

## Emerging and Re-emerging Nosocomial Infections in Hemodialysis, CDC Update

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Emerging/re-emerging hemodialysis-associated infections are caused by a variety of microbial agents. These agents include bloodborne pathogens and drug resistant bacteria (Table 1). Other agents are included in this article and the table either due to their potential to produce nosocomial infections (*Mycobacterium tuberculosis*) or because of public concern (Creutzfeldt-JaKob Disease Agent).

The first group of pathogens includes the bloodborne pathogens (hepatitis B and

transmission in hemodialysis units has long been recognized. HBV as demonstrated by the presence of surface antigen (HBsAg) occurs in very high titers in the blood of infected individuals. Studies in the 1970s demonstrated that HBV dried on environmental surfaces could remain infectious after a week and dried virus could probably remain infectious for longer periods of time. In addition, HBsAg, the marker for the intact virus, has been found on common environmental surfaces in hemodialysis facilities such as doorknobs, dialysis machine control panels, clamps, scissors and other items.

Transmission of HBV occurs by a variety of mechanisms and usually includes the following:

- ◆ Percutaneous inoculation (needlestick or sharps injury).
- ◆ Inoculation into mouth, eyes or mucus membranes (either through blood splatter or contaminated hands).

- ◆ Contamination of environmental surfaces and then transfer by hands.
- ◆ Contamination of multi-dose vials or shared patient care items.

One must remember that in the dialysis setting there has never been a case of hepatitis transmitted from a healthcare worker to a patient. It is an infected patient that is usually the source of infection in the dialysis unit.

In 1977, the Centers for Disease Control published the recommendations for control of hepatitis B virus in hemodialysis facilities. The recommendations included isolation, use of dedicated personnel and equipment, non-sharing of supplies and medications, routine cleaning of frequently touched environmental surfaces and patient care area, and serologic screening. Following the publication of these

recommendations and implementation of the recommendations there was a significant drop in both the incidence (acute) and prevalence (chronic) of infections. The addition of a vaccine has also contributed to the decrease in the incidence and prevalence of HBV in hemodialysis facilities.

Despite these recommendations there are still outbreaks of hepatitis B. These outbreaks are primarily due to breaks in infection control techniques and failure to identify infected patients. In addition there is wide spread belief in the nephrology community that the HBV vaccine is not effective. However, the data obtained from the 1995 and 1996 Annual Surveillance of Dialysis-Associated Diseases in the United States does not support this (Table 2).



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Pathogenic Agents	Nosocomial Transmission
<b>Bloodborne Pathogens:</b>	
Hepatitis B Virus (HBV)	+
Hepatitis C Virus (HCV)	+
Human Immunodeficiency Virus (HIV)	Not in the United States
Creutzfeldt-Jacob Disease	No
CJD	
Nv-CJD (Mad Cow's Disease)	
<i>Mycobacterium tuberculosis</i>	Potential Pathogen
<b>Antimicrobial Resistant Bacteria</b>	
Methicillin Resistant	+
<i>Staphylococcus aureus</i> (MRSA)	
Vancomycin Resistant Enterococci (VRE)	? Potential
Glycopeptide Intermediate Resistant <i>S. aureus</i> (GISA/ISA)	Potential

Table 1. List of microbial agents of concern to maintenance and acute hemodialysis facilities

C virus and the Human Immunodeficiency Virus). In the hemodialysis setting the most efficiently transmitted agent is hepatitis B virus (HBV).

### Bloodborne Pathogens

**Hepatitis B Virus.** In the early days of maintenance hemodialysis therapy the transmission of hepatitis B virus (HBV) was quite common. The mechanics of HBV

HBV Vaccinated	Numbers of Patients	1995	
		Incidence Number (%)	Relative Risk
None	36,091	36 (0.10)	2.4*
1-50%	105,060	63 (0.06)	1.5*
>50%	71,158	29 (0.04)	Ref
1996			
None	48,526	52 (0.11)	1.9*
1-50%	91,495	78 (0.08)	1.5*
>50%	79,596	44 (0.06)	Ref

\*P < 0.05 compared with the reference group

**Table 2. Effect of vaccination on the incidence of HBV in hemodialysis patients**

Patients who are not vaccinated have twice the risk in becoming infected with hepatitis B.

**Non A, Non B (NANB) Hepatitis.** Almost all NANB hepatitis in maintenance hemodialysis facilities is due to hepatitis c virus (HCV). HCV is a flavivirus that has multiple genotypes. Even within the genotypes there are closely related sequences or quasi-species. The antibody response that is elicited by infection is not protective and will not cross neutralize virus of other genotypes or quasi-species. It is possible for an individual to become infected with more than one type of HCV since infection does not produce immunity and up to 100 percent of individuals infected will have persistent infection.

Several risk factors are associated with infection with HCV (Table 3). Hemodialysis patients only account for one percent of the total HCV infected patients. What we do know about HCV in hemodialysis facilities can be summarized as follows:

- ◆ Prevalence increases with years on dialysis.
- ◆ Annual incidence is only 1-2 percent
- ◆ The prevalence in the United States hemodialysis patient population is only about 10 percent.
- ◆ The prevalence in staff members is only 1-2 percent.

Testing for HCV in the hemodialysis population consists of several methods, which include monthly liver enzymes, anti-HCV testing, and HCV RNA polymerase chain reaction (PCR). The CDC currently recommends that monthly liver enzymes (AST and ALT) be used to detect NANB hepatitis and does not recommend the use of anti-HCV or HCV RNA PCR testing. Monthly liver enzymes are more sensitive indicators of acute HCV infection.

Tests used to detect antibody to HCV usually require supplemental assays to rule out false positives. There is also much discussion in the literature about the use of PCR to detect the nucleic acid (RNA) /virus in infected individuals. However, there are some limitations to this methodology.

Drawbacks to PCR include:

- ◆ Special handling of patient serum
- ◆ Nonstandardized or licensed methods
- ◆ Problems with false positivity and negativity.
- ◆ Inter-laboratory differences.

Current CDC recommendations for patients who are anti-HCV positive do not exclude them from participating in hemodialyzer reuse programs or specialize any additional infection control measures above and beyond the usual dialysis unit precautions.

**Human Immunodeficiency Virus (HIV).** In the United States there is no evidence for the nosocomial transmission of HIV among patients receiving maintenance hemodialysis. However, outside the United State there have been nosocomial outbreaks of HIV reported in the press and literature. These outbreaks have occurred in Argentina, Columbia, Ecuador, and Egypt. The CDC was involved in the

**Table 3.**

Risk Group	% of HCV infected individuals
Low Socioeconomic Status	17
IDU	38
Sexual/Household	10
Transfusion	4
Occupational	2
Hemodialysis	1
None	1

investigation of the outbreak in Columbia. In this instance the most likely mode of transmission was due to the sharing of access needles among patients without appropriate disinfection or sterilization between patient uses.

