Safety during Equipment Inspections

Safety in the workplace is the responsibility of both the employer and the employee: each employer is obligated to provide a safe working environment, and each employee should strive to work in as safe a manner as possible. Inspecting medical devices involves some risks; to protect test personnel, staff, and patients, observe the special precautions noted in many of the procedures. When performing hazardous inspections, post signs to warn visitors and staff. Do not leave hazardous test setups unattended. Follow manufacturer or other appropriate guidelines concerning lasers, ionizing radiation, and chemical hazards. In addition, use common sense.

Electrical and Mechanical Devices

Inspecting medical devices for electrical safety involves proximity to voltages and currents that can cause injury to test personnel, staff, and patients. Deliberately simulating faults increases the need for caution.

Test a device's electrical safety before testing its performance. First, confirm the continuity between the chassis and the ground pin of the line cord plug before applying power. This continuity normally provides primary protection against shock to equipment users, patients, and test personnel. Also, leakage current measurements made through the power cord ground (as some electrical safety analyzers measure) will be erroneous unless there is continuity.

Do not test equipment that is in use on a patient. Electrical safety tests intentionally simulate faults that may be hazardous. Not only will the patient be exposed to unnecessary risks, but test results may also be misleading. Arrange with appropriate clinical personnel to disconnect the device from the patient, or have them advise clinical engineering when the device is no longer in use.

Do not test electrical power distribution systems on which patient equipment is operating. Some receptacle ground integrity tests may inject several amperes into the ground line and can cause hazardously high current to flow through a patient who is connected to a device on the branch under test, especially if the grounding is defective.

You can safely test receptacle wiring and measure line voltage and low-current ground resistance on branch circuits or receptacles in use.

Tests of isolated power systems temporarily lower the protective barrier normally associated with isolated power. If the receptacle has a ground-fault circuit interrupter (GFCI), power to all devices on the line could be shut off. This emphasizes the need to ensure that critical or life-support equipment is never powered from a GFCI-protected circuit.

Confirm that the outlet used to power the safety analyzer is correctly wired. Grounding the analyzer case through the receptacle ground prevents a shock hazard while testing a defective piece of equipment. A GFCI trip point measurement often uses the analyzer ground for a return path of the test current; if the analyzer is connected to an ungrounded receptacle, there may be line voltage (115 VAC) on the analyzer case. Do not touch the case of the equipment being tested, especially when measuring ungrounded leakage current.

To avoid damaging the device being tested or interrupting a fuse or circuit in the device or branch circuit panel, turn off devices with motors and compressors and wait until they completely stop before reversing hot-neutral polarity; turn off and wait 10 seconds for microprocessor-controlled devices, including computer and clinical laboratory analyzers. Also, turn off power to the device being tested if it is necessary to insert or remove modules.

HRC TOOLS FOR THIS TOPIC

The following tools and resources on this topic are available in your *HRC System*. Refer to this article, your *HRC* Index, the online system, and other *HRC* resources for help.

— **Checklist**

— **Online Help**

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Lead isolation testing involves line voltage use. We recommend performing the test only with equipment properly designed to allow safe application of the voltage to the patient leads. If an electrical safety analyzer is not available, devise or buy an adapter that limits the current flow to 1 mA or less to ground from any exposed terminals of the test setup. Do not touch patient leads during lead isolation testing, and avoid using exposed clips or improvised test setups that make it easy to accidentally contact the input circuit. Touching the leads may cause a shock even with a current-limiting resistor in the test circuit.

Testing pneumatic and mechanical devices can result in injuries such as crushed fingers, lacerations, and punctures and in hazards such as flying projectiles. When inspecting devices with cams, gears, levers, sliding components, or other moving parts (e.g., blood pumps, electric beds, x-ray film processors), keep fingers and clothing away from moving parts. Perform parts inspection, cleaning, and lubrication with power disconnected. Do not get underneath electric beds, patient lifts, radiology systems, or similar devices while they are connected to a power source or loaded.

Lockout/Tagout Requirements

Lockout and tagout procedures are protective measures that usually include the use of security devices such as padlocks applied to manual circuit breakers and cut-out switches or tags prominently placed on such devices to warn of work in progress. Locks are placed so that electrical service to a device will not be activated inadvertently by someone who is unaware of the work in progress.

