Title: **SAFE MEDICAL DEVICES**

Principle:

Because of the tremendous number and variety of medical devices used in the laboratory, the maintenance and quality checks performed on these devices becomes very important in preventing malfunctions which could contribute to patient death, injury, or continued illness. It is the intent of the Anatomic Pathology Department to keep these types of incidents to a minimum.

Procedure:

As of November 28, 1991, all "device user facilities" are required to report all deaths, serious injuries or serious illness which occurred in the user's facility and which there is a probability that a medical device caused or contributed to the event.

Glossary

1. A "device user facility" is defined as: all hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities.
2. The definition of a "Medical device" is: an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory which is . . .
   - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or
   - intended to affect the structure of any function of the body of man.
3. Serious illness or injury is defined by the Safe Medical Devices Act of 1990 (Public Law 101-629) as one that:
   - Is life threatening.
   - Results in permanent impairments of a patient's body structure of function.
   - Needs any immediate medical or surgical intervention to prevent permanent damage to a patient.

Time Frame

All reports will be initiated by the Office of Risk Management, in conjunction with Bioengineering. If the laboratory has been requested by this office to respond to a situation, such response should be completed as soon as possible. The FDA has indicated that facilities should report to them no later than 10 working days after a facility becomes aware of a reportable event. The 10 working days begins once the facility has made the determination that the event is in fact, reportable. Working days mean Monday through Friday, excluding weekends and federal holidays.

Reports

If a response has been requested by the Office of Risk Management, the final content of the report filed by that office would minimally include:

- The identity of the reporting facility.
- Product name, model, serial number.
- Manufacturer, if known.
- Description of the event.

In addition, the Office of Risk Management will submit a summary of the reports semi-annually. This summary must be submitted on January 1 and July 1 of each year. The summary would include:

- The name, address, telephone number, type of facility.
- Product name, model and serial number.
- Name and address of the manufacturer of the device.
- Brief description of the event reported to the manufacturer.

Written by: Heather Currens, SCT (ASCP), 8/13/2008

Approval of Procedure:

Medical Director Signature: M. Scott Jessup, MD

Date: 8/29/12

ANNUAL SIGNATURE REVIEW

PROCEDURE TITLE: SAFE MEDICAL DEVICES

Signature on this page insures that each procedure has been reviewed annually. Any changes will be reflected on the procedure by the revised date. GEN.73200

MEDICAL DIRECTOR	SIGNATURE	DATE
M. Scott Lucia, MD	M. Scott Lucia	8/29/12
	M. Scott Lucia	3/24/14