TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V406	(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.	Privacy must be provided for the use of a bedpan or commode during dialysis, initiating and discontinuing treatment when the vascular access is placed in an intimate area, for physical exams, and for sensitive communications. There should be sufficient numbers of privacy screens or other methods of visual separation available and used to afford patients full visual privacy when indicated. Exam rooms should have a door or other method to ensure privacy can be provided. Arrangements for private conversations may need to be outside of the patient treatment area in a private location.
V407	(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).	Each patient, including his/her face, vascular access site, and bloodline connections, must be able to be seen by a staff member throughout the dialysis treatment. Allowing patients to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes.
V408	(d) Standard: Emergency preparedness. The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, carerelated emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.	Medical emergencies which may be anticipated in the dialysis setting include, but are not limited to, cardiac arrest, air embolism, adverse drug reactions, suspected pyrogen reactions, profound hypotension or hypertension and significant blood loss. Direct care staff should be aware of how to recognize and respond to emergent patient medical conditions. Regularly-scheduled treatments are essential for dialysis patients. In the event of a natural or man-made disaster, immediate action must be taken to ensure prompt restoration of these treatments or to plan for the safe transfer of patients to alternate location(s) for their treatments. Each dialysis facility must have a facility-specific disaster/emergency plan and be able to respond accordingly. Disaster/emergency plans should address failure of basic systems such as power, source water, air conditioning or heating systems as well as treatment specific

Interim Final Version 1.1 Page 168 of 299

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V409	(1) Emergency preparedness of staff. The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—(A) What to do; (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and (D) How to disconnect themselves from the dialysis	failures such as the facility water treatment system or supply delivery. Dialysis facilities must consider the potential of and develop a plan for natural disasters in their geographic locations (e.g., hurricanes in FL and on the Gulf Coast, earthquakes in CA, ice storms in the northern states, floods near rivers) and man-made disasters (e.g., fires, power or water supply disruptions). Responsible staff and patients should be knowledgeable regarding the emergency plan should the facility be non-operational after a disaster. Non-expired emergency/evacuation supplies, including site dressings, saline, IV tubing, should be available to accommodate evacuated hemodialysis patients. Orientation for all staff must include emergency preparedness training, and annual training thereafter. "Evaluated" would require some feedback to ensure that the training was effective: either a passing score on a written test or demonstrated competency in the expected actions in an emergency situation. Staff must have sufficient knowledge of emergency procedures to educate patients/designees about how to handle emergencies, both in and outside of the facility. At a minimum, all of the listed components must be included in the staff and patient education programs. If problems are identified regarding training patients in emergency preparedness, refer to V412.

Interim Final Version 1.1 Page 169 of 299

TAG	REGULATION	INTERPRETIVE GUIDANCE
NUMBER		
	machine if an emergency occurs.	
V410	(ii) Ensuring that, at a minimum, patient care staff	All direct patient care staff (i.e., nurses and patient care technicians)
	maintain current CPR certification; and	must have current basic CPR certification.
V411	(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.	The minimum emergency equipment required is defined in V413. The emergency drugs to be kept onsite may be determined by the medical director and defined by facility policy.
		If the facility has chosen to use a defibrillator (rather than an Automated External Defibrillator [AED]), recognize that use of a defibrillator requires recognition of arrhythmias and knowledge of protocols to properly use the defibrillator. An AED can be used by any person with appropriate instruction. If a traditional defibrillator is present, written protocols approved by the medical director and a staff member trained and competent to use that equipment should be present whenever patients are dialyzing in the facility.
V412	(2) Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraphs (d)(1)(i) of this section.	Patients must have sufficient knowledge of emergency procedures to know how to handle emergencies, both in and out of the facility. Refer to V409 for the required areas of patient emergency education. Patients/designees should be instructed about the facility disaster/emergency plan. Patients/designees should know how to contact their facility during an emergency. Facilities should provide patients/designees with an alternate emergency phone number in case the facility phone is not answered and/or the facility is not functioning during a disaster. The patients/designees should be able to describe what they would do if they were not able to get to their regular dialysis treatment, including dietary precautions. Patients/designees should understand they must seek treatment promptly in the event that a natural or man-made disaster results in the closure of their facility. For emergencies occurring in the dialysis facility, patients should be able to verbalize how they would disconnect themselves from the

Interim Final Version 1.1 Page 170 of 299

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V413	(3) Emergency equipment. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.	evacuated. The facility should have a system in place to identify patients who will need assistance in disconnection and evacuation during an emergency. Medical records should include evidence of education in emergency evacuation and emergency preparedness, to include some measure of patient understanding, such as return teaching or demonstration. The emergency equipment, as listed, must be clean, accessible, and ready to use at all times. "On the premises" and "immediately available" may include the use of an emergency response team if the facility is located inside a building which includes such a response team (e.g., a hospital-based facility). The response time of personnel and equipment should be demonstrated as being less than 4 minutes.
		Refer to V403 for problems with maintenance of emergency equipment.
V414	(4) <i>Emergency plans</i>. The facility must-(i) Have a plan to obtain emergency medical system assistance when needed;	All members of the facility staff must be able to demonstrate knowledge of how to obtain emergency medical assistance, e.g., 911 system or equivalent for the locality.
V415	(ii) Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary; and	This annual evaluation process should include review of any medical or non-medical emergencies that have occurred during the year to determine opportunities for improvement, as well as re-evaluation of the plans/procedures for current appropriateness and feasibility.
		The facility must conduct drills or mock emergencies at least annually in order to determine the staff's skill level/educational needs and effectiveness of their plan.
V416	(iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.	The facility must contact and develop a communicative relationship with the local disaster management agency. This relationship will help expedite restoration of interrupted services due to an emergency or disaster. There should be some documented evidence of this contact.

Interim Final Version 1.1 Page 171 of 299

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
		In order to ensure life saving dialysis services will be available in the event of an emergency or disaster, facilities should collaborate with their ESRD Network, suppliers, utility service providers, and their State agencies for survey and for emergency preparedness as well as with other dialysis facilities. Resources available from the Kidney Community Emergency Response (KCER) Coalition can assist facilities in meeting this requirement.
V417	(e) Standard: Fire safety. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744 (a)(1)(i) of this chapter).	Effective February 9, 2009, dialysis facilities must comply with Chapter 20 (for new dialysis facilities) or Chapter 21 (for existing dialysis facilities) of the 2000 edition of the Life Safety Code (LSC) for Ambulatory Health Care Occupancies of the National Fire Protection Association (NFPA), 101. An "existing" facility is defined as a facility that has received approval of all of the required building permits (or completed all of the plan reviews in jurisdictions that do not require building permits) prior to February 9, 2009. A "new" facility is defined as a facility that has received approval of all of its building permits (or completed all of its plan reviews in jurisdictions that do not require building permits) after February 9, 2009. A facility that is undergoing major renovations or a facility that is relocating after February 9, 2009, is also classified as a "new" facility.
		These chapters of the LSC were written for ambulatory health care occupancies. Because dialysis facilities do not use anesthesia and only use life-support equipment intermittently for emergency purposes, certain sections of these chapters do not apply. The non-applicable portions are part of section 20.2.9.2 and the part of section 21.2.9.2 which require the facility to provide an "essential electrical system (EES)" in accordance with NFPA 99 if "general anesthesia or life support equipment" is used. "Life support equipment" is defined as electrically-powered equipment whose continuous operation is

Interim Final Version 1.1 Page 172 of 299

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
TAG NUMBER	REGULATION	necessary to maintain a patient's life. Alternatively, Chapter 5 of the LSC allows a dialysis facility a performance-based option for meeting the LSC occupant protection, structural integrity, and systems effectiveness goals and objectives. The Fire Safety Evaluation System (FSES), NFPA 101A, a fire safety equivalency system, cannot be used in place of compliance with the requirements of Chapters 20/21 New/Existing Ambulatory Health Care Occupancies, 2000 edition, NFPA 101 since there is no FSES for Ambulatory Health Care Occupancies. A dialysis facility is classified as an "ambulatory health care occupant." However, a dialysis facility may be located in a mixed
		occupancy building. If a dialysis facility is located in a building with other tenants, it must be separated from the other tenants on the same floor by a one-hour fire wall. For purposes of this regulation, when a portion of the dialysis facility is used intermittently by another entity (e.g., an exam room is used for the nephrologist's office practice) it is not intended that the portion used intermittently would be separated from the dialysis facility by a one-hour fire wall.
		If the dialysis facility is located within a hospital, but not separated from the hospital by 2-hour fire wall construction, the dialysis facility must meet the hospital LSC requirements. If a hospital-based chronic outpatient facility provides acute services for hospitalized patients in the same space and within the hospital walls, the outpatient dialysis facility must meet the more-stringent hospital chapters of the LSC.
		Survey instructions found in State Operations Manual (SOM), Appendix I, are used as applicable, along with the Fire Safety Survey Report Form, 2786U to survey for fire safety. The fire safety standard will be surveyed by a fire specialist from the State Agency; generally,

Interim Final Version 1.1 Page 173 of 299