Occupational Safety and Health Administration (OSHA) regulations codify requirements for lockout and tagout procedures to reduce the risk of injury from energized sources during maintenance and servicing (29 CFR 1910.147). The regulations protect against electrical mishaps, as well as injury from other energy sources such as mechanical (both stored, as in compressed springs, and kinetic), pneumatic, hydraulic, thermal, and chemical sources. Thus, a lockout can — and should — be applied to a pressurized steam valve and an electrical switch box, as well.

Lockout is accomplished when all of the technicians (maintenance personnel) servicing a piece of equipment ensure that all power sources to the device are turned off and apply a lock (usually a keyed or combination padlock) to the switch(es) before beginning work. This ensures that the unit can be energized only when the last technician has completed work and has removed the lock. Where a switch provides for only one lock, a key box is provided into which the single key for the lock can be placed; the box, in turn, has multiple lock holes so that each technician can place a lock on the key box.

Tagout is a comparable, though less secure, procedure. Under OSHA regulations, it may be used where providing lockout is not feasible and where adequate procedures that provide the necessary protection are in place and properly understood. A durable and prominent tag, with appropriate information clearly displayed on it, is placed on the disconnecting means at the time the unit is de-energized. The tag warns others not to turn the power on and is removed only by the technician after work is completed. The tag is usually accompanied by some means (e.g., a sturdy nylon wire tie) that impedes operation of the disconnecting device.

Clinical engineering personnel commonly work with line cord and plug-connected devices. Servicing these devices, whether they are portable or mobile or operate in fixed locations, is exempted from these requirements, *provided that the line cord and plug are under the exclusive control of the person doing the servicing*. In these cases, lockout is accomplished simply by unplugging the device.

Service personnel should practice lockout or tagout of hard-wired devices such as radiology equipment, CT and MRI scanners, and film processors. Lockout/tagout also applies to major installed appliances and systems (e.g., steam and ethylene oxide sterilizers, cart washers, blanket and solution warmers, hyperbaric chambers). (Likewise, plant engineering personnel should use these procedures on air handlers, trash compactors, incinerators, boilers, pumps, and elevator equipment.) Clinical engineering personnel should respect and pay attention to these procedures as they are encountered. Where isolation devices for such equipment lack lockout provisions, tagout procedures must be used. New installation or major replacement, repair, renovation, or modification of equipment must include energy-isolating devices with lockout provision.

Employers must develop documented energy-source control procedures appropriate for the equipment in their facility and ensure that employees are trained in those procedures. Employers must also conduct inspections at least annually to ensure that these procedures are carried out and that requirements of the standard are being met.

Below is a checklist of typical procedures that should be performed diligently within an institution to reduce the risk of injury and ensure conformity with the standard's requirements:

- Identify all energy-isolating devices that must be locked or tagged out.
- Carry out lockout/tagout procedure:
  —Notify affected personnel.

—Shut off equipment by normal means.

—Operate isolators (e.g., switches, valves, disconnects); relieve or protect against stored energy (see below).

—Lock out or tag out device.

—Operate normal controls to be certain that equipment will not operate.

—Be sure that controls are returned to off/neutral position after this test.

- Perform service or maintenance.
- After completion of service or maintenance:

—Replace guards, remove tools.

—Check area to be sure that no personnel are exposed.

—Be sure that controls are returned to off/neutral position.

—Remove lockout/tagout and related protective devices.

—Operate isolating devices to restore energy to equipment.

The OSHA requirements also stress the need to protect against exposure to stored energy, which can be released suddenly and unexpectedly. Some of the activities that must be considered include blocking spring-loaded components that might accidentally be tripped, chocking mobile devices, immobilizing counterweights so they cannot fall, and discharging pressurized chambers or charged capacitors. While steps taken to provide such protection would not strictly be viewed as locking or tagging out, they are, nevertheless, important to implement.

The OSHA standard generally requires employers to document specific procedures for the equipment on the property. However, one exception relieves the need to document lockout/tagout procedures for specific machines or equipment when a series of eight specific conditions are met. The essence of these conditions can be summarized as follows: The device is supplied from a single power source that can be totally isolated by a single lockout device and has no potential for releasing any form of stored energy after shutdown; the employee authorized to service the device has exclusive control over the lockout device, and the maintenance poses no risk to other employees; and the employer has had no accidents with this device that resulted from unexpected activation or re-energization during maintenance or servicing.

