

Safety Program

A. National Patient Safety Goals

In 2002, the Joint Commission established National Patient Safety Goals, intended to address the fact that health care takes place within complex systems that at vulnerable point directly affect the patient. Recommendations for improvements, related to these goals, became standards and requirements in 2004. Two of these goals, goal 5 and goal 6, directly affect the biomedical engineering departments. These goals are discussed next.

1. Goal 5: Improve the Safety of Using Infusion Pumps (APR.20)

Problems involving the use of infusion pumps have led to deaths and near fatal drug overdoses. Most problems have been caused by pumps that do not provide protection from the free-flow of intravenous fluid/medication into the patient (Stiefel, 2004)

- a) The hospital ensures free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization. (APR.20.1)*

CIRACET does not provide maintenance or repair to infusion pumps and PCA devices. However if included as part of the service contract CIRACET will assure that the Hospitals infusion pump inventory receives proper maintenance and repair. CIRACET will be in charge of the repairs management, PMs and that the contracted company for this service complies with this National Patient Safety Goal.

2. Goal 6: Improve the Effectiveness of Clinical Alarm Systems (APR.21)

The purpose of this goal is to ensure that device alarm systems are in good condition and can be heard by nurses and other healthcare professionals when something goes wrong with the device or the patient.

CIRACET will take care of the technical side of compliance. The following tasks are performed as part of the goals requirements; 1) list of all types of biomedical equipment alarms, 2) confirm that all equipment with alarm is included in the inventory, 3) determine if preventive maintenance for alarm system is adequate for all equipment, 4) document the implementation of clinical alarm maintenance.

(See Appendix F for List of Equipment with clinical alarms.)

The two goal requirements are:

- a) The hospital has implemented regular preventive maintenance and testing of alarm systems. (APR.21.1)*

All medical devices with alarms are included in the Equipment Maintenance Management Program, therefore, alarms and audible signal testing is performed during the regular

device preventive maintenance. (See Appendix F for a list of the medical devices with alarm, frequency of preventive maintenance and the revised inspection protocols.)

During the qualitative tests in a preventive maintenance, the biomedical technicians will check the alarm functions (1.23) and volume (audible signal) (1.24). (See Preventive Maintenance Form in Appendix D.)

b) The hospital assures that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noises within the unit. (APR.21.2)

CIRACET biomedical technicians will verify, whenever applicable, the device's parameter settings to check if these are appropriate according to standards, or hospital's common practices. Also, and as part of the preventive maintenance, biomedical technicians will check the signal's volume but they will not be responsible of verifying if the signal is sufficiently audible.

It is not necessary to perform scientific measurements of the actual decibels an alarm emits or specific acceptable sound levels. The Commission has stated that simple observation during routine operations of a patient care unit, coupled with input from staff on the unit, should be sufficient to evaluate if the hospital is meeting requirement b.

It has been reported that the majority of the alarm problems stem from user error. Typically, the problem is the result of an inappropriate alarm setting or an alarm that is turned off. Sometimes, users are not even aware that a device has an alarm. Training, therefore, should play an important part in the effort to meet this safety goal. Users must be adequately trained in what an alarm means, what to do when it sounds, and when an emergency response is needed.



B. Safety Recalls and Alerts

CIRACET receives medical equipment hazard notices and recalls from various sources, including directly from manufacturers and publications. The main source used by CIRACET for obtaining the best up-to-date information is MedWatch. MedWatch is the FDA Safety Information and Adverse Event Reporting Program that serves both healthcare professionals and the medical product-using public. They provide important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products.

In the event of a Safety Recall CIRACET's engineers will verify if the equipment being recalled is on the inventory. If the equipment is in inventory a recall memorandum will be made available to the Plant Facilities Director.

MedWatch also allows [healthcare professionals](#) and [consumers](#) to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting can be done [on line](#), by phone, or by submitting the MedWatch 3500 form by mail or fax. Reporting to the FDA or any other agency will be the Hospital's responsibility. CIRACET will provide any necessary information and will cooperate in any tasks related to a safety issue.

CIRACET also complies with the User Reporting Requirements of the Safe Medical Devices Act of 1990. CIRACET will report to the Plant Facilities Department and the Safety Committee of any patient incident related to the malfunction of a medical equipment. The Safety Committee or the person designated by the hospital will be responsible of reporting the incident to the FDA as required by the Safe Medical Devices Act of 1990. (EC.6.10.7)

C. Safety Committee Support Activities

CIRACET administrative staff will meet with the Safety Committee as required by the Hospital. We will provide information regarding; maintenance requirements, clinical alarms, medical device incidents, clinical equipment risks and any other information requested. Also, information about deficiencies, conditions involving medical equipment, and opportunities for improvement will be reported. It is also expected that each hospital will provide recommendations to CIRACET on how to improve the equipment management program. Monthly service and preventive maintenance reports will also be provided.



D. Staff Safety

CIRACET has established a Safety Program that focus on providing training and the appropriate knowledge to the employees on how to work safe, and maintain a safe environment. Training includes manual material handling, electrical safety, radiation, fire prevention, blood borne pathogens, and infection control. A copy of the training will be available upon request.

CIRACET Equipment Maintenance Management Program Safety Policy

Policy

CIRACET maintains a safe environment for technical and administrative staff involved in medical equipment management. It is up to every individual to help assure not only his or her personal safety, but also the safety of patients, and the safety of other staff and visitors. Our engagement with healthcare institutions is based on assuring that clinical equipment is maintained to provide safe and effective performance.

Description

1. CIRACET staff shall report any work-related injury or illness to their immediate supervisor, and complete an Incident Investigation Report.
2. CIRACET staff shall observe and comply with the Safety and Health section of the Employees Manual.
3. CIRACET staff will attend any training provided by a Hospital whenever required.
4. CIRACET staff will use personal protective equipment when necessary.
5. CIRACET staff is provided with Infection Control and Blood Borne Pathogens guidelines that should be followed at all times when servicing biomedical equipment.
6. CIRACET staff will assure that safe working conditions are being provided when servicing;
 - a. Radiographic Equipment
 - b. Autoclaves/Sterilizers
 - c. Suction Pumps
 - d. Infusion Pumps, etc.
7. CIRACET has major responsibility for ensuring that biomedical equipment is maintained to provide safe and effective performance. This is in keeping with the Joint Commission Accreditation of Healthcare Organizations.



E. Infection Control

CIRACET staff receives an orientation on Blood Borne Pathogens and Infection Control when recruited and at least once every two years.

CIRACET staff is not allowed to receive equipment for maintenance or repair if it is not cleaned, and/or sterilized. Biomedical Technicians are not responsible for cleaning or disinfecting the equipment. However, they are instructed to use a disinfectant/cleaner solution on the equipment before starting any job repair or maintenance. Also, personal protective equipment (gloves, masks, static wrist band) should be used whenever needed.