**Purpose:**

The purpose of the medical device reporting (MDR) program is to identify medical device related incidents as soon as possible after their occurrence in order to initiate corrective action, prevent or minimize the occurrence of similar incidents, and comply with the reporting requirements of the U.S. Food and Drug Administration (FDA) regulations and the federal Food, Drug, and Cosmetic Act.

**Policy:**

It is the policy of <<*Name of your Hospital*>> that all mandatory reportable serious injuries caused by a medical device (see supportive data below) will be reported to the FDA MedWatch Program.

**Supportive Data:**

1. Medical Device: A “device” is defined as an instrument, apparatus, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, that is:
   1. Recognized in the official National Formulary or in the United States Pharmacopeia, or any supplement to them;
   2. Intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or
   3. Intended to affect the structure or any function of the body of humans or other animals, that does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals, and that is not dependent upon being metabolized for the achievement of any of its intended principal purposes.

This definition is taken from 21 USC Part 321[h]. Examples of medical devices include catheters, infusion pumps, hospital beds, patient restraints, suture material, syringes, defibrillators, pacemakers, tampons, wheelchairs, and in vitro diagnostics.

1. Serious Injury: The term “serious injury” is defined as an injury or illness that:
   1. Is life-threatening;
   2. Results in permanent impairment of a body function or permanent damage to a body structure; or
   3. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

This definition is taken from 21 USC Part 360[i][b][5][B] and 21 CFR Part 803.3[m].

**Procedure:**

1. Reporting Procedure

Any individual who witnesses, discovers, or otherwise becomes aware of information that reasonably suggests that a medical device may have caused or contributed to the death of or serious injury to a patient or employee of <<*Name of your Hospital*>> is:

* 1. To take emergency measures to minimize and care for the injury to, discomfort of, and threat to life of patients and personnel.
  2. To notify the attending physician for the patient.
  3. Responsible for immediately reporting the incident to his or her Department Manager or the Risk Manager and the Administrator or the Administrator on Call (AOC).
  4. Obligated to make an immediate verbal report and to complete an Event Report form. The Department Manager must immediately report this information to the Risk Manager or the Administrator or AOC.
  5. **Required to preserve the suspected incident-related devices, packaging, and associated disposables attached.**

1. Specific Responsibilities
   1. Quality Risk Management (QRM) Department:
      1. The Risk Manager shall have overall responsibility for implementing and managing the hospital’s medical device reporting program. This responsibility shall include establishing and maintaining a hospital-wide system for documenting medical device incidents, reviewing and analyzing all reportable incidents, completing and submitting appropriate reports to outside agencies, and monitoring all recommended follow-up actions and improvement plans resulting from the event for follow through.
      2. The QRM Department shall, in cooperation with the Plant Operations Manager or designee, the Materials Manager or designee, applicable clinical managers, and outside specialists, when appropriate, conduct an investigation of the event to determine whether a device caused or contributed to the event and why. The results of the investigation should be reviewed by the Administrative Council and other applicable physicians and personnel. They shall adopt recommendations for corrective action. The Risk Manager shall use the MDR decision pathway to document the decision making process.
   2. Mandatory Reporting: The QRM Department shall be responsible for submitting appropriate reports to the FDA and/or the medical device manufacturer in accordance with federal law and regulation. The law requires the following:
      1. <<*Name of your Hospital*>> must report patient deaths to the FDA and the manufacturer, if known, within 10 working days of becoming aware that a device caused or contributed to the incident. Reports shall be made using FDA Mandatory Reporting Form 3500A or an electronic equivalent.
      2. <<*Name of your Hospital*>> must report serious injuries to the medical device manufacturer (or to the FDA, if the manufacturer is unknown) within 10 working days of becoming aware that a device caused or contributed to the incident. Reports shall be made using FDA Mandatory Reporting Form 3500A or an electronic equivalent.
      3. “Becomes aware” refers to the time when the Risk Manager acquires knowledge of the event.
      4. Annual summaries of reports must be submitted to FDA on January 1 of each year. Reports shall be made using FDA Form 3419 or an electronic equivalent. If no medical device reports are submitted within the calendar year, an annual summary report is not required.
      5. The FDA Annual Report 3419 must be sent directly to the FDA at the following address:

