

# Greater New Orleans Surgery Center

## ANNUAL REVIEW OF THE EQUIPMENT MANAGEMENT PLAN

Page 1 of 1

Reviewed: August 1, 2001;  
~~08/01/2003, 05/01/2009~~  
Implemented: August 1, 2001;

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### PURPOSE:

To maintain the currency and consistency of equipment management policies and procedures and to evaluate the usefulness of the equipment program's performance standards.

### POLICY:

Greater New Orleans Surgery Center will evaluate annually the objectives, scope, organization, and effectiveness of the equipment management program.

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# Greater New Orleans Surgery Center

## EQUIPMENT AND PRODUCT RELATED OCCURENCES

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Reviewed: August 1, 2001

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### PURPOSE:

To outline procedures for responding to any equipment or product-related occurrences whether or not they resulted in patient injury.

### POLICY:

For the safety of employees, patients and visitors, equipment or products used for providing direct patient care or in other areas of the facility which malfunction, break or otherwise fail, causing real or potential injury to a patient, visitor or employee shall be removed from service immediately.

### PROCEDURE:

- A. Any equipment malfunction, break or failure, causing real or potential injury to a patient, visitor or employee shall be removed from service immediately and an Incident Report completed.
- B. Equipment that can be removed from service shall be taken to the Clinical Manager's office, tagged as out of service and locked up.
- C. Equipment that cannot be removed from the area shall be guarded to prevent tampering until the risk manager and/or safety officer have been notified and, along with the administrator, have approved any further actions or repairs. The risk manager shall immediately notify Corporate Risk Manager Office for other instructions.
- D. The equipment must be preserved as potential evidence in defending or documenting a claim on behalf of the facility against the manufacturer or other party. Facility staff shall make no attempts or contracts to repair the equipment or otherwise tamper with it or to allow anyone access to the equipment until notified by Corporate Risk Manager for other instructions.
- E. Each person having custody of the equipment should document his or her involvement to preserve the "chain of custody" which is essential to preserve the equipment as evidence. A copy of all prior service reports shall be provided to the risk manager.
- F. Any products that may be involved in a potential claim shall be immediately removed from service and forwarded to the risk manager. Other products in the same lot should be removed from service and secured.
- G. Upon investigation, the risk manager or the administrative designee shall notify the manufacturer of the product or equipment and the U.S. Food and Drug Administration (FDA),

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## EQUIPMENT AND PRODUCT RELATED OCCURANCES

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\_\_\_\_\_ as dictated by the Safe Medical Devices Act of 1990 (SMDA). A copy of these guidelines is \_\_\_\_\_ maintained in the corporate risk manager's office.

H. \_\_\_\_\_ An Incident Report should be completed for any equipment occurrence regardless of the degree of severity.

I. \_\_\_\_\_ Prior to placing the equipment back in service, the department director shall obtain approval from the risk manager (or administrator-on-call) and/or the safety officer.

J. \_\_\_\_\_ Incidents will be tracked

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## PATIENT OWNED ELECTRICAL EQUIPMENT

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### PURPOSE:

To establish a procedure for safely controlling the use of patient owned electrical equipment in the facility.

### POLICY:

The Maintenance Department is responsible for safety-checking patient owned electrical equipment used in the facility.

### PROCEDURE:

A. Authority to approve use of any patient owned electrical equipment is assigned to the Clinical Manager.

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B. Approval will be for the duration of the patient's current stay. Because the condition of the equipment may have changed, approval of equipment used during a prior stay will not be valid for a renewed admission.

C. When a patient requests permission to use his own electrical equipment, the Clinical Manager or designee must test the equipment with the patient to ensure it is in proper working order.

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D. Under no circumstances can any patient owned equipment be connected to the center's master antenna system (VCR's, televisions, electronic games, etc.).

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E. Only equipment that has three prong plugs or equipment that is double insulated will be permitted.

¶ E. The equipment will be inspected promptly by the maintenance department and returned to the nursing unit. ¶

F. Equipment must be in good repair and have no breaks in insulation, frayed cords, etc.

¶ F. If equipment is safe for use, it will be tagged with a small yellow sticker containing the date inspected and the initials of the inspector.¶

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## RENTAL EQUIPMENT

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### POLICY:

Greater New Orleans Surgery Center will establish guidelines for the safe use of rental equipment.

### PROCEDURE:

All rented medical equipment will have a predelivery inspection performed at delivery. This inspection is designed to ensure that the equipment is safe and performs within the respective manufacturer's technical specifications. All critical safety, performance, and electrical safety features are tested during the predelivery inspection. The contracted rental company performs the predelivery inspection.