The standard does not describe responsibility for or obligations to outside service personnel. It seems reasonable, however, to assume that hospitals are responsible for installing lockout capabilities on their equipment and for providing lockout/tagout devices to outside repair persons, whereas training is the responsibility of the companies employing these service personnel.

Even with lockout and tagout procedures implemented, CEs, BMETs, or other engineering/maintenance personnel may find an open disconnect or other energy-control device that is not locked or tagged out. Under no circumstances should anyone close an open switch or other energy isolator (with or without lockout or tagout devices) without being absolutely certain that it is safe and appropriate to do so.

Compressed Gases

Compressed gas cylinders must be handled carefully to avoid being contaminated or dropped. High pressures can turn connectors into projectiles. The Compressed Gas Association's (CGA)* *Characteristics and Safe Handling of Medical Gases* provides recommended practices for handling medical gases, including many of the following:

- Never permit oil (e.g., from oily hands or gloves), grease, or other combustible substances to come in contact with cylinders, valves, regulators, gauges, hoses, and fittings. Oil and certain gases (e.g., oxygen, nitrous oxide) may combine with explosive violence.
- Use commercial leak-detector solutions or a mild soapy water solution to detect gas leaks. Use only oxygen-compatible leak-detector solutions on oxygen and nitrous oxide systems.
- Do not deface or remove any markings (e.g., labels, decals, tags, stenciled marks) used to identify the contents of a cylinder.
- Never attempt to repair or alter cylinders, stem valves, or indexing pins. Replace the cylinder with a new one, and return the damaged cylinder to the vendor.
- Never drop cylinders or permit them to strike each other violently. Ensure that all cylinders are securely mounted or chained so that they cannot roll or fall during use or while in storage.
- Never drag, roll, or slide cylinders. Never use a cylinder valve as a handle to move a cylinder. Move larger cylinders, even for short distances, with a suitable truck, making sure that the cylinder-retaining chain or strap is fastened in place.
- Do not use regulators, pressure gauges, or manifolds intended for use with a particular gas or group of gases with cylinders containing other gases.
- Never interconnect medical gases without appropriate check valves. They may become contaminated by the feedback of other gases or foreign material.

* Compressed Gas Association (CGA), Suite 1004, 1725 Jefferson Davis Hwy, Arlington, VA 22202; (703) 412-0900.

- Always use pressure-reducing regulators when withdrawing the contents of gas cylinders, because regulators deliver a constant, safe working pressure. Do not use needle valves or similar devices without pressure-regulating mechanisms in place; excessive pressures may develop downstream of such devices and may result in injury or equipment damage.
- Ensure that the threads on regulator-to-cylinder valve connections or the pin-indexing devices on yoke-to-cylinder valve connections are properly mated. Never force connections that do not fit.
- After removing the protective valve cap and with the opening pointed away from all personnel, slightly and briefly open the valve to clear the outlet of any dust and dirt. Do not do this with cylinders containing flammable or toxic gas.
- When opening a valve, point the outlet away from all personnel. Never use wrenches or tools except those provided or approved by the gas supplier; incompatible tools may damage the valve. Use only nonferrous (e.g., brass, aluminum) tools in the presence of flammable or combustion-supporting gases to prevent sparks. Never hammer the valve wheel when attempting to open or close the valve.
- Open the cylinder valve slowly and keep it fully open when the cylinder is in use.
- Use secure fittings to prevent a tube or connector from suddenly disconnecting and whipping about or becoming a projectile. Do not use friction fittings (e.g., hose barbs, Luer slip) for 50 psi and higher circuits — use threaded or positive-locking devices.
- Before disconnecting regulating devices from cylinders, close the cylinder valve and release all pressure from the regulator. Cylinder valves should be closed at all times except when the gas is actually being used.

Lasers

Inspecting and maintaining lasers is a dangerous but necessary process that demands far greater care than is required with most devices. According to a summary of U.S. Food and Drug Administration (FDA) medical-laser incident reports from late 1984 to April 1995, many of the accidents that occurred during laser maintenance can be attributed to a failure to follow basic laser safety precautions. Personnel who inspect or service lasers should receive special training from the manufacturer or from a qualified alternative training source.

Laser energy can cause serious injury. This hazard is especially great when an interlock is overridden or in any other situation where the energy does not diverge significantly over long distances. Under some circumstances, the beam may not diverge significantly even a full room length or more from the laser (an unfocused laser beam from a mirrored articulating arm or from an exit port can harm tissue or burn material across a room). Therefore, exercise great care whenever an unfocused laser beam is accessible.

Area security and use of personnel protective devices and practices should be consistent with hospitalwide laser safety procedures and/or approved by the Laser Safety Committee. Windows should be covered with absorbing or laser-opaque material to prevent transmission of laser energy into other areas. (Window covers are not necessary with carbon dioxide lasers.) Wear appropriate laser safety eyewear at all times whenever the laser is in the operating mode. *Warning:* Verify that laser safety eyewear are appropriate for the specific wavelength laser being used (e.g., YAG lasers are becoming available in different wavelengths; glasses appropriate for a Ho:YAG 2,100 nm wavelength are not appropriate for Er:YAG lasers at 2,940 nm). The American National Standards Institute (ANSI) standard Z136.1-1993, *Safe Use of Lasers,* calls for protective eyewear to be labeled with the wavelength for which protection is afforded. Laser safety eyewear may not protect the wearer from the aiming system light. Do not stare directly into the aiming system beam or the therapeutic laser, even when wearing laser safety eyewear. Eyewear should be inspected periodically for physical condition and light leaks (see Section 4.6.2.7 of the ANSI standard). Avoid placing the laser beam path at eye level (sitting or standing).

Do not perform IPM procedures when a patient is present or clinical staff is working. Do not aim the laser across a path that a person might normally use as a thoroughfare. Post doors to the room with an appropriate laser safety sign that identifies that the laser is in use and that it is unsafe to enter the room without authorization by the service person performing the procedure. A second person should be present, especially during procedures of recognized risk, to summon help in case of an accident.

The laser should remain in the Off position when not in use. When in use, the laser should be in the Standby/Disabled mode. Do not switch it to the Operating mode until the procedure is about to begin and the laser and its delivery system are properly positioned. If the procedure must be interrupted, disconnect the laser from line voltage; remove the laser operating key, and store it in a controlled location.

Do not use the laser in the presence of flammable anesthetics or other volatile substances or materials (e.g., alcohol, acetone) because of the serious risk of explosion and fire. Remove from the working area or cover with flame-resistant opaque material all reflective surfaces likely to be irradiated by the laser beam. Whenever possible, use a firebrick or other nonflammable material behind the target material (e.g., black Delrin) when the laser is to be activated. A carbon dioxide fire extinguisher should be readily available.

Some surgical lasers use high voltages (e.g., 20 kV), which can be lethal. Capacitors may store charges long after the device has been disconnected from line voltage. Consult the manufacturer's recommended procedures for servicing high-voltage laser circuits, and avoid contact with any portion of the high-voltage circuit until the charge has been drained. When possible, disconnect the laser from line voltage before entering the laser cabinet, and use insulated gloves for those procedures in which contact with a high-voltage source is possible (and the gloves are not otherwise contraindicated). Ensure that equipment intended to be used to measure, drain, or insulate high voltages carries the appropriate insulation rating (e.g., above 20 kV).

Report any laser accident immediately to the laser safety officer (or equivalent) and to the hospital risk manager.

For a comprehensive discussion of laser safety, see ANSI Z136.1-1993, *Safe Use of Lasers*, and Z136.3-1995, *Safe Use of Lasers in Health Care Facilities*. Also refer to the *Surgery and Anesthesia* section.

Radiology Equipment

Personnel working on equipment that emits ionizing radiation (e.g., x-rays) must be knowledgeable in radiation safety procedures. For personnel not already familiar with the safety and maintenance of this equipment, radiation safety should be included as a formal part of their training in this area. Even if maintenance personnel spend far less time than users (technicians and physicians), they should be aware of occupational radiation exposure issues and take practical steps to minimize exposure. In addition to radiation exposure issues faced by typical users, maintenance personnel should also take precautions against special risks such as the following:

- Excessive or unnecessary radiation exposure from unintentional activation or activation with normal protective components of the device removed or disabled.
- Risk of exposure to high voltages made accessible during maintenance procedures; contact with these voltages can lead to serious injury or death.
- Thermal risks from contact with a hot tube or tube housing or with the hot oil that insulates the x-ray tube. (Contact with oil might occur if the tube is damaged from overheating.) For personnel safety and to avoid damaging the tube, do not exceed the tube rating for housing or anode heat capacities.
- Mechanical risks (e.g., crushing) caused by component movement associated with inadvertent activation (or brake mechanism release) and by disconnection of compensating weights, brakes, or other restraining components. Also, precautions must be taken against movement of the compensating weights when removing the corresponding components, such as the x-ray tube or image intensifier.
- Chemical risks from fixer and developer solutions in film processors and, on old x-ray generators, the polychlorinated biphenyl (PCB) insulating fluid used in transformers.

Personnel Exposure Limits

To ensure safety, personnel exposure to radiation should be kept as low as reasonably possible. Personnel exposure to radiation is commonly specified in dose equivalent units Current federal regulations limit whole-body occupational exposure to 5 rem (50 mSv) per year (29 CFR 1992). The cumulative lifetime occupational limit specified by current federal regulations is 5 × (N-18) rem, or 50 × (N-18) mSv, where N is the age of the worker.

Continuing improvement of our understanding of the effects of low levels of radiation is likely to lead to lower limits. In 1990, the National Academy of Sciences (NAS) published its BEIR V report, in which it suggested that harmful effects of low-level radiation may be higher — by a factor of two to three — than previously thought (NAS 1990). The limits recommended by the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP), which typically are the basis for federal limits, have already been lowered. NCRP now recommends a lifetime limit of (1 × age) rem, or (10 × age) mSv, which represents a significant reduction from the previously recommended limit (NCRP Report 91, 1987); for example, at age 55, this represents a reduction in the allowed lifetime limit from 185 rem (1,850 mSv) to 55 rem (550 mSv). The annual limit recommended by NCRP remains the same. ICRP has effectively lowered its annual limit to 2 rem (20 mSv) per year; however, a provision in its recommendation states that 2 rem per year is the average during five years, with the annual maximum limit of 5 rem (50 mSv) for any given year (ICRP 1990).

Precautions during IPM

- Wear a lead apron and thyroid shield at all times during x-ray exposure, or use overhead or mobile lead shields.
- Maintain the greatest possible reasonable distance from the x-ray source and all scattering material.

- Do not place hands or fingers in the x-ray beam. If unavoidable, wear lead gloves.
- Keep x-ray exposure time to a minimum.
- For tests that require the use of cine or serial film changer acquisitions, staff should leave the room, if possible, when these images are being acquired because much higher exposure rates are used for these images than in conventional fluoroscopy.
- Radiation badges should be worn by all personnel and should be processed monthly. A radiation safety officer should review all badge readings and take immediate remedial actions if exposures exceed expected limits.
- Take precautions against radiation exposure, high voltage, thermal, mechanical, and chemical risks associated with inadvertent activation, device disassembly and removal, or disabling of protective features.
- It is critical that personnel performing IPM or servicing of radiology devices receive initial and periodic training to raise their awareness of radiation safety and to help them use optimum protection practices.

Infection Control

Clinical engineering personnel face a risk of infection during medical equipment maintenance and should take appropriate infection control measures. Disease can be transmitted by several modes; for clinical engineering personnel, contact transmission and, to a lesser extent, airborne transmission are the most likely modes. Contact transmission can occur through direct contact with an infected patient, droplet contact (e.g., from a cough or sneeze), or indirect contact (i.e., from handling equipment that is contaminated by infectious material from a patient). Airborne transmission can occur through inhaling disease-causing microorganisms on dust particles or infectious residue on evaporated droplets (droplet nuclei); the airborne transmission of tuberculosis (TB) by this process is a particular risk in healthcare facilities. To protect against unnecessary exposure to infectious diseases, clinical engineers should be familiar with basic infection control practices, as well as disinfection, sterilization, and decontamination procedures that may be necessary before servicing medical devices.