MDR Reporting

Center for Devices and Radiological Health

Food and Drug Administration

PO Box 3002

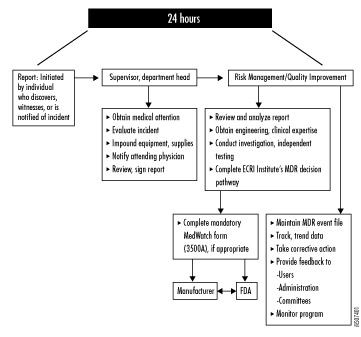
Rockville, MD 20847-3002

The same address can be used when mandatory device-related reports must be submitted to the FDA. The hospital can also fax the mandatory reporting form to the FDA. Call the FDA’s data entry staff at 240.276.3000 before faxing the report. Staff will provide a fax number for submitting the report.

* 1. Voluntary Reporting:
     1. FDA Form 3500 is to be completed for voluntary reporting of serious adverse events, product problems, or product use errors with medications (drugs or biologics); medical devices (including in-vitro diagnostics); combination products (medications and medical devices); human cells, tissues, and cellular and tissue based products; nutritional products (dietary supplements, medical foods, infant formulas); and cosmetics.
     2. Form 3500 could be submitted to either the FDA or the manufacturer, or both.
     3. The submission of Form 3500 is purely voluntary and not mandated by law or regulation.
     4. The QRM Department shall ensure that all data collected from the hospital’s medical device reporting program shall be incorporated into the hospital-wide event-reporting program, the results of which are communicated to the Quality Committee and the Safety Committee.
     5. The QRM Department shall be responsible for maintaining an MDR event file for a period of two (2) years from the date of the event. The file must contain:
     6. Reports submitted to the FDA and manufacturers.
     7. Information on or references to:
     + Documentation of deliberations using the ECRI Institute’s MDR Pathway form (see attachment and instructions);
     + References to other information, such as patient records or engineering reports; and
     + Information that leads to the conclusion that an event is not reportable.
     1. If the Risk Manager is not available, the Administrator or AOC will assume the above responsibilities.
  2. Plant Operations (PO) Department (for equipment related incidents) or the Materials Management (MM) Department (for product related incidents):
     1. The PO/MM Manager shall play a key role in maintaining the medical device reporting program, investigating incidents, and evaluating the safety of devices.
     2. The PO/MM Managers shall obtain relevant information regarding previously reported hazards, recalls, and problems with respect to device-related incidents through contact with the FDA. All such information shall be shared with the QRM Department.
     3. The PO/MM Managers shall assist the QRM Department in collecting the device information, service and history information, and other information required under this policy.
     4. The PO/MM Managers shall assist in conducting an investigation of the device-related incident, evaluating the safety of the device, and determining whether the device, along with the relevant supplies, accessories, and packaging, should be impounded, repaired, or returned to service.
     5. <<*Name of your Hospital*>> is not required under the SMDA to return the device to the manufacturer.

1. Medical Device Reporting Information Flow

This medical device reporting program flowchart shows the communication channels for reporting incidents internally as well as for reporting to outside agencies.



1. User Error
   1. The fact that a device was involved in an incident does not in itself trigger a mandatory report. More analysis is needed. For each event, it is important to ask whether there was or may have been attribution on the part of the device or whether the device was or may have been a factor in the death or injury.
   2. User error may be invited by a manufacturing, design, or labeling problem. If so, then the injury or death may have been attributed to the device, or the device may have been a factor in the event, and a report should be submitted, focusing on how the device caused or contributed to the error.
2. Explanted Devices

Certain explantations will be reportable because they will meet the definition of serious injury (i.e., the implant caused or contributed to the necessity for surgical intervention to preclude permanent damage or impairment). This would be the case with an implant that malfunctions or fails. However, not all explantations will be reportable. The elective removal of a mammary implant would not be reportable in the absence of a device failure or malfunction (e.g., rupture). Also, the removal or replacement of an implant that has reached its labeled end of life would not be reportable in the absence of premature failure.