Another mode of transmission is patient to healthcare worker through sharp injuries. There has been one documented case of HIV transmission from a patient to a patient care technician following a needlestick injury with a large hollow bore needle (access needle). To date there have been an additional 3 possible (not confirmed) cases all due to sharps injuries in patient care technicians.

### Prion Disease

**Creutzfeldt-Jakob Disease (CJD).** Spongiform encephalopathies are caused by pathogenic agents that have been termed prions, infectious amyloids, or unconventional viruses. They include diseases entities such as Kuru, CJD, Familial CJD (GSS), Bovine spongiform encephalopathy (mad Cow disease, new variant (nv)-CJD), Scrapie, Chronic wasting disease, and transmissible mink encephalopathy. The most common form in humans is CJD. There is no cure or treatment for CJD and it is invariably fatal. CJD has gained increasing notoriety since the reports of nv-CJD (mad cow disease) have surfaced in Europe. CJD is included in this discussion because of several requests for information from practitioners in the hemodialysis industry. Issues that they were interested in included disinfection of equipment and other infection control procedures following the identification of a hemodialysis patient with CJD.

First of all, one must realize that CJD is not a bloodborne disease. Epidemiologic studies at CDC (Schonberger LB, Belay ED, Holman RC 1998. Creutzfeldt-Jakob Disease and Blood Safety) have shown that receipt of blood products is not a risk factor for CJD. Table 4 shows the documented risk factors associated with CJD.

Depth electrodes	2
Lab exposure	3
Corneal transplant	68
Dura mater	3
Human cadaveric growth hormone	76
Human cadaveric pituitary gonadotropin	4
Contaminated neurosurgical instruments	4

**Table 4. Reported Mechanisms of Iatrogenic or occupationally-Acquired Episodes of CJD.**

Some hemodialysis facilities have been told by manufacturers of single pass hemodialysis machines that patients who have CJD should be given a designated machine. Additional recommendations have included disinfecting the machine with undiluted bleach following use and once the patient expires the machine should be discarded and destroyed. These recommendations are certainly extreme. A more reasonable approach to disinfection/sterilization of medical equipment used on CJD patients is to use different protocols based on the risk of patient material contaminating the equipment. Since hemodialysis equipment does not come into contact with brain or central nervous system tissue standard cleaning and disinfection protocols should be more than sufficient.

### Tuberculosis

In the early 1990s there was an increase in the number of tuberculosis (TB) cases primarily associated with the HIV/AIDS epidemic. Not only was TB back after many years in decline, but multiple drug resistance (MDR) had appeared. MDR-TB was involved in nosocomial outbreaks in acute care facilities and correctional facilities with subsequent infections in the healthcare workers.

A survey conducted in New Jersey in 1994 found that patients with end stage renal disease (ESRD) were at increased risk of developing tuberculosis. This increased risk is probably due to impaired immune function that accompanies uremia and ESRD. In addition the annual surveillance data collected by the Hospital Infections Program (CDC) showed that at least 8 percent of U.S. hemodialysis facilities treated at least one person with active TB. Individual dialysis centers treating a higher proportion of minority and foreign born patients, have also reported a higher incidence of TB.

Since ESRD patients are at increased risk of becoming infected with *Mycobacterium tuberculosis* and once infected have a more rapid disease progression, tuberculosis skin testing (TST) should be performed.

- ◆ All patients should receive at least on TST to identify latent infections.
  - ◆ If patients are exposed to persons with active TB, it is likely periodic re-screening may be necessary.
  - ◆ ESRD patients who are contacts of a person with active TB should be re-tested.
  - ◆ A recent study of energy in ESRD patients found only 18 percent to be anergic.
- ◆ Patients with positive skin tests who have not had previous treatment or prophylaxis for TB and who have no medical contraindications should be offered preventive therapy, usually 6 months of isoniazid.

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### General Recommendations for Tuberculosis in Hemodialysis Facilities

CDC. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994.  
MMVVR 1994;43 (No. RR-13)

Easier to treat patients with active pulmonary tuberculosis in an acute setting where TB isolation room, appropriate engineering controls and respiratory protection programs are available.

Patients can be admitted back to the unit when on appropriate therapy and are considered non-infectious

### Drug Resistance an Emerging Infectious Disease Threat

Resistance to antibiotics is an increasing problem in healthcare delivery systems. There are five microorganisms that have major public health importance. These include methicillin resistant *Staphylococcus aureus* (MRSA), MDR-TB, penicillin resistant *Streptococcus pneumoniae*, vancomycin resistant enterococci (VRE), and *Staphylococcus aureus* with reduced susceptibility to glycopeptide antibiotics (vancomycin). Hemodialysis facilities have been concerned primarily with two of these organisms, MRSA and VRE.

MRSA has been a nosocomial pathogen in many healthcare facilities for quite some time and vancomycin has been the drug of choice for treating MRSA infections. Forty-eight percent of U.S. hemodialysis centers have one or more patients with MRSA. In addition, both mupirocin and rifampin have been employed in an attempt to eradicate carriage of the organism. The increasing use of vancomycin for whatever reasons has led to the emergence of vancomycin resistant enterococci (*Enterococcus faecium* and *E. faecalis*). Enterococci are the most frequent organisms associated with blood stream infections in the acute care setting. Risk factors for development of infection with VRE include:

- 1) Severe underlying disease
- 2) Immune suppression
- 3) Intraabdominal or cardiothoracic procedure
- 4) Indwelling urinary or central catheter
- 5) Prolonged hospitalization
- 6) And receipt of antimicrobials especially vancomycin

The percentage of dialysis facilities that treat patients with VRE has almost doubled between 1995 and 1996 (11.5 percent to 21.3 percent). When asked about vancomycin usage, 5.2 percent of all patients were receiving vancomycin in December of 1996. Dialysis centers that had a higher proportion of patients with central catheters had a higher percentage of VRE.

#### **Staphylococcus aureus with Reduced Susceptibility to Glycopeptide Antibiotics (GISA/VISA).**

A hospital in Japan in May of 1996 reported a 4-month old boy developed a surgical wound infection with MRSA. He received vancomycin for a period of 29 days, however, the fever and purulent discharge continued. The antimicrobial therapy was changed and the *Staphylococcus aureus* isolate was found to have an MIC to vancomycin of 8ug/ml (Intermediate Resistance).

