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TABLE OF CONTENTS

DENTAL INFECTION CONTROL AND OCCUPATIONAL HEALTH COURSE

2000 OSAP ANNUAL SYMPOSIUM

FOOD AND DRUG ADMINISTRATION ISSUES NEW SAFETY STANDARD

NEEDLE SAFETY

NEEDLESTICK INJURY PREVENTION

OSHA TRAINING REQUIREMENTS

PROPOSED ERGONOMICS REGULATION

TUBERCULOSIS VACCINE

NEW WORKPLACE SAFETY AND HEALTH PROGRAM

HEPATITIS C VIRUS

ENVIRONMENTAL SURFACE DISINFECTION

INFECTION CONTROL Q&A

developments. Contact OSAP for information on membership and upcoming programs.

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FOOD AND DRUG ADMINISTRATION ISSUES NEW SAFETY STANDARD

The Food and Drug Administration (FDA) has issued a new safety standard for electrical wires that connect from medical/dental devices that contact patients. Devices include medical monitors and transmitters, but may also include root canal apex locators, pulp vitality testers, desensitizing devices and electrosurgery units.

These devices have connections with an electrode at one end that attaches to the patient. The other end attaches to the medical/dental device, which may accidentally be plugged into a live electrical outlet instead of the device, possibly leading to injury. Twenty-four injuries have been reported in the last 15 years. The standard requires that cables or leads be protected making them impossible to mistakenly inserted into electrical outlets. This standard was established to prevent deaths or injuries from improperly connected medical/dental devices.

The connections will be required to meet the new standard within one to three years depending upon the extent of risk. The regulations can be viewed in the Code of Federal Regulations (CFR) at 21 CFR Part 898 or online at www.fda.gov/bbs/topics/ANSWERS/ANS00796.html.

NEEDLE SAFETY

On 2 May 2000, the Occupational Safety and Health Administration (OSHA) reported to the American Dental Association (ADA), that dentists should continue evaluating new safety needles. It is up to the employer (the dentist) to determine what engineering controls can be utilized in his or her workplace to reduce or eliminate exposure to needlesticks to workers and whether or not they would be effective for the unique situations dentists often face," the director of the national OSHA policy office told the ADA.

Presently, data on the safety and effectiveness of needle safety devices for intraoral applications is limited. According to the FDA, the devices currently on the market were cleared by the FDA on the basis that they were substantially equivalent to traditional devices. These devices were not evaluated for their ability to reduce percutaneous injuries. A recent preliminary study of these devices performed at the University of the Pacific suggested that the injury rate actually increased when the devices were used.

The ADA has reported these findings to OSHA. At this time, OSHA does not expect dentists to conduct clinical trials. The ADA is establishing appropriate design and performance criteria for the evaluation of safe needle devices and has called for device manufacturers to submit their products to the ADA Acceptance Program for evaluation. It has also called for independent research on the safety and effectiveness of these devices. The ADA is also working on a Request for Proposal for research funding related to needle safety devices for consideration by the ADA Health Foundation Board.

OSHA is considering revising the Bloodborne Pathogens Standard to aid in reducing needlestick injuries for all healthcare workers. At this time a target date has not been set issuing the revised regulations. Recently, OSHA issued new instructions to compliance officers on enforcing the Bloodborne Pathogens Standard for needle safety. The compliance directive, CPL 2-2.44D, Enforcement Procedures for Occupational Exposure to Bloodborne Pathogens, took effect 5 November 1999. The purpose was to provide guidance to OSHA compliance officers about how to enforce the Standard. Also the directive provides insight to employers about what a compliance officer would be looking for in an inspection

situation.

The revised compliance directive updates information regarding the evaluation of workers for hepatitis C following an exposure incident. It also emphasizes the need for an annual review of each facilities exposure control plan, including the consideration of engineering controls and work practices to reduce the risk of exposure to bloodborne pathogens.

NEEDLESTICK INJURY PREVENTION

Employers must provide a safe working environment that includes safer needle devices and effective safety programs to protect dental healthcare workers from needlestick injuries. Needlestick injuries can occur in many ways, thus a combination of prevention strategies should be considered.