Basic Infection Control Practices

Good personal hygiene and common sense are instrumental to developing an effective infection control program. Infection control practitioners should provide clinical engineering personnel with training that includes review of general principles of TB and bloodborne pathogen transmission and prevention, as well as voluntary hepatitis B virus (HBV) immunization and postexposure follow-up procedures. Below are some basic infection control practices that are appropriate for clinical engineering personnel:

- Wash hands routinely — when hands are obviously soiled, after handling soiled equipment, after removing protective gloves, before eating, and before leaving the hospital.
- Do not eat, drink, chew gum, smoke, or apply cosmetics in work areas.
- Wear a lab coat or other appropriate outer garment to prevent contaminating street clothing. Do not take lab coats home. Have them washed frequently in the hospital laundry.
- Wear gloves when in contact with equipment that may have come in contact with blood, body fluids, or other infectious materials (e.g., surgical instruments, transducers, sensors, breathing circuits). *Caution:* Wearing gloves does not protect against cuts and puncture wounds; exercise care when handling contaminated medical equipment.
- Do not touch clean items (e.g., doorknobs, telephones, test equipment, computer terminals, keyboards) with soiled gloved hands.
- Wear face shields or masks and protective eyewear during cleaning and decontamination procedures that are likely to aerosolize or splash droplets of blood or body fluids into mucous membranes.
- Wear gowns or protective aprons during cleaning and decontamination procedures that are likely to aerosolize or splash droplets of patient material onto clothing.
- Where there is a special concern about exposure to aerosolized infectious agents, especially TB, take appropriate respiratory precautions, including wearing a respirator approved by the National Institute for Occupational Safety and Health (NIOSH). However, first obtain training on the use and fit-testing of the respirator. Follow your hospital's TB control plan.
- Do not rub eyes or other mucous membranes.
- Inspect or repair devices that normally require cleaning, disinfecting, or sterilizing only after such procedures are completed. Clean, disinfect, or sterilize these devices again before returning them to patient care areas.
- Use standard hospital procedures when entering, leaving, and working in areas that pose special infection control problems (e.g., surgical suites, dialysis units, nurseries, neonatal ICUs, burn units, isolation rooms, critical care areas). Patients in these areas may be unusually susceptible to infection, and the inspector may be at considerable risk, as well.
- Follow the hospital's TB control plan when entering, working in, and leaving areas where confirmed or

suspected infectious TB patients are present (e.g., a negative-pressure TB isolation room).

- Even if the patient is not in the area, continue to follow appropriate procedures when entering an isolation room or area where a TB patient was present until the area has received final cleaning and adequate time has passed. Check your hospital's policy for the appropriate time to wait; the Centers for Disease Control and Prevention (in: Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. *Fed Regist* 1994 Oct 28; 59[208]:54292, 54279) implies that cleaning personnel require personnel protective equipment for at least 69 minutes after the patient has left if the room has an air exchange rate of 6 air changes per hour (ACH) and 99.9% removal efficiency is to be achieved. (This time can be increased as much as tenfold to take into account non-ideal air mixing. Also, the time will depend on the air exchange rate [6 ACH is the minimum recommended rate for an isolation room] and the desired percent removal efficiency.)
- Any device that is visibly soiled with patient material — even if dried — or that has been in contact with patient fluids or tissues should be treated in accordance with the facility's bloodborne pathogens exposure plan. However, even if a device appears to be clean, do not handle it in an unhygienic manner. Consideration and awareness of infection control issues may be particularly appropriate for the following devices (even when they appear to be clean):
  - —Dialysis equipment. In addition to a routinely high risk of equipment contamination by bloodborne pathogens, some dialysis units may be dedicated to patients with HBV or human immunodeficiency virus (HIV); consider maintaining separate, dedicated tool sets for servicing dialysis equipment and for units dedicated to patients with HBV or HIV.
  - —All devices or items in the OR and ER, especially footswitches of devices used during surgery (e.g., electrosurgical units).
  - —Any handheld items or other items that can be found in beds (e.g., nurse call buttons, remote controls for television sets, pillow speakers, blood-pressure cuffs, telemetry transmitters).
  - —Clinical laboratory equipment, including centrifuges, in which blood splashes and fragments of glass from broken blood collection tubes may be present; vacuuming the interior may be necessary.
  - —Breathing circuits.
  - —Blood warmers.
  - —In general, devices from any area where body fluids are spilled, splashed, or routinely handled, as well as devices that are in contact with or contain patient material. While device contact is usually limited to or contained within a disposable set, fluid squirts, leaks, spills, or handling by personnel whose hands are contaminated often results in device contamination (e.g., in dialysis equipment, blood warmers, autotransfusion units).

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