DON'T LOSE THE EVIDENCE
Sequestering Equipment after an Incident

MEDICAL DEVICE ACCIDENT INVESTIGATION – GETTING IT RIGHT CAN SAVE LIVES

You’ve just had a serious incident involving one or more medical devices and the accessories attached to them. What you do next with this equipment is critical. Because the devices may provide key evidence for determining what went wrong, each one must be carefully set aside and cataloged. Here’s how to proceed.

Medical-technology-related accidents frequently involve not only the device itself, but also its accessories. Physiologic monitors, ventilators, electrosurgical units, and infusion pumps, for example, all have disposable or reusable accessories that should be sequestered when an incident occurs.

Unfortunately, clinical staff often neglect to preserve all equipment involved in an incident, especially accessories, disposable devices, associated packaging, and identifying data. The resulting problems involving evidence and incident-related medical devices can significantly complicate subsequent investigations. It is important to understand these issues and ensure that proper procedures are followed.

PROCEDURES TO FOLLOW AFTER AN INCIDENT

When a device-related incident occurs, a number of steps have to be taken quickly. One key step in your response will be dealing with the devices that were or might have been involved.

Capital equipment should not simply be sent to clinical engineering for repair; rather, it should be sequestered until a decision can be made on the need and protocol for its inspection. Disposable devices, especially those that may be contaminated, should be kept in sealed containers or biohazard bags. All incident-related products that are sequestered should be labeled with the patient’s name, the date and time, and the signature of the person responsible for collecting and securing the device. Storage should be in a locked area, separate from where routine maintenance takes place, to avoid confusing sequestered devices with devices in use. A log-in/log-out procedure should be used for internal access to the incident devices.

Photographs of the equipment and the room in which it was used, as well as photographs of any injuries, should be taken as soon as possible after the incident, preferably before the equipment is sequestered. Control settings should not be changed on devices that have been involved in an incident (unless this is necessary to minimize injury at the time the incident occurs).

Error codes, device settings, and alarm conditions may be stored in the memories of many microprocessor-controlled devices, whether battery or line powered. This data is usually essential to a thorough investigation. In such cases, clinical engineering should be consulted before turning off the device, unplugging it, turning it back on, or removing its battery. Likewise, the hospital should not clean or process devices without first discussing the procedures with an experienced independent third-party investigator or manufacturer. Cleaning or processing equipment to the manufacturer may be appropriate. But before sending any device to the manufacturer, the hospital should document its own associated independent testing.

While most manufacturers are committed to safe and effective products, it is naive to think that all reported problems could seriously hinder any subsequent investigation. Similarly, storage and shipment conditions must be considered to prevent damage to the device. For example, a membrane blood oxygenator involved in an incident should be protected from freezing. If it is frozen, ice could rupture the membranes, making subsequent leak testing invalid.

Most equipment, of course, can soon be returned to service because it will be obvious that it played no role in the injury. However, no suspect device should be returned to service until it has been properly tested and eliminated as a possible cause of patient injury.

INVOLVING DEVICE MANUFACTURERS AND CONDUCTING AN INVESTIGATION

When notified of a potential problem with a device, a manufacturer may offer to examine the device without charge to the hospital and/or exchange, replace, or refund the cost of the device. If the device-related incident has involved death or significant injury to a patient or staff member, the manufacturer should not be permitted to take equipment or disposables from the hospital because the hospital then loses all access to them.

For serious injuries or deaths, the optimum form of investigation is to sequester the equipment and related items and to arrange to examine or “autopsy” the equipment with representation of the hospital, the manufacturer, and an independent investigator all present simultaneously and for the duration of the process.

For cases in which injury did not occur and litigation is unlikely, returning will result in constructive action by a manufacturer or its distributor. Here are a few examples of manufacturer responses that hospitals have reported to ECRI Institute when incident-related devices were returned to the manufacturer:

• The device was accidentally damaged during testing.
• The device was sent back to the hospital months ago! Didn’t you receive it?
• The original complaint was never received.

The investigation of device-related incidents can be significantly aided by cooperation from the manufacturer. In the event of litigation, a hospital’s position may be strengthened if it has approval of the facility’s legal counsel and administration. Otherwise, the facility’s ability to perform or contract for an investigation will be hampered, or valuable legal evidence will be lost.

This article is an excerpt from a Health Devices article posted on ECRI Institute’s Health Devices System, Health Devices Gold, and SELECTplus membership websites on March 5, 2014. To purchase this article or to learn more about membership programs, visit www.ecri.org or call (610) 825-6000, ext. 5891. For additional perspectives on this issue from ECRI Institute’s Accident and Forensic Investigation Group, visit www.ecri.org/accidents.