I. STATEMENT OF PURPOSE:

To identify and report events in which a medical device may have been involved in an adverse event that may have caused or contributed to a patient's death, serious illness, or significant harm.

To provide the Food and Drug Administration (FDA) and/or manufacturer with required information while ensuring that hazardous devices are removed from service.

II. STATEMENT OF POLICY:

The Safe Medical Devices Act of 1990 (Public Law 101-629) requires that whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death, serious illness, or serious injury of a patient, a report has to be filed within 10 working days after healthcare professionals become aware of the reportable event. Summary reports of serious events must be filed with the FDA annually on January 1, if any reports were filed during the previous calendar year.

III. DEFINITIONS:

**Patient of the facility** means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.  

**Serious injury** means an injury or illness that:
- Is life threatening,
- Results in permanent impairment of a body function or permanent damage to a body structure, or
- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**Medical device** is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition and is not a drug or biologic.

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Updated: January 2017
SAMPLE: Safe Medical Devices Act Reporting Requirements Policy

**Caused or contributed** means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:
- Failure;
- Malfunction;
- Improper or inadequate design;
- Manufacture;
- Labeling; or
- User error

**Tracked devices:**
The tracking provisions of section 519(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 360i(e), were added in 1990 by the Safe Medical Devices Act (SMDA) and amended in 1997 by FDAMA. Device tracking enables the FDA to require a manufacturer to promptly identify product distribution information and remove a device from the market.5

The types of devices subject to a tracking order may include any Class II or Class III device:
- the failure of which would be reasonably likely to have serious adverse health consequences;
- which is intended to be implanted in the human body for more than one year; or
- which is intended to be a life sustaining or life supporting device used outside a device user facility.6

**Device user facility** is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility, which is not a physician's office.7

**Final distributor** means any person who distributes a tracked device intended for use by a single patient over the useful life of the device to the patient. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.8

**IV. Procedure**

1. Any person, including a healthcare provider or staff member, who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests a medical device has or may have caused or contributed to the death, serious illness, or serious injury of a patient within the facility shall immediately notify the risk management professional* or designee and follow the verbal report with a written/electronic event report as soon as possible. Involved equipment shall be immediately removed from service and secured to ensure that the equipment and related attachments remain intact. (See the Medical Equipment Control policy and procedures**.)

2. Upon notification, risk management shall carry out the following:
   2.1. Validate the removal of the medical device in question, label it, and place it in a secure location.
   2.2. Ensure that the needs of the patient, family members, and/or individual who may have been harmed by the device have been addressed.
   2.3. Inform [insert name of department] that the medical device is subject to investigation (Refer to Medical Equipment Control policy and procedures**).
   2.4. Immediately begin an investigation of the event.
2.5. Directly oversee any analysis of the medical device by authorized personnel (e.g., biomedical staff members). A determination may be made as to whether user error or device malfunction was a contributing factor in the death, serious illness, or harm to the patient and/or individual.

2.6. Ensure that the manufacturer or service representatives of the medical device does not attempt to repair or remove the involved medical device from the facility. A medical device shall not be released to a manufacturer or vendor until approved by legal counsel and/or risk management.

2.7. Notify the facility’s medical professional liability carrier of the adverse event and/or potential claim.

3. When the preliminary investigation is completed, a report of the preliminary findings should be presented to a designated oversight (e.g., risk management) committee* within 24 hours of completion. At that time the committee* shall decide whether to accept the findings or recommend additional investigation.

4. If the committee* accepts the findings that the medical device has or may have caused or contributed to an FDA reportable event, risk management shall prepare and submit a Medical Device Report (MDR) Form 3500A to either the FDA or manufacturer or both within 10 working days after healthcare professionals first became aware of a reportable event. Sections A – E of Form 3500A shall be completed following the FDA Coding Manual.

Equipment/medical device records necessary for the completion of the FDA 3500A form are found in the equipment file system located in [insert name of department]. Note: If a patient dies while in restraints or it is reasonable to assume the patient’s death was secondary to the use of restraints, the risk management professional will notify CMS, as required by 42 CFR 482.13(g).

5. The responsibility for submitting reports to the FDA and/or manufacturer is the responsibility of risk management. If the device may have contributed to or caused death, serious illness, or significant harm, an MDR must be submitted to both the FDA and the manufacturer, if known. If the preliminary findings suggest that the event is not an FDA-mandated reportable event, the committee* or risk management professional may submit a voluntary report of device failure, user error, or malfunction to the FDA, as well as the manufacturer, using the FDA Form 3500.

6. All pertinent material collected as a result of the investigation shall be treated in accordance with the facility’s event reporting and investigation of adverse event policies (e.g., root cause analysis [RCA]).

7. MDR Forms (FDA 3500 and 3500A) shall be kept for a minimum of two years. [NOTE: This may vary depending on the statute of limitations in the specific state.]

8. An annual report of serious events submitted to the FDA using form 3500A is required. The risk management professional* shall submit the annual report using FDA Form 3419 (or an electronic equivalent) on or before January 1 for events that were reported from January through December in the prior year.

9. It is the responsibility of organization’s leaders and department managers, as well as the chief medical officer, to communicate the content of this medical device reporting policy to appropriate staff members.
10. Information on the requirements of the Safe Medical Devices Act and the facility’s policies and procedures on handling and reporting medical device events will be addressed during the orientation of new staff members.

11. Orientation and ongoing education on the requirements of the Safe Medical Devices Act shall be provided for facility staff members annually.

12. The risk management professional* shall be responsible for updating facility policy and procedures, as indicated, and for reporting changes to the managers of affected departments and the medical staff.

* Indicates the need to insert the position/committee name used in your organization

** Indicates the need to reference your organization’s policy and procedures regarding medical equipment control

References
1. 21 CFR §803.3.
2. Ibid.
4. 21 CFR §803.3.
8. 21 CFR §821.3.

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