1. Needlestick Injuries

If a person is exposed to infectious material via a needlestick resulting from a device failure and is subsequently treated medically or surgically to prevent permanent impairment, the event is reportable by the hospital because it involves a serious injury. Not every first-aid measure will constitute medical intervention. For example, the application of a bandage or simple cleaning of the site of a needlestick does not constitute medical intervention. However, use of stitches or administration of a tetanus shot or a gamma globulin shot is considered medical intervention and would require the submission of a mandatory report by the hospital.

1. Protection of Confidential Information
   1. <<*Name of your Hospital*>> shall carefully guard patient and clinician (physician and/or nurse) identities that are involved in an adverse event. They need not be disclosed anywhere on FDA Form 3500A or 3500.
   2. A numerical or other identifier shall be used in the patient identification section of the forms. Do not use the patient’s social security number.
   3. If patient records are copied and attached to the FDA report form (this is voluntary, not required), ensure that the patient’s identity is deleted on each page.
   4. <<*Name of your Hospital*>> event reports, documents on deliberations, plant operations/materials management reports, and follow-up investigation reports should not be attached to or sent with the Form 3500A or 3500 report.
   5. The name, address, telephone number, email address (if available), and occupation of the initial reporter (i.e., Risk Manager) must be reported on FDA Form 3500A or 3500.
   6. The individual who completed the <<*Name of your Hospital*>> Event Report shall not be identified on FDA Form 3500A or 3500.
   7. The <<*Name of your Hospital*>> Event Report shall not be filed in the FDA MDR file in the Risk Manager’s office.
   8. The SMDA states that user facility <<*Name of your Hospital*>> reports are not admissible into evidence and may not otherwise be used in any civil action involving private parties. This does not extend to reports made by medical device manufacturers or distributors.
2. Public Availability of Reports
   1. Certain information from reports submitted under the medical device reporting (MDR) requirements, including any U.S. Food and Drug Administration (FDA) record of a telephone report, is available for public disclosure. Before public disclosure of a report, FDA will delete from the report:
      1. Any information that constitutes trade secret or confidential commercial or financial information;
      2. Any personal, medical, and similar information (including the serial number of implanted devices) that would constitute an unwarranted invasion of personal privacy;
      3. Any names and other identifying information of a third party voluntarily submitting an MDR report (this includes physicians, healthcare professionals, or other hospital employees, unless they are designated the MDR contact person); and
      4. <<*Name of your Hospital*>> identifiers.
   2. FDA will disclose to a patient requesting a report of all information in the report concerning that patient.
   3. FDA will not disclose the identity of <<*Name of your Hospital*>> when we make a medical device report except in connection with:
      1. an action brought to enforce the MDR requirements, including the failure or refusal to furnish material or information;
      2. a communication to a manufacturer of a device that is the subject of a report required by <<*Name of your Hospital*>>; or
      3. a disclosure to employees of the U.S. Department of Health and Human Services and to the Department of Justice or to duly authorized committees and subcommittees of the U.S. Congress.
3. Staff Education and Training

The risk manager will periodically provide information and instructions on <<*Name of your Hospital*>>’s medical device reporting program to all appropriate staff. This will include the legal requirements, <<*Name of your Hospital*>>’s internal policies, and the appropriate use of <<*Name of your Hospital*>>’s event reporting form.

1. FDA Audits and Inspections

The U.S. Food and Drug Administration (FDA) has the authority to inspect the premises of <<*Name of your Hospital*>> without prior notice. An inspection will generally occur for one of two reasons: to investigate specific device problems or to conduct an audit for compliance with hospital reporting requirements contained in federal law and regulation. FDA inspectors will present themselves to administration and request permission to inspect. It is in <<*Name of your Hospital*>>’s best interest to be prepared to assist in a well-organized, smooth, and thoughtful manner. The following procedure should be followed whenever an FDA inspection is requested.

* 1. **NOTIFY AUTHORITIES**  
     Immediately notify the risk manager and/or the Administrator/AOC.
  2. **VERIFY CREDENTIALS**
     1. Examine inspectors’ credentials and notice of inspection, if any. If there is any doubt about authenticity,
     2. contact FDA’s CDRH (Center for Devices and Radiological Health) to verify that it is an authorized inspection.
  3. **HOLD AN OPENING CONFERENCE**

Determine the exact reason for and nature of the visit, and identify relevant staff and locations that might be pertinent to the inspection. Notify the relevant manager who is responsible for the department or area that is to be inspected. **Note:** The facility has the sole power to determine whether and under what circumstances facility personnel may speak to the FDA.