Employers

- (1) Should implement the use of improved engineering controls to reduce needlestick injuries. This includes eliminating the use of needle devices where safe and effective alternatives are available.
- (2) Implement the use of needle devices with safety features and evaluate their use to determine which are most effective and acceptable.
- (3) Analyze needlestick and other sharps-related injuries in your workplace to identify hazards and injury trends. Data from injury reporting should be compiled and assessed to identify (1) where, how, with what devices, and when injuries are occurring, and (2) the groups of healthcare workers being injured.
- (4) Ensure that dental healthcare workers are properly trained in the safe use and disposal of needles.
- (5) Modify work practices that pose a needlestick injury hazard to make them safer. Hazards that can be eliminated by changing work practices include injuries due to recapping, failing to dispose of a needle device properly, and passing or transferring such a device.
- (6) Promote safety awareness in the work environment. Many needlestick injuries are due to unexpected circumstances such as sudden movement by a patient or collision with a coworker. Dental healthcare workers should be trained to be constantly alert to the injury potential when an exposed needle or other sharp device is being used.
- (7) Establish procedures for and encourage the reporting and timely follow-up of all needlestick and other sharps-related injuries. Needlestick injury reporting is critical to (1) ensure that all dental healthcare workers receive appropriate post-exposure medical management and (2) provide a record for assessing needlestick hazards in the workplace.
- (8) Evaluate the effectiveness of prevention strategies and provide feedback on performance. Employers must ensure that the dental healthcare workers are adopting the recommended prevention strategies and that the changes have the desired effect. A forum should be provided to assess worker perceptions, evaluate compliance, and identify problems.

Dental healthcare workers should be aware of the hazards posed by needlestick injuries and should use safety devices, if available, and improved work practices including the following.

Workers

1. Avoid the use of needles where safe and effective alternatives are available.
2. Use devices with safety features provided by your employer.
3. Plan safe handling and disposal before beginning any procedures using needles or sharps.
4. Dispose of used needle devices and disposable sharps promptly in appropriate sharps disposal containers.
5. Report all needlestick and other sharps-related injuries promptly to ensure that appropriate medical care is provided.
6. Tell your employer about hazards from needles observed in the workplace.
7. Participate in bloodborne pathogen training and follow recommended infection prevention practices.

OSHA AND TRAINING REQUIREMENTS

OSHA standards require appropriate and timely training as a strategy to reduce risk to employees. Dental clinics are mandated to provide employees with initial and/or annual training on hazards and the protective measures that must be used to decrease the risk of occupational exposure.

Trainers must be qualified to instruct the subject matter being presented. Trainers must have completed a training program for teaching their respective subjects, or have the academic credentials and instructional experience necessary for teaching the subjects. Train-the-trainer education can be obtained through the OSHA Training Institute. These courses provide basic and advanced training in safety and health, emphasizing OSHA policies and standards, as well as hazard recognition and hazard-abatement techniques.

It is important that the training is organized and the language and meaning are clear to all employees. Trainers should (1) provide an overview of the material to be learned; (2) relate, wherever possible, the new information or skills to the employee's goals, interests, or experience; and (3) reinforce what the employees learned by summarizing the program's objectives and the key points of information covered. The resources available for training will determine the frequency of training activities, the length of the sessions, the instructional techniques, and the individual(s) best qualified to present the subject matter.

It is important that the training be interactive, allowing employees to participate and ask questions. This ensures that the knowledge/skills are properly learned, and allows for correction if necessary. Many times during inspections, compliance officers will interview a representative sample of employees to ensure appropriate training occurred.

Documentation of training is imperative. Training records must be established that includes (1) dates of the training session; (2) contents of the training session; (3) names and qualifications of trainers; and (4) names and job titles of attendees. Employee training records must be maintained for three years, and must be available to employees on request for examination and copying.

Why train? Training is very critical for all employees, and not just because OSHA mandates it. An effective program of safety and health training can result in fewer injuries and illnesses, and can lead to better morale for all facilities.

PROPOSED ERGONOMICS REGULATION

The Academy of General Dentistry (AGD) met with OSHA on 8 May 2000 to discuss the proposed ergonomics standard. The AGD expressed opposition to the proposed standard, and recommended that dentistry should be exempted. The government's own data show that musculoskeletal discomfort is not a problem in dental offices. Regardless, as OSHA's draft proposed rule is currently written, general dentists could be swept into a regulation with incredibly costly compliance implications, said AGD President Dr Russo.