A little over a year later the first case of GISA or VISA appeared in the United States in a long term peritoneal dialysis patient in Michigan. The patient had developed peritonitis with a vancomycin sensitive strain of MRSA and after multiple course of iv and intraperitoneal vancomycin therapy GISA had emerged. Fortunately the isolate was susceptible to other antimicrobials such as rifampin, chloramphenicol, trimethoprim-sulfamethoxazole, and tetracycline. Since this first case, there has been another case also peritonitis in a person with acute renal failure receiving peritoneal

**Table 5. Hepatitis B Vaccine Dosage Schedules**

Product/ Group	Dose	Schedule
<b>Recombivax HB</b>		
Patients	40 ug (1ml)*	3 doses at 0,1,6 months
Staff	10ug (1ml)	3 doses at 0,1,6 months
<b>Engerix-B</b>		
Patients	40 ug (ml)**	4 doses at 0,1,2,6 months
Staff	20 ug (1ml)	3 doses at 0,1,6 months or 4 doses at 0,1,2,6 months
* Special formulation		
** Two 1.0-ml doses administered at one site		

dialysis. These cases suggest that we must be vigilant and careful in selection of antimicrobial agents and to adhere to recommended guidelines.

### Infection Control Precautions for Dialysis Units Dialysis Unit Precautions

In 1977, CDC published precautions to prevent transmission of HBV in dialysis centers (1). In 1987, universal precautions were developed to prevent transmission of all bloodborne pathogens, including HBV and HIV, in health care and other settings (2). In 1996, an updated system of precautions, termed standard precautions, was published to replace universal precautions for the hospital and most healthcare settings (3). The infection control measures currently recommended for dialysis units incorporate features of each of these guidelines. These measures are effective against HBV, the most highly transmissible organism in hemodialysis units; therefore, they should also be effective against other viruses (e.g., HCV) and bacteria (e.g. VRE).

Note that dialysis unit precautions are more stringent than universal or standard precautions. For example, standard precautions require the use of gloves only when touching blood, body fluids, secretions, excretions, or contaminated items. In contrast, dialysis unit precautions require glove use whenever patients or hemodialysis equipment is touched. Standard precautions do not restrict the use of supplies, instruments, and medications to a single patient, dialysis unit precautions specify that none of these be shared between any patients.

Since dialysis patients may, known or unknown to the staff, be infected or colonized with a variety of bacteria and viruses, the following precautions should be used during care of **all dialysis patients at all times.**

Assign each patient a (1) dialysis chair or bed and machine; and (2) supply tray (tourniquet, antiseptics, if possible blood pressure cuff). Avoid sharing these items.

Do not share clamps, scissors, other nondisposable items unless sterilized or disinfected between patients. Prepare and distribute medications from a centralized area. Medication carts should not be used. Separate clean and contaminated areas; for example, handling and storage of medications and hand washing should not be done in the same or adjacent area to that where blood samples or used equipment are handled.

Disposable gloves should be worn by staff members for their own protection when handling patients or dialysis equipment and accessories. Gloves should be worn when taking blood pressure, injecting saline or heparin, or touching dialysis machine knobs to adjust flow rates. For the patient's protection the staff member should use a fresh pair of gloves with each patient to prevent cross-contamination. Gloves also should be used when handling blood specimens. Staff members should wash their hands after each patient contact.

Avoid touching surfaces with gloved hands that will subsequently be touched with ungloved hands before being disinfected.

Staff members may wish to wear protective eyeglasses and masks for procedures in which spurring or spattering of blood may occur, such as cleaning of dialyzers and centrifugation of blood.

Staff members should wear gowns, scrub suits, or the equivalent while working in the unit and should change

out of this clothing at the end of each day.

After each dialysis, (1) change linen; (2) clean and disinfect the dialysis bed/chair and nondisposable equipment (especially control knobs and other surfaces touched by gloved hands).

Crowding patients or overtaxing staff may facilitate cross-transmission. Avoid clutter and allocate adequate space to facilitate cleaning and house keeping.

Staff members should not smoke, eat or drink in the dialysis treatment area or in the laboratory. There should be a separate lounge for this purpose. However, all patients may be served meals. The glasses, dishes and other utensils may be cleaned in the usual manner by the hospital staff. No special care of these items is needed.

### Hepatitis B Virus

Because HBV is so highly transmissible in hemodialysis center, several precautions in addition to those outlined above have been recommended specifically to deal with this pathogen.

Patients and staff should be vaccinated and screened as per **Recommendation for Hepatitis B Vaccination and Serologic Surveillance in Chronic Hemodialysis Patients and Staff.**

HBsAg-positive patients should undergo dialysis in a separate room designated only for HBsAg-positive patients. They should use separate machines, equipment and supplies, and most important, staff members should not care for both HBsAg-positive and susceptible patients on the same shift or at the same time. If a separate room is not possible, they should be separated from HBV susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on a dedicated machines. Anti-HBs-positive patients may undergo dialysis in the same area as HBsAg-positive patients or they may serve as a geographic buffer between HBsAg-positive and HBV susceptible patients; in either instance they may be cared for by the same staff member. When the use of separate machines is not possible, the machines can be disinfected by using conventional protocols, and the external surfaces can be cleaned or disinfected with soap and water or a detergent germicide.

Although there is no evidence that patients or staff members in centers that reuse dialyzers are at a greater risk of acquiring HBV infection, it might be prudent that HBsAg-positive patients not participate in dialyzer reuse programs. HBV can occur in high concentration in blood, and handling dialyzers used on HBsAg-positive patients during the reprocessing procedures might place staff members at risk for HBV infection.

### MRSA and VRE

CDC recommends contact precautions for care of hospitalized patients infected or colonized with MRSA, VRE, or certain other antimicrobial-resistant bacteria (3,4). Dialysis unit precautions as outlined above include many of the measures recommended under contact precautions. However, under contact precautions (but not dialysis unit precautions) a private isolation room and (in certain instances) a separate gown are recommended. These measures were recommended to prevent possible transmission via contaminated envi-

Vaccination/Serologic Status and Frequency of Screening			TABLE 6	
Group	Screening Test	Vaccine Nonresponder or Susceptible*	Vaccine Responder or Natural Immunity**	Chronic HBV Infection
<b>Patients</b>				
	HBsAg	Every month	None	Every year
	Anti-HBs	Every 6 months	Every year	If HBs become negative
<b>Staff</b>				
	HBsAg	Every 6 months	None	Every year
	Anti-HBs	Every 6 months	None	If HBs become negative

\* Anti-HBs <10mIU/ml  
 \*\* Anti-HBs > 10mIU/ml  
 \*\*\* HBsAg positive for at least 6 months; or HBsAg positive, anti-HBc positive, IgM anti-HBc negative

**CONTINUED: From Page 3**

ronmental surfaces such as counter tops and bed rails. Hospitalized patients spend nearly 24 hours a day in their hospital bed, whereas dialysis patients spend only 3-5 hours three times a week in the dialysis unit. Note that feces are the main reservoir for VRE. The potential for bacterial contamination of environmental surfaces would appear to be much greater in hospitalized patients than in most dialysis outpatients.

Dialysis unit precautions should be used for care of all patients; at present we do not advise additional precautions for most patients with MRSA or VRE. However, additional precautions would be prudent for patients with infective material that can not be contained (e.g., would drainage that can not be contained by dressings and is culture-positive for MRSA or VRE; or a positive stool culture for VRE and fecal incontinence, a colostomy, diarrhea, or poor hygiene). For these patients, if an isolation room is not available, enhanced attention to patient separation and environmental cleaning might be sufficient. Staff should wear a separate gown when caring for such patients.

Dialysis units should reevaluate their compliance with dialysis center precautions and improve precautions for care of all patients where necessary. Another approach would be cohorting – assigning patients with known MRSA or VRE to certain dialysis stations at one end of the unit, use dedicated staff to care for them, and ensure that strict precautions are used at these stations.

**Prudent Vancomycin Use**

Prudent vancomycin use is another important issue discussed in the CDC guideline "Recommendations for Preventing the Spread of Vancomycin Resistance" (4). Antibiotic use can be considered in three categories: prophylaxis given to uninfected patients in an attempt to prevent infection; empiric therapy, given to patients with signs and symptoms of infection, pending culture results; and continuing therapy, given after culture results are known.

Prophylaxis with vancomycin should not be given, other than for certain surgical procedures (4).

Empiric treatment with vancomycin is appropriate, pending culture results, in patients with beta-lactam allergy, or in instances where serious infection with beta-lactam resistant gram-positive bacteria (i.e., MRSA or *Staphylococcus epidermidis*, which are generally beta-lactam resistant) is likely. Knowing the percent of *S. aureus* that are methicillin-resistant in your area, and the percent of serious infections due to *S. epidermidis*, is important in determining empiric antibiotic coverage.

Continuing treatment depends on culture results. If the patient has allergy to beta-lactam antibiotics, or if beta-lactam resistant bacteria are isolated (with the exception of single blood cultures positive for *S. epidermidis*), vancomycin is appropriate. Depending on susceptibility results, alternative antibiotics (e.g., cephalosporins) with dosing intervals at 48 hours, which would allow post-dialytic dosing, could be used. A recent study suggests that cefazolin given 3 times a week provides adequate blood levels (5).

**Recommendations for Hepatitis B Vaccination and Serologic Surveillance in Chronic Hemodialysis Patients and Staff**

The Centers for Disease Control and Prevention (CDC) and the Immunization Practices Advisory Committee (ACIP) have published guidelines for protection against infection with hepatitis B virus (6). This appen-

dix is meant to collate, summarize, and update, but not replace, sections of these guidelines that deal specifically with hemodialysis patients and staff. If a patient or staff member is exposed to hepatitis B virus, the recommendations of the ACIP (7) should be followed.

**Initial Testing for Hepatitis B Virus Markers**

Hemodialysis patients and staff should be tested for hepatitis B surface antigen (HBsAg) and antibody to HBsAg (anti-HBs) when they begin dialysis or employment in the center. They are classified as infected if HBsAg-positive; immune if anti-HBs positive ( $\bullet$ 10 milli-international units per milliliter (mIU/ml) on at least two consecutive occasions; or susceptible if HBsAg-negative and anti-HBs negative (<10 mIU/ml). For infection control purposes, testing for antibody to hepatitis B core antigen (anti-HBc) is not necessary. However, if testing is done, individuals who are HBsAg-negative and anti-HBc positive have had past hepatitis B virus infection and are immune.

**Hepatitis B Vaccination**

All susceptible patients and staff should receive hepatitis B vaccine (dosage schedules in Table 5), be tested for anti-HBs 1-2 months after the final dose of vaccine, and be followed up as outlined. Vaccination of immune (anti-HBs  $\bullet$ 10mIU/ml on two consecutive occasions) persons is not necessary, but also is not harmful.

**Screening and Follow up**

Screening and Follow up depends on the result of anti-HBs testing 1-2 months after the final dose of vaccine (Table 6). Unvaccinated immune individuals can be screened and followed up as if they were vaccine responders.

Patients, Responders. Patients who are anti-HBs positive (>10 mIU/ml) after vaccination are responders. They should be tested for anti-HBs each year (Table 6). If the level of anti-HBs falls below 10 mIU/ml, they should receive a booster dose of hepatitis B vaccine and be tested for anti-HBs each year.

Patients, Non-Responders. Patients who are anti-HBs negative (<10 mIU/ml) after vaccination are non-responders. They may be revaccinated with one or more doses of vaccine and retested for anti-HBs 1-2 months later. If they are then anti-HBs positive ( $\bullet$ 10 mIU/ml), they can be reclassified and treated as responders (see above). If they continue to be non-responders (anti-HBs <10 mIU/ml), they should be considered susceptible to HBV infection and tested for HBsAg every month and anti-HBs every 6 months (Table 6).

Staff, Responders. Staff who are anti-HBs positive (>10 mIU/ml) after vaccination are responders. They do not need any further routine anti-HBs testing (Table 6). If exposed to blood from a patient known to be HBsAg-positive, such staff members should be tested for anti-HBs; if still anti-HBs positive ( $\bullet$ 10 mIU/ml), no further action is required; however, if they have become anti-HBs negative (<10 mIU/ml), they should receive a booster dose of vaccine.

Staff, Non-responders. Staff who are anti-HBs negative (<10 mIU/ml) after vaccination are non-responders. At the center's discretion, they can be revaccinated with one or more doses of vaccine, and retested for anti-HBs 1-2 months later. If they then become anti-HBs positive ( $\bullet$ 10 mIU/ml), they should be reclassified and treated as responders (see above). If they are not revaccinated, or are still anti-HBs negative (<10 mIU/ml) after vaccination, they continue to be non-responders. Non-responders should be considered

susceptible to HBV infection and tested for HBsAg and anti-HBs every 6 months (Table 6). If they are exposed to the blood of a person known to be HBsAg-positive, they should either receive 2 doses of hepatitis B immune globulin (HBIG), or receive 1 dose of HBIG and 1 dose of hepatitis B vaccine. They may receive similar treatment if exposed to the blood of a person known to be at high risk for hepatitis B.

**Recommendations for Screening for Non-A Non-B Hepatitis (Hepatitis C)**

The assay for antibody to hepatitis C virus (anti-HCV) identifies a high proportion (80 percent to 90 percent) of persons with chronic non-A, non-B hepatitis. For patients with acute non-A, non-B hepatitis, however, there may be a prolonged interval between exposure or onset of hepatitis and antibody seroconversion. Persons negative for anti-HCV during their acute illness should be retested at least six months later to make a final diagnosis. Patients with a diagnosis of non-A, non-B hepatitis who remain negative for anti-HCV may have hepatitis C but fail to elicit an immune response detectable by the current assay, they may be infected with a second agent of non-A, non-B hepatitis, or their hepatitis may have another cause (viral or nonviral). Thus, the diagnosis of acute non-A, non-B hepatitis must continue to rely on the exclusion of other etiologies of liver disease even with the availability of a licensed test for anti-HCV.

Historically, it was recommended that patients be tested monthly for alanine aminotransferase (ALT) or aspartate aminotransferase (AST) to detect possible non-A, non-B hepatitis infections, particularly occurring in clusters, that might indicate a problem with infection control practices. Isolation of dialysis patients with presumed non-A, non-B hepatitis in separate rooms on dedicated machines was not considered necessary or recommended, instead, the use of basic barrier precautions or what are now called universal precautions was emphasized. The availability of a commercial test for anti-HCV does not change these recommendations for the control of non-A, non-B hepatitis in the dialysis center.

1. Dialysis unit precautions as outlined in Appendix II should be used for all patients.

2. Patients who are positive for anti-HCV or have a diagnosis of non-A non-B hepatitis, do not have to be isolated from other patients or dialyzed separately on dedicated machines. In addition, they can participate in dialyzer reuse programs.

3. Patients should be monitored for elevations in ALT and AST monthly. Elevation in liver enzymes currently are more sensitive indicators of acute hepatitis C than anti-HCV.

4. Routine screening of patients or staff for anti-HCV is not necessary for purposes of infection control. Dialysis centers may wish to conduct serologic surveys of their patient populations to determine the prevalence of the virus in their center, and in the case of patients or staff with a diagnosis of non-A, non-B hepatitis, to determine medical management. In addition, if liver enzymes screening indicates the occurrence of an epidemic of non-A, non-B hepatitis in the dialysis setting, anti-HCV screening on serum samples collected during and subsequent to outbreaks may be of value. However, since anti-HCV in an individual cannot measure infectivity, its usefulness for infection control in the dialysis center setting is limited.

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# AAMI Standards, Education Provide Guidance for Safe, Effective Dialysis

**BY NICOLAS TONGSON**

In the rapidly changing world of dialysis treatment, AAMI's (Association for the Advancement of Medical Instrumentation) standard development activities, sponsorship of educational courses and conferences, and certification programs provide invaluable guidance on safe and effective hemodialysis practice. AAMI's unique multi-disciplinary composition of engineers, researchers, technicians, physicians, nurses, manufacturers, and government professionals make it a significant forum for dialysis experts from all sectors of the renal community. AAMI's standards are widely recognized in the U.S. and around the world.

## Standards

AAMI has published four American National Standards on dialysis – Hemodialysis Systems (RD5), Hemodialyzers (RD16), Hemodialyzer Blood Tubing (RD17), and Reuse of Hemodialyzers (RD47). These standards, developed by the AAMI Renal Disease and Detoxification Committee, reflect the consensus of manufacturers, physicians, nurses, technicians, patient representatives, researchers, and government officials.

A collaborative effort between the American Society for Artificial Internal Organs (ASAIO) and AAMI was initiated in the late 1960s to develop a standard for hemodialysis systems. Publication was delayed until ongoing work at the Minneapolis Medical Research Foundation (Regional Kidney Disease Program) on identifying risks and hazards associated with conventional hemodialysis systems was finalized. In addition, the AAMI Technology Assessment Conference "Issues in Hemodialysis," held in early 1981, provided an opportunity to discuss and refine the standard. The AAMI hemodialysis systems standard was published in 1982.

A thorough review of the hemodialysis systems standard was started in 1986, and a second edition was issued in 1992 with substantive changes. The principal areas of change were the additions of provisions for bicarbonate dialysis, requirements for ultrafiltration controls or monitors, and a section on bacteriology of aqueous bicarbonate concentrate.

In keeping with AAMI's policy to periodically review standards to keep them current, Hemodialysis Systems was once again reviewed by the committee in 1996. Work on the third edition of this important standard is ongoing. The standard has been divided into three documents and each will be published as a stand-alone standard. American National Standards on water quality for dialysis, concentrates, and equipment will be published.

AAMI's development, publication, and subsequent revision of the voluntary Hemodialysis Systems standard is an example of successful consensus building. The people, institutions, regulators, and industry with an interest in the work are well-represented on AAMI's Renal Disease and Detoxification Committee. These leaders in the dialysis community provide a strong foundation for the development of these standards.

For more information on AAMI's Standards Program, please call (703) 525-4890 or visit our website at [HYPERLINK http://www.aami.org](http://www.aami.org). To place an order for dialysis documents or for information on how to order, please call AAMI's Customer Service Department at (800) 332-2264.

## Education

AAMI has sponsored two courses (dialyzer reprocessing and water quality for dialysis) for more than 15 years, usually held at AAMI's Annual Meeting.

These courses are directed primarily to doctors, nurses, and technicians who specialize in nephrology. The goal of the courses is to help dialysis professionals stay current so that they are better able to

apply consensus recommendations to real-life situations. These courses emphasize changes over the previous year, or seen on the horizon, in technology, relevant government requirements and recommendations, as well as applicable AAMI standards, in addition to providing guidance on the basics of safe and effective dialysis. Past courses have been cosponsored by the U.S. Food and Drug Administration, ASAIO, National Association of Nephrology Technologists/Technicians, National Renal Administrators Association and the Renal Physicians Association and have been endorsed by the American Nephrology Nurses Association.

The current monographs on Water Quality for Dialysis (WQD) and Current Concepts in Hemodialyzer Reprocessing (HDR) are based on select presentations from courses held in 1992, 1995, and 1997. Water Quality for Dialysis contains eight papers and addresses the microbiologic qualities of water for hemodialysis, aspects of pre- and post-treatment reverse osmosis membrane technology, monitoring of hemodialysis water treatment systems, and FDA regulations of water purification systems for hemodialysis. Current Concepts in Hemodialyzer Reprocessing contains nine papers covering the history of reprocessing, microbiologic considerations, monitoring and anticoagulation strategies, personnel and quality assurance issues, and Health Care Financing Administration adoption of AAMI guidelines. The conference report Hemodialyzer Reuse in the 1990s: Practice, Regulation, and Patient Safety (HEMO) is based on the AAMI 1994 Hemodialyzer Reuse Conference.

AAMI's landmark 1994 conference on hemodialyzer reuse helped establish the appropriateness of the practice. But the debates have not ended – questions remain about the various dialyzer reprocessing techniques, the effect of reuse on dialyzer function, and the economics of reuse. "It is appropriate that the clinical, research, and manufacturing communities gather again to share their concerns and findings," says Nathan W. Levin, MD, Medical & Research Director, Renal Research Institute, LLC. Major new epidemiological studies are likely to be released by year's end that address patient outcomes and the effect of reuse on dialyzer function. There is also new data about sterilizing and disinfecting techniques. In addition, manufacturers are developing new uses for hemodialysis equipment. In addition to the need to update the clinical knowledge base, regulators and standard-setting bodies are also seeking industry input on issues related to reuse, particularly the FDA's proposal that a voluntary expiration date standard be developed.

Carolyn Y. Neuland, PhD, Office of Device Evaluation, CDRH, FDA, explains that "FDA believes an expiration date for hemodialyzers, hemoconcentrators, and hemofilters is important. A new, voluntary standard would ensure that users of these products are informed about the safe, useful shelf life of these products and that their performance would not deteriorate and compromise safety." FDA has proposed test parameters, but questions have been raised about whether these tests actually prove degradation or merely measure failure rate.

## International work

AAMI also serves as the secretariat of international subcommittees (ISO/TC 150/SC 2 and IEC/TC 62/SC 62D) that develop standards for dialysis. In addition, the AAMI Renal Disease and Detoxification Committee serves as the U.S. Technical Advisory Sub-Group (Sub-TAG) to the international working groups that develop dialysis standards. This gives AAMI a prominent voice in developing dialysis standards that are accepted worldwide. This international

work provides a forum for exchanging current information on how to practice safe and effective hemodialysis.

Through AAMI and the American National Standards Institute (ANSI), the U.S. contributed to the development of the following international standards: ISO 8637:1989, Haemodialyzers, haemofilters and haemoconcentrators

ISO 8638:1989, Extracorporeal blood circuit for haemodialyzers, haemofilters and haemoconcentrators. IEC 60601-2-16:1998, Medical electrical equipment – Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment.

Other international standards that are in progress include peritoneal dialysis equipment, water for dialysis requirements, concentrates requirements, plasmafilters, and the second edition of ISO 8637 and 8638.

## Certification of health care technical specialists

Technicians who repair and maintain dialysis machines can be certified by the International Certification Commission for Clinical Engineering and Biomedical Technology (ICC). AAMI serves as the secretariat for ICC.

Certification is formal recognition by the ICC that a technician has demonstrated theoretical, as well as practical knowledge of the principles of biomedical equipment technology specialties or clinical engineering. Such recognition results from successful completion of a written examination.

The Board of Examiners for Biomedical Equipment Technicians, operating under the direction of the United States Certification Commission (USCC) and the ICC maintains the certification programs for biomedical equipment technicians (CBET) as well as radiology equipment specialists (CRES) and clinical laboratory equipment specialists (CLES).

AAMI recognizes that in today's health care environment, technology is a vital component. The need for a work force knowledgeable in the theory of operation, underlying physiological principles, and safe application of biomedical equipment is a central concern of many hospitals and companies. Certification demonstrates that successful applicants have the knowledge to ensure a safe and reliable health care environment. To this end, AAMI offers a two-day course entitled "BMET Evaluation and Review" every year at its Annual Meeting and also offers a Study Guide for BMET Certification (available in hardcopy and electronic format).

For more information on AAMI, please visit our website at [HYPERLINK http://www.aami.org](http://www.aami.org).

## Conference Offers Updates on Hemodialysis Reuse

The latest findings of epidemiological studies on hemodialysis patient outcomes, cutting-edge applications of hemodialysis equipment, and the economics of reuse will be examined at AAMI's conference, "Hemodialysis in the 21st Century: Practice, Regulation, and Economics."

The conference, chaired by Nathan W. Levin, MD, Medical & Research Director, Renal Research Institute, LLC, will be held in June 1999 during AAMI's annual meeting in Boston, Mass.

Co-sponsoring the conference are the Center for Devices and Radiological Health, FDA; American Nephrology Nurses' Association; Health Industry Manufacturers Association; National Association of Nephrology Technologists/Technicians; National Kidney Foundation; National Renal Administration Association; and Renal Physicians Association.

More information is available from AAMI at [www.aami.org/meetings/meetings.html](http://www.aami.org/meetings/meetings.html) or by calling (800) 332-2264.

# The National Conference on

## January 21-22—The Westin Innisbro



The Renal Research Institute, in conjunction with the National Kidney Foundation, is presenting a comprehensive, two day educational seminar for practicing nephrologists.

The meeting contains three segments:

1. New hemodialysis and peritoneal dialysis technology.
2. New epidemiologic information from USRDS and other selected sources.
3. A series of debates on major controversies in the ESRD and Dialysis.

in these issues

### DAY 1 — Thursday, January 21

7:00-7:30 A.M.	CONTINENTAL BREAKFAST/COFFEE	
7:30-7:35	Welcome— <i>Morning Session Chair, Nathan Levin, M.D.</i>	
7:35-8:20	Keynote address Cardiac disease and the dialysis patient	Eberhard Ritz, M.D.
8:20-8:40	<b>Debate-</b> Does superior ESRD care in Europe	Claudio Ronco, M.D. ( <b>Yes</b> )
8:40-9:00	explain the superior clinical outcomes?	William Owen, M.D. ( <b>No</b> )
9:00-9:25	Panel Discussion	William Owen, M.D. Claudio Ronco, M.D. Phillip Held, Ph. D. Frank Gotch, M.D.
9:25-9:50	Coffee Break	
9:50-10:20	The measurement and significance of co-morbidity in dialysis	Sheldon Greenfield, M.D.
10:20-10:40	<b>Debate-</b> Is there material danger in the use of	Alan Collins, M.D. ( <b>Yes</b> )
10:40-11:00	intravenous iron?	Steven Fishbane, M.D. ( <b>No</b> )
11:00-11:25	Panel Discussion	Alan Collins, M.D. Steven Fishbane, M.D. Eric Young, M.D. Harold Feldman, M.D.
11:25-11:55	Hospitalization and its relationship to intermediate outcomes in dialysis patients	Edmund Lowrie, M.D.
11:55-12:25	Lunch Break (excellent box lunch)	
12:25-12:55	SMR-SHR-STR An analysis and evaluation of the USRDS methods	Robert Wolfe, Ph.D.
12:55-1:25	Description and current status of the	Phillip Held, Ph. D.
1:25-1:45	Dialysis Outcomes & Practice Patterns Study (DOPPS)	
1:25-1:45	<b>Debate-</b> Is the clinical effectiveness of single use, high efficiency cellulosic membranes equal to that of high flux membranes with reuse?	Steven Bander, M.D. ( <b>Yes</b> ) Robert Hootkins, M.D. ( <b>No</b> )
2:05-2:30	Panel discussion	Steven Bander, M.D. Robert Hootkins, M.D. Friedrich Port, M.D. William Clark, M.D. Glen Chertow, M.D. William Clark, M.D.
2:30-3 :00	Cost effectiveness of acute and maintenance dialysis	
3:00-3:30	Solute kinetics and therapy quantification in acute renal failure	
7:30-8:30	Cocktail Party (Cash Bar)	
SPECIAL TALK	ESRD regulatory and legislative Update	William Vaughn House of Representatives Ways and Means Committee Minority Desk

# Dialysis: Advances In ESRD

## Book Resort—Tarpon Springs, Florida

Kidney Foundation and Fresenius Medical Care will be organizing a  
 sts, research academicians and fellows.



**National Kidney  
 Foundation®**

databases.

s fields, supported by panel discussions involving experts with experience



**Fresenius Medical Care**

### DAY 2 — Friday, January 22

7:00-7:30 A.M.	CONTINENTAL BREAKFAST/COFFEE	
7:30-7:35	Welcome— <i>Morning Session Chair, J. Michael Lazarus, M.D.</i>	
7:35-8:05	The future role of dialysis technology	Claudio Ronco, M.D.
8:05-8:35	Wall Street perspective of dialysis industry	Elaine Claar Campbell Managing Director Credit Suisse/ First Boston
8:35-8:55	<b>Debate-</b> Should nurses have a larger role in the outpatient dialysis setting than currently?	Christine Price, R.N., M.S.N. ( <b>Yes</b> ) Emil Paganini, M.D. ( <b>No</b> )
8:55-9:15		
9:15-9:35	Panel Discussion	Christine Price, R.N., M.S.N. Emil Paganini, M.D. Gail Wick, R.N., M.S.N. Marcia Keen, Ph. D., R.N.
9:35-9:55	Break	
9:55-10:25	Current paradigms in appropriate initiation of dialysis Afternoon Session Chair — <i>José Diaz-Buxo, M.D.</i>	Brian Pereira, M.D.
10:25-11:25	Techniques to improve PD utilization in the U.S.	Alan Kliger, M.D. Andrew Levey, M.D. Peter Blake, M.D. Richard Swartz, M.D. Frank Gotch, M.D.
11:25-11:55	On-Line clearance A new adequacy measurement— how to use it	
11:55-12:15	Discussion on adequacy measurement	Bernard Canaud, M.D.
12:15-12:45	Lunch Break (excellent box lunch)	
12:45-1:15	Biofilm and its effect on the dialysis patient	William Costerton, Ph. D. Michael Lysaght, Ph.D.
1:15-1:45	New strategies for absorptive and other methods of additional removal of uremic toxins	
1:45-2:15	Analysis of new methods for access monitoring	Thomas Depner, M.D.
2:15-2:30	Update on new vascular access device—VascA	John Moran, M.D.
2:30-2:45	Update on new vascular access device—BioLink	Bernard Canaud, M.D.
2:45-3:15	New strategies for reducing intradialytic symptoms	Matthias Kraemer, Ph. D.

To register please contact RRI, 207 E. 94th, New York, NY 10128  
 Telephone 212-360-4900 Fax 212-360-7233  
 email: [scevallos@rriny.com](mailto:scevallos@rriny.com)

# What Can I Expect With an OSHA Inspection?

By Lawrence K. Park, MSPH, CHCM

Corporate Director Health, Safety,  
Environmental Affairs, and Engineering  
Fresenius Medical Care North America.

According to Title 29 Part 1903, Section 1 of the Code of Federal Regulations:

The Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1590 *et seq.*, 29 U.S.C. 651 *et seq.*) requires, in part, that every employer covered under the Act furnish to his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees. The Act also requires that employers comply with occupational safety and health standards promulgated under the Act, and that employees comply with standards, rules, regulations and orders issued under the Act which are applicable to their own actions and conduct. The Act authorizes the Department of Labor to conduct inspections, and to issue citations and proposed penalties for alleged violations.

In reviewing the above paragraph, let us address the first issue of the employer providing a place of employment free from recognized hazards that are likely to cause death or serious physical harm to his employees.

An example of this type of hazard in a dialysis facility would be tuberculosis. According to the OSHA Fact Sheet 93-43 entitled "Enforcement Policy on Tuberculosis (TB)," (which is based on the October 8, 1993 agency wide enforcement policy):

Inspection for occupational exposure to TB shall be conducted in response to employee complaints and as part of all industrial hygiene compliance inspections in workplaces where the Centers for Disease Control (CDC) has identified workers as having a greater incidence of TB infection. These workplaces are health care settings, correctional institutions, homeless shelters, long-term care facilities for the elderly and drug treatment centers.

Citations based on the general duty clause will be issued only to employers whose employees work on a regular basis in one of the five types of facilities listed above by the CDC as having a higher incidence of TB than the general population, and whose employees 1) have potential exposure to the exhaled air of an individual with suspected or confirmed tuberculosis, or 2) were exposed to a high hazard procedure performed on an individual who may have tuberculosis and which has the potential to generate potentially infectious airborne respirators secretions.

To prove a violation of the general duty clause, it must be shown that the employer failed to keep the workplace free of a hazard to which his or her employees were exposed, that the hazard was recognized, that the hazard was causing or likely to cause death or serious physical harm, and that a feasible and useful method to correct the hazard existed.

Second, the employer must comply with occupational safety and health standards promulgated with the Act. At Fresenius Medical Care North America, we utilize a facility checklist to ensure regulatory compliance with the following OSHA programs which may be relevant to your dialysis facility:

- 1903.2 (Posting of job safety and health notice)
- 1904.1 (Purpose and Scope – Recording and Reporting Occupational Injuries and Illnesses)
- 1904.2 (Log and Summary of Occupational Injuries and Illnesses)
- 1910.35 (Definitions – Means of Egress)
- 1910.36 (General Requirements-Means of Egress)
- 1910.37 (General Means of Egress)
- 1910.38 (Employee Emergency Plans and Fire Prevention Plans)
- 1910.95 (Occupational Noise Exposure)
- 1910.101 (Compressed Gases – General Requirements)
- 1910.132 (General Requirements – Personal Protective Equipment)
- 1910.133 (Eye and Face Protection)
- 1910.134 (Respiratory Protection)
- 1910.145 (Specification for Accident Prevention Signs and Tags)

- 1910.146 (Permit Required Confined Spaces)
- 1910.147 (The Control of Hazardous Energy – Lockout/Tagout)
- 1910.151 (Medical Service and First Aid)
- 1910.157 (Portable Fire Extinguishers)
- 1910.158 (Standpipe and Hose Systems)
- 1910.159 (Automatic Sprinkler System)
- 1910.1000 (Air contaminants)
- 1910.1001 (Asbestos)
- 1910.1020 (Access to Employee Exposure and Medical Records)
- 1910.1030 (Bloodborne Pathogens)
- 1910.1048 (Formaldehyde)
- 1910.1200 (Hazard Communication)

In addition, there are resources available from OSHA which can be used as a reference to assist in the compliance effort in the dialysis clinic and some of them are listed below:

## 1. US Department of Labor Program Highlights Fact Sheets:

- No. OSHA 93-02 "Inspecting for Job Safety and Health Hazards"
- No. OSHA 93-05 "Record Keeping Requirements"
- No. OSHA 93-09 "Back Injuries – Nation's Number One Workplace Safety Problem"
- No. OSHA 95-24 "Safety with Video Display Terminals"
- No. OSHA 93-32 "Control of Hazardous Energy Sources"
- No. OSHA 93-43 "Enforcement Policy for Tuberculosis"
- Bloodborne Facts – 1992
- No. OSHA 92-97 "Occupational Exposure to Formaldehyde"
- No. OSHA 93-41 "Workplace Fire Safety"
- No. OSHA 93-44 "OSHA Emergency Hotline"
- No. OSHA 92-19 "Responding to Workplace Emergencies"
- No. OSHA 93-03 "Eye Protection In the Workplace"
- No. OSHA 93-26 "Hazard Communication Standard"
- No. OSHA 92-01 "Job Safety and Health"
- No. OSHA 93-07 "Improving Workplace Protection For New Workers"
- No. OSHA 92-46 "Bloodborne Pathogens Fact Sheet – Summer of Key Provisions"
- No. OSHA 92-08 "Protecting Yourself with Personal Protective Equipment"

## 2. US Dept. of Labor Booklets

- Access to Medical and Exposure Records – OSHA 3110 (1993)
- All About OSHA – OSHA 2056 (1995)
- Asbestos Standard for General Industry – OSHA 3095 (1995)
- Employee Workplace Rights – OSHA 3021 (1994)
- Chemical Hazard Communication – OSHA 3084 (1995)
- Consultation Services for the Employers – OSHA 3047 (1997)
- How to Prepare for Workplace Emergencies – OSHA 3088 (1995)
- Occupational Exposure to Bloodborne Pathogens – OSHA 3127 (1996)
- Bloodborne Pathogens and Acute Care Facilities – OSHA 3128 (1992)
- Personal Protective Equipment – OSHA 3077 (1998)
- Brief Guide to Record-keeping Requirements for Occupational Injuries and Illnesses – OMB No. 1220-0029
- Log and Summary of Occupational Injuries and Illnesses (Form OSHA 200)
- Hospitals and Community Emergency Response – What you Need to Know – OSHA 3152 (1997)
- Record-keeping Guidelines for Occupational Injuries and Illnesses – OMB No. 1220-0029
- Supplementary Record of Occupational Injuries and Illnesses (Form OSHA 101)
- Hearing Conservation – OSHA 3074 (1995)

- Lockout/Tagout) Control of Hazardous Energy – OSHA 3120 (1994)
- Material Safety Data Sheet – OSHA 174
- OSHA Inspections – OSHA 2098 (1996)
- OSHA Publications and Audiovisual Programs – OSHA 2019 (1998)
- Respiratory Protection – OSHA 3079 (1993)
- Video Display Terminals – OSHA 3092 (1996)

## 3. US Department of Labor Field Inspection Reference Manual (FIRM)

4. US Department of Labor Directives – developed by OSHA to provide a standardized system of inspection procedures for compliance staff and contains information on the application of a particular standard, or providing guidance regarding OSHA's policies and procedures.

## 5. US Department of Labor Technical Manual

## 6. US Department of Labor Posters

- Attention Drivers OSHA 3113 (1994)
- Confined Spaces Can Kill – OSHA 3140 (1994)
- Job Safety and Health Protection – OSHA 2203 (1997)

## 7. Code of Federal Regulations

- Title 29 Code of Federal Regulations Part 1901.1 to 1910.999 (General Industry)
- Title 29 Code of Federal Regulations Parts 1910.1000 to End (General Industry)

Finally, OSHA has established a system of inspection priorities and they are listed below as stated in OSHA's Publication No. 2056:

• Imminent Danger – First priority is imminent danger. Imminent danger is any condition where there is reasonable certainty that a danger exists that can be expected to cause death or serious physical harm immediately or before the danger can be eliminated through normal enforcement procedures.

• Catastrophes and Fatal Accidents – Second priority is given to investigation of fatalities and catastrophes resulting in hospitalization of three or more employees. Such situations must be reported to OSHA by the employer within 8 hours. Investigations are made to determine if OSHA standards were violated and to avoid recurrence of similar accidents.

• Employee Complaints – Third priority is given to employee complaints of alleged violation of standards or of unsafe or unhealthful working conditions.

• Programmed High-Hazard Inspections – Fourth priority are programs of inspection aimed at specific high-hazard industries, occupations or health substances. Industries are selected for inspection on the basis of such factors as the death, injury and illness incidence rates and employee exposure to toxic substances. Special emphasis may be regional or national in scope, depending on the distribution of the workplaces involved. Comprehensive safety inspections in manufacturing will be conducted only in those establishments with lost work-day injury rates at or above the most recently published BLS national rate for manufacturing. States with their own occupational safety and health programs may use somewhat different systems to identify high-hazard industries for inspections.

• Follow-up Inspections – Finally, a follow-up inspection is conducted to determine if the previously cited violations have been corrected. If an employer has failed to abate a violation, the compliance officer informs the employer that he/she is subject to "Notification of Failure to Abate" alleged violations and propose additional daily penalties while such failure or violation continues.

Finally, to assist you after an OSHA inspection has occurred, there is a publication from OSHA entitled "Employer Rights and Responsibilities following an OSHA Inspection – OSHA No. 3000." The publication reviews the step to take after an inspection, the types of violations (willful, serious, repeated, other), posting requirements, employer options, informal conference and settlement, contest process, petition for notification of abatement, temporary and permanent variances, etc.

There are many resources to assist in your efforts in preparing and doing well during an OSHA inspection.