* 1. **ASK IF PHOTOGRAPHS WILL BE TAKEN**

If photographs will be taken, contact the Marketing Department, and request that a photographer accompany the team. As an alternative, contact the Administrator/AOC to determine who will accompany the team to take photographs.

* 1. **ASSEMBLE THE INSPECTION TEAM**

The inspection team should include the risk manager, plant operations manager, manager of the department to be inspected, photographer, and others, as appropriate. The team should accompany the FDA inspectors. If photographs are taken, take the same photographs with the hospital’s camera. If documents are reviewed or copied, copies of the same documents should be maintained by the hospital in an inspection file kept in the risk manager’s office.

* 1. **CONFIDENTIAL RECORDS**

FDA is authorized to access, verify, and copy information in <<*Name of your Hospital*>>’s MDR event file. The privacy rule of the Health Insurance Portability and Accountability Act allows disclosure of protected health information to FDA with respect to FDA activities such as medical product adverse event reporting. In such cases, <<*Name of your Hospital*>> can provide information containing protected health information without obtaining patient authorization. Route requests for confidential records (e.g., patient records, event reports, quality assurance records, attorney correspondence) to the hospital’s risk manager or the Administrator/AOC. No such material should be released without the prior approval by the Administrator/AOC.

* 1. **RECORD LABELING**

Label any records that are released as confidential and not subject to release under the Freedom of Information Act.

* 1. **REQUESTS FOR DEVICES**

Do not grant requests to test, inspect, or remove an incident-related device from the hospital without prior review by and approval of the hospital’s Administrator/AOC. Such action could result in the loss or destruction of legal evidence and could hamper the hospital’s ability to conduct or contract for an investigation.

* 1. **CLOSING CONFERENCE**

Arrange for a conference room in which the team can be assembled for a closing conference. During the closing conference, determine whether any deficiencies have been found and what corrective actions should be taken. Offer any additional information that might reduce or eliminate the deficiency.

1. In Summary - Action Review Checklist if an Event Occurs:
   1. Review the <<*Name of your Hospital*>> Event Report.
   2. Sequester and test the suspect device, accessories, and disposables.
   3. Identify device information (make, model, lot, serial number, age).
   4. Interview employees.
   5. Contact the manufacturer.
   6. Review ECRI Institute’s *Health Devices Alerts* database of medical device problem reports for similar incidents.
   7. Document findings.
   8. Make recommendations to prevent future occurrences.
   9. Complete U.S. Food and Drug Administration Form 3500A.
   10. Retain appropriate documents in medical device reporting event files.
   11. Document why Form 3500A was not submitted, if appropriate.
   12. Ensure that preventive follow-up recommendations are implemented.
   13. Report summary information to both the Quality and Safety Committees.

**Attachments:**

Attachment A: FDA Form 3500A: MedWatch for Mandatory Reporting\*

Attachment B: FDA Form 3500: MedWatch for Voluntary Reporting\*

Attachment C: FDA Form 3419: Annual User Facility Report\*

Attachment D: ECRI Institute’s MDR Decision Pathway and Instructions

Attachment E: SJLH Medical Device Event Investigation Form

\*Note: The most current version of the above forms may be downloaded from the FDA’s website at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm> . This form may also be completed online and printed for submission.

**References:**

1. ECRI Healthcare Risk Control Risk Analysis: Laws, Regulations, and Standards 15, March 2008

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| --- | --- |
| **Rule/Cite/Tag:**  Safe Medical Devices Act of 1990  FDA Modernization Act, December 1997/May 1998 | |
| **Hospital Policy Cross Reference:**  Event Reporting Procedure | |
| **Revision and/or Replacement Date(s):**  Safe Medical Devices Act Reporting Regulation Procedure, 012297 | |
| **Approved by:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name, VPSS/Quality Risk Manager  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name, CEO | **Date Approved:**    \_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |