate, continuous monitoring system is in place. For further information about the hemodialysis safety alert, contact A.W. Thomas, Office of Training and Assistance (HFZ-250), CDRH, Rockville, MD 20857. FAX (301) 443-8810.

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