UNIVERSITY OF TOLEDO

SUBJECT: PRODUCT ALERT/RECALL/HAZARD Procedure No: ME-08-003

PROCEDURE STATEMENT

There shall be a program which provides appropriate response on all product recalls, alerts and hazards.

PURPOSE OF PROCEDURE

To protect the safety and well-being of patients, staff, and visitors by providing information and corrective action as necessary in response to potential product related defects or hazards.

PROCEDURE

Product Safety Coordinators

- The Director of Biomedical Engineering Services shall serve as the Product Safety Coordinator for Medical Equipment.
- The Senior Director of Supply Chain shall serve as the Product Safety Coordinator for Products and Supplies.
- The Legal Nurse Specialist in the Office of Legal Affairs shall serve as the Product Safety Coordinator for Implantable Devices.

Procedure

- All medical equipment, product, supply or implantable device recalls, alerts and hazard notices received from government or private agencies, manufacturers, distributors or any other source shall be reported to the applicable Product Safety Coordinator along with associated documentation.
- Any piece of medical equipment, product, supply or implantable device identified by the users as having inherent defects in its design or intended application that may present an unsafe condition in the use of the piece of medical equipment, product, supply or implantable device shall be reported by the user to the applicable Product Safety Coordinator. The medical equipment, product, supply, or implantable device shall be identified by manufacturer, distributor, model or catalog number, log number, description and shall include all other information necessary to specify the product(s) of concern.
- The Product Safety Coordinators will manage electronic alerts through the ECRI notification system.
- The Product Safety Coordinators will maintain documentation sufficient to confirm notice distribution, acknowledgement, and actions taken.
- Documentation required to respond to government or private agencies and/or manufacturers or distributors of the products must be sent via the applicable Product Safety Coordinator or their delegate.
- Communications to affected patients regarding alert and hazard notices for implantable devices is coordinated through the Product Safety Coordinator for Implantable Devices.
- The Product Safety Coordinators shall provide quarterly reports of product recall/alert/hazards to the UT Safety & Health Committee.

Source: HSC Safety Committee

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