Once accepted by the purchasing department, the Clinical Manager will be contacted to visually inspect each piece of equipment and record pertinent information (i.e.; manufacturer, model and serial numbers) to be added to the facilities computerized maintenance schedule. This will serve as a reminder to perform follow up inspections on the rented equipment; however, inspection due dates are monitored by the contracted rental company. Also, the contracted rental company performs all maintenance inspections.

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Rental equipment performance complaints should be submitted to the purchasing or Clinical Manager for follow-up with the rental company.

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## REPORTING MECHANISM FOR EQUIPMENT FAILURES AND USER ERRORS

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### PURPOSE:

To identify and document equipment failures and user errors.

### POLICY:

The risk manager and the Clinical Manager are responsible for tracking equipment failures and user errors.

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The Performance Improvement Council is responsible for evaluating equipment failures and user errors.

### PROCEDURE:

- A. Clinical department managers are responsible for recognizing user errors and reporting them to the maintenance manager.
- B. User errors or failures of any medical equipment in the facility will be documented on the Incident Report form within 24 hours of the incident involving center equipment, regardless of the magnitude.
- C. On a bi-monthly basis, a summary of Incident Reports pertaining to user error or equipment failures is then prepared by the risk manager and reported to the Performance Improvement Council.
- D. The PI Committee will review the incidents, recommend action, and ensure follow-up corrective action.
- E. This policy covers all center medical equipment.

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## RESPONDING TO PRODUCT AND/OR EQUIPMENT RECALLS

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### PURPOSE:

To protect patients and employees from potentially defective equipment and supplies.

### POLICY:

For the safety of employees, patients and visitors, potentially defective products and equipment shall be removed from the center inventory in accordance with the protocol outlined when notice of a recall or potential defect is received.

### PROCEDURE:

- A. Upon receipt of a notice of recall or potential defect in products or equipment used by the facility, the safety director or risk manager will distribute copies of the notice to the appropriate department(s).
- B. The department director will investigate the inventory and remove the products or equipment identified in the notice.
- C. The notice shall be signed and returned to the safety director.
- D. An Incident Report will be generated if there is any concern regarding past use of the recalled or potentially defective items.
- E. The manufacturer (or the originator of the hazard/recall notice) shall be contacted by the risk manager to discuss appropriate action regarding the.
- F. The risk manager shall coordinate with other appropriate department managers the implementation of any action to be taken regarding the hazard/recall notice.
- G. Information regarding these incidents will be reported to the Performance Improvement Council.

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## SPECIALIZED EQUIPMENT

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### PURPOSE:

To identify the responsibilities of those departments that utilizes specialized equipment.

### POLICY:

The Administrator does not have the expertise to maintain specialized or high technology equipment; therefore, it shall be the responsibility of the Clinical Manager to maintain an equipment list, maintenance records, and service records of all specialized services. Equipment manuals and documentation of staff training for the department utilizing the equipment will maintain all specialized high technology equipment used.

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Training records for specialized equipment shall include records of new employee training and inservice that address equipment and/or operating procedures that are new or have changed during the year, or have had a significant number of failures or user errors associated with them. Equipment failures and user errors will be tracked by the Clinical Manager and reported to the Performance Improvement Council.

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## UNSAFE MEDICAL DEVICES

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### PURPOSE:

To insure that unsafe medical devices are identified and removed from use.

### POLICY:

The Clinical Manager and the contracted bio-medical service is responsible for assuring that all electrical medical equipment is in the proper working condition.

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### PROCEDURE:

A. The following steps shall be taken if a patient, staff member or visitor is injured or killed as a result of using an electrical medical device.

1. The Clinical Manager and Bio Medical staff shall be contacted so that the following steps can be taken:

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- a. The equipment shall immediately be labeled as out of service.
- b. The equipment shall be immediately relocated to the Administrators office where it will remain secured.

2. The Clinical Manager shall take the following steps:

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- a. An Incident Report shall be completed so that the problem can be investigated and tracked by Risk Manager.
- b. The bio-medical technician will be directed to immediately inspect all similar equipment to assure its safe operation.
- c. The Risk Manager will contact the Corporate Risk Manger.
- d. The Risk Manager shall send a certified letter to the device manufacturer and to the Food and Drug Administration outlining the particular device and the details of the incident.
- e. The equipment shall remain secured in the Administrator's office and be available to legal and investigator agents with the approval of Corporate legal advisors.

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