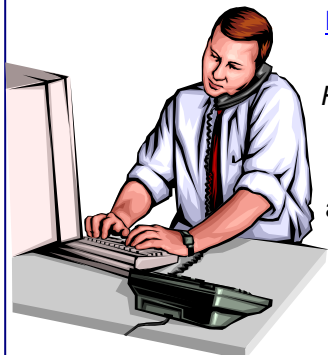


Report Medical Device Incidents Online

The Safe Medical Device Act (SMDA) is designed to provide a way for the FDA and manufacturers to identify and correct medical device problems in quickly.

In 1998, the FDA audited the UK Hospital for its compliance with the MDA. Although the Hospital was found to be largely compliant, investigators did make some suggestions for improvement.

In order for the Hospital to comply, faculty and staff must report all medical device incidents, including those caused by user error, within 24 hours of discovery. To file a report online, go to



<http://www.hosp.uky.edu/patient/safety> and click on *Make a Report*. The hospital uses this information to report to the manufacturer and/or the FDA all medical device failures that cause or contribute to the death, serious illness, or serious injury to a patient.

By definition, a *medical device* is any instrument, apparatus, machine, implant, in vitro reagent, or their components that is

- Recognized in the National Formulary or in the U.S. Pharmacopoeia, or any supplement to them
- Intended for use in the diagnosis, mitigation, treatment, or prevention of disease or other conditions
- Intended to affect the structure or any function of the body and does not achieve its intended purpose through chemical action or metabolism.

For the purposes of reporting, *patient* includes an employee who sustains a serious injury or illness as the result of working with a medical device.

Routine Safety Information Not Common Knowledge

By Tomi Ross, Hospital Safety Officer

The 2003 staff safety survey revealed that employees do not know the basics about equipment and utilities safety. Employees averaged 76% on questions pertaining to medical equipment and 86% on those pertaining to utilities.

Those results are startling when you consider that much of the information is printed on the back of the badge card, covered in Safety CBLs, outlined in policy, or printed in the safety newsletter.

Here's a recap of the questions and answers.

Q: What number would you call to report a Hospital telephone outage?

A: 334
80% answered correctly.

Q: What kind of medical equipment needs to be inspected by Clinical Engineering before it is placed in service?

A: All medical equipment
75% answered correctly.

Q: What number would you call if a piece of medical equipment needed immediate service?

A: 3-6383
77% answered correctly

Q: What color outlet indicates emergency power?

A: Red
96% answered correctly.

Q: Who would you call to report a power failure?

A: PPD
83% answered correctly.

In 2003, the survey was given as a multiple-choice exam through NetLearning. In previous years, the survey was a paper and pencil test, given to employees by their supervisors.



Proposed 2005 Patient Safety Goals and the Environment of Care

The JCAHO is proposing substantial changes to its patient safety goals in 2005, including adding several standards and revising existing ones. The proposed changes can be reviewed at: <http://www.jcaho.org/>.

Several of the changes emphasize the significant role that environmental components play in patient safety, particularly in the areas of hazard surveillance, medical equipment management, and fire prevention and response.

OR Fire Burns Patient at Johnson City, NY, Hospital

On March 16, 2004, an operating-room fire seriously injured a 78-year-old patient at Wilson Memorial Regional Medical Center in Johnson City, NY, during a routine biopsy, according to reports from the Binghamton, NY, Press & Sun-Bulletin.

Although the fire marshal officially ruled the fire accidental, the hospital has been cited for failing to call the fire department immediately. Witnesses on the surgical team described a frantic scene in which surgeon fought the fire with his hands.

The patient suffered second-degree burns to her face and neck when a cauterizing tool caught surgical drape and an airway tube on fire. The surgeon performed an emergency tracheotomy so the patient could breathe after she was burned.

Securing Needle and Syringes

JCAHO requires that hospitals secure needles and syringes in patient care areas.

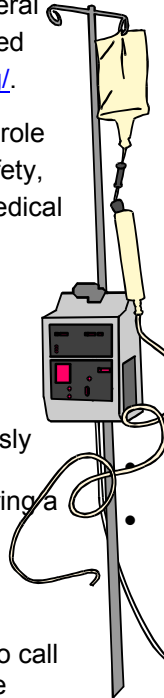
The mandate falls under JCAHO standard MM.2.30, the security of medications standard, which states that "medications must be secured in accordance with the hospital's policy and law and regulation so that unauthorized persons cannot obtain access to them."

For the most part, JCAHO surveyors have adopted the CMS definition of secured; that is "being locked in containers in a room or under constant observation."

Medical Equipment Basics for Hospital Employees

- Clinical Engineering must inspect all medical equipment before it is put into service. This includes vendor- and patient-owned equipment.
- There are two types of equipment inspection tags:

1. A dark green tag that lists "Next Inspection Due" date. Equipment with this tag requires preventive maintenance.
2. A lime green tag that lists date when equipment was last inspected. Equipment with this tag does not require preventive maintenance.



If a piece of medical equipment does not have one of these two tags, it has not been inspected.

Call 3-6383 to reach Clinical Engineering.

- Do not hide or hoard medical equipment. This practice does not ensure that equipment will be available when you need it. It only prevents Clinical Engineering from inspecting and maintaining equipment essential to patient care.

Disaster Drill Schedule for June

UK Hospital will participate in a 22-county regional disaster drill on June 17 from 1-10 p.m. The exercise will test the community's ability to respond to an influx of patients and a weapons of mass destruction (WMD) event.

UK Hospital will implement the Hospital Emergency Incident Command System (HEICS) and will exercise all aspects of command and response required by the scenario.

Federal, state, and local agencies, as well as 20 acute care hospitals will play. "For the first time ever, we've got the National Guard, the KY Department for Public Health, regional emergency management agencies, and local fire, police, EMS, and coroner services all playing together," said Gerald Cartier, VA Regional Coordinator.