

Impounding Incident-related Devices

Despite the best efforts of clinical engineers and other safety personnel, incidents do occur in hospitals. A complete Action Plan for dealing with incidents is included in your red Health Devices Alerts Action Items binder. A summary of this plan appears in the poster on the next page.

Unfortunately, whether for a lack of understanding or simply a lack of time, clinical staff often neglect to preserve all equipment involved in an incident, especially disposable devices and the associated packaging and identifying data. The resulting problems involving evidence and incident-related medical devices can significantly complicate the investigations needed for risk management and Safe Medical Devices Act (SMDA) purposes. (See "Safe Medical Devices Act: FDA Issues Final Regulation on Medical Device Reporting" elsewhere in this issue.) It is important that clinical engineers understand these issues and help ensure that proper procedures are followed.



Procedures to Follow after an Incident

When an incident occurs, all devices and disposables that might have been involved should be impounded until they can be inspected. (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 impounded.) 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).

For many microprocessor-controlled devices, whether battery or line powered, error codes may be stored in the device's memory. These codes are usually essential to a thorough investigation. In such cases, clinical engineering should be consulted before turning off the device, unplugging it, or removing its battery.

Likewise, devices should not be cleaned or processed without first discussing the procedures with an experienced independent third-party investigator or manufacturer. Cleaning or processing 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 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 offer a refund for 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. The hospital should not simply send such devices to their manufacturers or distributors as a matter of general routine, nor should vendors be permitted unwitnessed access to the devices for inspection or repair.

For serious injuries or deaths, the optimum form of investigation is to impound 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. (ECRI maintains well-equipped investigation and documentation facilities and a forensics laboratory to facilitate comprehensive investigations.)

For cases in which injury did not occur and litigation is unlikely, returning equipment to the manufacturer may be appropriate. But before sending any device to the manufacturer, the hospital should document its own or any associated independent testing. (It is easier to investigate problems immediately after their occurrence, when details are more easily recalled and equipment and personnel are available.)

As outlined in the sample letter on page 34, the manufacturer should agree to and sign off on several conditions before the hospital returns the device for testing. Correspondence with the manufacturer and shipment of the device should be sent by certified mail, return receipt requested. Shipping documents should be carefully filed. Consideration will have to be given

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Accidents Happen — An Immediate Action Plan

Immediately after every significant incident:

- ✓ Take emergency measures to minimize and care for injury to, discomfort of, and threat to life of patients or personnel (e.g., thermal burns, electric shock, contusions, lacerations, fractures, cardiac arrhythmias, interruption of normal respiration, loss of consciousness).
- ✓ Take appropriate action to minimize damage to equipment and the environment.
- ✓ Notify the attending physician who has legal responsibility for the patient.
- ✓ Impound all equipment attached or contiguous to the injured party in the same room or areas. Do not disconnect or change the relative physical positions of equipment or connecting cables, except as absolutely necessary to avoid further injury or damage. Retain and preserve any disposable products that may have been involved (e.g., drapes, electrodes), as well as their packaging materials.
- ✓ Follow ECRI's Action Plan for Handling Medical Device Hazards, Recalls, and Internal Incidents (printed in the red *Health Devices Alerts* Action Items binder).
- ✓ Call ECRI, (610) 825-6000, for telephone assistance or on-site investigation, if needed.

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to who insures the device during transport to and from the manufacturer.

While most manufacturers are committed to safe and effective products, it is naive to think that all reported problems will result in constructive action by a manufacturer or its distributor. Hospitals have reported to ECRI

Sample Letter for Returning Devices to Manufacturers

Sirs:

We are prepared to return [DESCRIBE PRODUCT, INCLUDING INDIVIDUAL IDENTIFYING DATA SUCH AS SERIAL NUMBERS AND HOSPITAL EQUIPMENT CONTROL NUMBER] for your evaluation. During its use, the following occurred: [DESCRIBE THE MALFUNCTION].

We request that you review this device for defects that may be associated with the incident described above. However, before we return the device, we would appreciate your acceptance of the following conditions:

1. You will notify us by letter immediately upon your receipt of the device.
2. Within 30 days of your receipt of the device, you will provide to us a complete report of your findings, conclusions, and recommendations concerning the device in question, including preparation for testing, test methods, and results.
3. No testing that results in the destruction of this device or associated accessories will be undertaken without prior written authorization from me to proceed.
4. The device and all related accessories sent to you will be returned to us promptly upon the completion of your examination, or sooner, at our request.
5. You will maintain appropriate control and transportation records to avoid compromising the identity of this device or its value as legal evidence.

We await your written acceptance of these terms and appropriate packing and shipping instructions. Please return a signed copy of this agreement. Thank you for your cooperation.

Yours truly,

[NAME]

[TITLE]

Agreed to and accepted on [DATE] by [NAME/TITLE].

cc: ECRI

Clinical Engineering Department

the following responses when incident-related devices were returned to the manufacturer:

- The manufacturer claims the device was never received, although it was picked up by a salesman and/or shipped to the factory (illustrating why hospitals should send the device by return-receipt transport or other verifiable means).
- The device was inadvertently damaged during shipment, making any possible testing of doubtful validity.
- The device was accidentally damaged during testing.
- The device was tested, and there was nothing wrong with it (no information on what was tested, or how, is ever provided).
- 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 complete records of all correspondence with the manufacturer, as well as evidence that hospital procedures for incident investigations were followed. If a manufacturer discovers a defect in its product and issues a hazard or recall, then the hospital will have contributed to the prevention of similar incidents in other hospitals.

Requests from the Food and Drug Administration (FDA) or local authorities to test, inspect, or remove an incident-related device from the facility should not be granted without the prior review and 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.

The Impact of SMDA

FDA's SMDA problem reporting requirements make it even more important for hospitals to be aware of device-related incidents, to effectively control the involved products, and to perform an incident investigation. Guidelines on effective medical device incident investigation will be presented in ECRI's upcoming *Final Report — Medical Device Reporting under SMDA: A Guide for Healthcare Facilities and Manufacturers*, which is slated for publication in early 1996. (Also see "Safe Medical Devices Act: FDA Issues Final Regulation on Medical Device Reporting" on the next page.) □