The AGD has charged that OSHA has not adequately assessed the potential impact of its proposed ergonomics rule on dentistry, and that the proposal was fundamentally flawed. The AGD feels the proposed rule would fail to improve dental office safety.

Public hearings on the proposed ergonomics rule have been completed. OSHA is now reviewing all submitted information. Publication of the final regulation is pending.

TUBERCULOSIS VACCINE

On 6 July 2000, a team of researchers unveiled a strategic plan that sets guidelines for developing an effective tuberculosis (TB) vaccine. The strategic plan identifies TB as a global health priority and encourages an international collaboration effort to develop a vaccine. The strategic plan appears in a special TB supplement in the *Clinical Infectious Diseases Journal*.

Fifty-four million people are infected annually with TB worldwide, killing an estimated 1.5 to 3 million each year. The only currently available TB vaccine called BCG, is largely ineffective and interferes with skin tests used to diagnose the disease. The BCG vaccine is not recommended for general use in the United States.

NEW WORKPLACE SAFETY AND HEALTH PROGRAM

OSHA's new workplace safety and health program proposed rule has been delayed. It would require all employers to establish comprehensive workplace safety and health programs to ensure compliance with OSHA standards and the general duty clause of the Occupational Safety and Health Act. The general duty clause requires that work environments be free from recognized hazards. This new proposed rule could cover a wide range of hazards that have not been addressed through specific rulemaking including nitrous oxide and latex allergies.

The proposed rule would require employers to set up a program to systematically manage safety and health. The following core elements would be required: management leadership and employee participation, hazard assessment, hazard prevention and control, training, and evaluation of program effectiveness.

HEPATITIS C VIRUS

The risk of contracting hepatitis C virus (HCV) from an accidental needlestick is 20 to 40 times greater than the risk of human immunodeficiency virus (HIV). This finding was presented at the International Conference on Emerging Infectious Diseases sponsored by the Centers for Disease Control and Prevention and the American Society for Microbiology.

Dr. Robert T. Ball, an epidemiologist from South Carolina Department of Health, surveyed 66 healthcare facilities in South Carolina gathering information on HCV and HIV in cases where healthcare workers were occupationally exposed to blood or body fluids.

Responses from 53 hospitals (80%) showed that 1,668 healthcare workers had been exposed to either HCV or HIV in 1998. Of the patients involved, 1,451 were tested for HCV and 1,508 for HIV. Overall, 5.2% were infected with HCV and 2.3% with HIV.

These rates are significantly higher than the general population at 1.5% and 0.3% respectively, Dr. Ball noted.

HCV is more prevalent in the general population than HIV, and logically is a greater threat to healthcare workers experiencing accidental needlesticks, yet data suggests that HCV is less often tested for after accidental needlesticks than HIV. **It is important that all healthcare workers be made aware of the risk, and to ensure that source patients are tested for HCV as part of the protocol, if possible.**

ENVIRONMENTAL SURFACE DISINFECTION

Cleaning and disinfecting environmental surfaces is an important component of an effective infection control program. Many operatory surfaces may become contaminated with patient materials during dental

treatment (e.g., direct contact with blood or saliva-contaminated hands, splash/spatter, contact with contaminated instruments). This contamination has the potential to transfer pathogens from the environmental surfaces to the patient and dental healthcare worker. The Centers for Disease Control and Prevention (CDC) and the American Dental Association (ADA) recommend cleaning and disinfecting operatory surfaces between patients to limit the potential spread of microorganisms. The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard requires that contaminated work surfaces be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as is feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

An alternative to environmental surface cleaning and disinfection, is the use of fluid-resistant barriers. These materials protect surfaces, and are simply removed and replaced between patients. Barrier-protected surfaces should be cleaned and disinfected any time the barrier has been compromised.

Ideal characteristics for a surface disinfectant include rapid, broad-spectrum kill, antimicrobial activity in the presence of bioburden, residual activity, minimal toxicity, odorless, inexpensive, easy-to-use and surface compatibility. No product today possesses all these characteristics. Selecting a surface disinfectant requires evaluating the advantages and disadvantages of a product based on clinical needs. The following questions should be addressed before purchasing a disinfectant.

1. Is it inactivated by organic matter?
2. Is it affected by hard water?
3. Does it leave a residue?
4. Is it corrosive by nature?
5. Is it a skin/eye/respiratory irritant?
6. Is it toxic?
7. Does it have an effective shelf life?

When evaluating products, make sure the product is registered as a hospital-level disinfectant by the Environmental Protection Agency (EPA). Other qualities include a tuberculocidal kill time of 10 minutes or less, and virucidal claims against lipophilic/hydrophilic viruses in 10 minutes or less. Another consideration is compatibility. The best resource is the manufacturer of the equipment. Most manufacturers do extensive testing on materials to determine which chemicals are least harmful. Also determine the shelf life, particularly for products that require mixing with water. Many of these products lose their efficacy quickly and need to be changed frequently. Also obtain a Material Safety and Data Sheet for all disinfecting products. Pay particular attention to the personal protective equipment recommended while using the product.

Choosing a disinfectant with cleaning properties will save time and limit the number of products required. Complex phenols (synthetic phenols), iodophors, and chlorines are considered appropriate for environmental surface disinfection by the CDC and ADA. The ADA also states that phenol-alcohol combined products are appropriate, but the high alcohol content requires that a separate cleaning agent be used prior to disinfection. Newer disinfectant categories of products have recently been developed including alcohol-quaternaries and halogen formulations that meet current criteria for surface disinfectants.

Chlorines

Agents containing chlorine (sodium hypochlorite, chlorine dioxide) offers economical, rapid, broad-spectrum antimicrobial activity. Most diluted solutions must be prepared daily. Sodium hypochlorite, at 0.5% in a commercial disinfectant or household bleach diluted 1:10 to 1:100, is an effective surface disinfectant. The disadvantage is that it can corrode some metals, can destroy fabrics, and irritate skin/mucous membranes. Chlorine dioxide is an effective disinfectant and is germicidal in three minutes on pre-cleaned surfaces, but is extremely caustic to tissues and so requires a well-ventilated work area.

Complex phenols

Complex phenols are compounds with more than one phenolic agent that works together to offer residual broad-spectrum biocidal activity. These chemicals are excellent cleaning agents and disinfectants. They are effective in the presence of detergents and compatible with metals, glass, rubber, and plastics. They may leave a residual film on treated surfaces though. Most diluted synthetic phenols are limited to one day of use.

Alcohol-quaternary ammonium compounds

These compounds are effective cleaning and disinfecting agents with low toxicity. They are somewhat sensitive to the presence of organic materials and anionic detergents.

Iodophors

Iodophors combine iodine with a water-soluble surfactant or carrier that offers exceptional cleaning and disinfection capabilities. They are unstable at higher temperatures though, and may discolor some surfaces. They provide residual activity, but are inactivated by alcohol and hard water. They must be prepared daily.

Phenol-alcohol combination

These compounds contain a phenolic agent in an alcohol base. They are recommended for disinfecting non-porous surfaces. They may cause porous surfaces to dry and crack. A separate precleaning agent is required to remove bioburden prior to application.

Halogen formulations

These agents are usually supplied in tablet form for simple dilution and reduced storage. They are fast acting with broad-spectrum activity.

The following are inappropriate disinfectants for environmental surfaces.

Alcohols

Alcohols have good antimicrobial activity but are poor cleaning agents, and are ineffective in the presence of tissue proteins found in blood and saliva.

Glutaraldehydes

Glutaraldehydes are highly toxic. Direct contact with soft tissues can result in irritation, hypersensitivity, and other dermatologic reactions. These products should not be used outside of a closed container due to the potential for respiratory irritation.

Hydrogen peroxide formulations

These agents are effective as instrument immersion disinfectants but are unsuitable for disinfecting environmental surfaces because of significant material incompatibilities. These chemicals can degrade vinyl, corrode some metals and can damage laminated surfaces.

Simple quaternary ammonium compounds

These compounds are not tuberculocidal and so are not appropriate for dental operatory disinfection.

Operatory surfaces can be classified as touch, transfer or splash/spatter/aerosol surfaces. Touch surfaces can be touched and contaminated during dental procedures. These surfaces should be cleaned

and disinfected between patients or covered with a single-use, liquid impervious barrier that is changed between patients. If a covered touch surface is compromised, it should be cleaned and disinfected before applying a new barrier for the next patient. Surfaces covered with barriers should be cleaned and disinfected at the end of each clinical day and covered with a new barrier before the first patient for the next day. (Examples: dental light handle, dental unit handles/controls, dental chair switches). Transfer surfaces are usually contacted by contaminated instruments. The protocol is the same as for touch surfaces. (Examples: instrument tray, handpiece holders). Splash/spatter/aerosol surfaces are all other surfaces in the operatory, and should be cleaned daily.

Note: Appropriate personal protective equipment must be used during operatory clean-up procedures. Heavy-duty utility gloves, mask, and protective eyewear should be worn when cleaning and disinfecting environmental surfaces to protect skin and mucous membranes.

COMPRESSION NEUROPATHIES

Compression neuropathies affect thousands of workers each year according to the National Institute of Health (NIH). The link between dental work and the development of musculoskeletal injuries in the work environment is increasing. This includes new cases of cumulative trauma disorders such as Carpal Tunnel Syndrome (CTS) and Thoracic Outlet Syndrome (TOS).

Carpal Tunnel Syndrome

CTS is the most common compression neuropathy of the upper extremity. Forty-seven percent of CTS cases are diagnosed as work-related. CTS is a potentially disabling nerve compression disorder which affects the median nerve as it passes through the carpal tunnel of the wrist. Wrist bones on three sides and the transverse carpal ligament on the fourth side form the carpal tunnel. The blood supply, flexor tendons of the fingers, and the median nerve pass through the tunnel.

Compression of the median nerve in the tunnel is characterized by inflammation and swelling in the tendons, nightly hand discomfort, paresthesia, hand blanching or coldness, weakness, tingling, severe pain, morning stiffness, numbness or tingling of the fingers in the median nerve distribution, and if left untreated, atrophy of the muscles in the area.

Occupational risk factors common in dentistry include: poorly fitting gloves, static or awkward postures, force, mechanical stress, vibratory hand equipment, extremes in temperatures, frequent repetitive movements of fingers/hands, forceful pinching and gripping, resisted hand and finger motions, duration of action/location of load, equipment and/or instrument selection, and lack of education or preventive practice.

Thoracic Outlet Syndrome

TOS is a disorder that may result from compression of several nerves at the base of the neck or upper chest, or the brachial plexus (upper arm). Symptoms vary based on location, duration, frequency, and degree of the neurovascular compression. The main symptoms are pain, paresthesia, numbness, coldness, weakness or blanching.

Causes of TOS include: poor posture, trauma, stress, prolonged work above one's head, carrying or lifting heavy objects, chronic vibrating trauma, and anatomical variations.

Some of the risk factors found in dentistry are difficult to avoid to help prevent these types of injuries. Proper selection of instruments, handpieces, gloves and an ergonomic education program with proactive prevention strategies (i.e., patient scheduling, exercises, environmental/equipment/procedural assessments) are important efforts to manage existing disorders and prevent new injuries.

INFECTION CONTROL Q&A

Q: What are the latest recommendations regarding dental unit waterlines?

A: Today, research continues to validate water treatment methods and water-quality monitoring indicators. It is important that we strive to provide the highest quality treatment water available. All dental clinics should consult the manufacturer of their dental units before initiating any waterline treatment protocol. The following are the latest recommendations available.

1. Follow current ADA and CDC recommendations to flush lines for several minutes each morning. Flush handpieces and air/water syringes for 20-30 seconds between patients. Also, if recommended by the dental unit manufacturer, install and maintain antiretraction valves to prevent oral fluids from being drawn into dental waterlines.
2. Do not heat dental unit water. Warming the water promotes biofilm formation.
3. Options to improve the quality of water include a separate reservoir, chemical treatment protocols, point-of-use filters, and sterile water delivery systems.
4. Use of a separate water reservoir system will eliminate the inflow of municipal water into the dental unit. This allows better control over the quality of source water for patient care, and would eliminate interruptions in dental treatment when local health authorities issue boil-water notices. Contact the manufacturer of the dental unit for a compatible system and treatment protocols before purchasing.
5. Use sterile solutions for all surgical irrigations.
6. Educate and train all dental healthcare workers on effective treatment measures to ensure compliance and minimize risks to equipment and personnel.
7. Monitor scientific and technological developments to identify improved approaches, as they become available.
8. Ensure any sterile water system or device marketed to improve dental water quality has received FDA clearance.

Compliance with treatment protocols is critical for long-term success. Control of biofilm depends on technique factors, effective personnel training, and an established standard operating procedure.

Q: How do I explain the issue of dental unit waterlines to my patients in an easy-to-understand and nonthreatening manner?

A: When discussing this with your patients you would like to be concise but may have to tailor your answer based on the patient's interests and scientific knowledge. The following represent the key points to discuss with your patient.

1. Dental unit waterlines are small tubes (pipes) that deliver water to equipment such as the high-speed handpiece (drill), air/water syringe and ultrasonic scaler (point out devices in operatory). During certain dental procedures, water is used: to cool the equipment, wash and flush away debris, or is used with ultrasonic energy to remove calculus (tartar) or stain from teeth.
2. When water is used during a dental procedure, suction is used immediately to vacuum up the water and debris.
3. Microorganisms (germs) that are also found in domestic water supplies, and drinking fountains can contaminate dental unit waterlines.
4. Any surface exposed to water for a long period of time can develop a biofilm (organized layer of germs and their products). This problem is common to many areas where water supplies are delivered through small pipes or tubes like the dental unit waterlines.
5. Microorganisms (germs) found in dental unit waterlines pose a negligible threat to the public and dental team.
6. At present, there are no studies that show increased health risks to dental patients. The bulk of microorganisms (germs) should not cause disease in normal, healthy individuals, but may lead to illness in medical compromised patients (weak body defense system).

7. There are several options to lessen the problem and reduce the risk including: flushing the waterlines at the beginning/end of the day, and between patients, independent water reservoirs, chemical treatment of the waterlines, and point-of-use filters.
8. **Explain to the patient exactly what your clinic does to address the issue.**

Q: Our clinic is considering purchasing a dry heat sterilizer. What are dry heat sterilizers? Are there different types, and what are the operational recommendations?

A: Dry heat (DH) sterilization involves heating air with the transfer of heat energy from the air to the instruments. The main advantage of DH is that carbon steel (burs) do not corrode as may happen with a steam autoclave and the processed items come out dry.

Since DH uses no pressure (such as steam autoclaves or chemical vapor sterilizers) longer, hotter treatment cycles must be run. Unless instruments are properly separated, heat diffusion in and around crowded relatively cool items can be retarded.

There are two types of DH called static-air and forced-air. Static-air types are often referred to as dry heat ovens. Air is heated in the chamber by electric coils found on the floor of the unit. Hot air rises and heat is transferred to the instruments. Sterilization occurs in one-two hours at 320°F (160°C). Proper warm-up (usually 15 to 30 minutes from a cold start) is important. When the operational temperature is reached, the sterilization process begins. Once the cycle is started, the sterilizer door should never be opened until the end of the cycle. Forced-air types are often called rapid heat transfer sterilizers. Heated air is mechanically circulated through the chamber. Heating of instruments is accomplished more quickly. Warm-up time is shorter than the static-air type sterilizer. However, the cycle time must start only when the sterilization conditions have been reached.

The following operational recommendations should be followed.

1. Use only units that are FDA-cleared as sterilizers. Household ovens and toaster ovens are unacceptable.
2. Check cycle timing and operational temperatures each day the unit is used. Keep a logbook of recorded values.
3. Observe a warm-up period prior to starting a treatment cycle. When operational temperatures are present, cycle timing can begin.
4. Do not open the unit's door during the cycle. Door opening results in a significant temperature drop. If the door is opened, the cycle must be restarted.
5. Use tubing, wrapping materials, cassettes and trays designed for DH sterilization. Closed containers can be used, but cloth and most types of paper should be avoided.
6. Do not sterilize plastic items or adhesive tapes. This can lead to distortion, burning or toxic gas release.
7. Separate items on all levels by at least ½ inch. Trays or packs should be no more than two layers deep with the top layer at a right angle to the lower one. Adequate air circulation is important. Avoid overloading.
8. Clean the unit with a mild detergent once per week. Units should be rinsed well and allowed to air dry. Check the chamber door and insulation. Always unplug the unit prior to cleaning and inspecting.
9. Use an appropriate chemical indicator strip as recommended by the manufacturer.
10. Place a biological indicator within a tray, pack, pouch or cassette at least once per week. *Bacillus subtilis* spores are used to test DH. Use a spore test to confirm appropriate kill in closed containers.