|  |  |
| --- | --- |
|  |  |
| **SUBJECT/TITLE:** | **Medical Device Reporting Policy** |
|  |  |
| **PURPOSE:**  **SCOPE:** | 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 Federal Food, Drug and Cosmetics Act and the Safe Medical Device Act (SMDA) of 1990.  Institutional |
|  |
| **DEFINITIONS:** | Medical Device: an instrument, apparatus, implement, machine,  contrivance, implant, in vitro agent, or other similar or related article,  including any component, part, or accessory, which is:   * Recognized in the official *National Formulary*, or the *United States Pharmacopeia*, or any supplement to them; * Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or * Intended to affect the structure of any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.   Device Failure: A device failure is the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.  Incident: An incident is any event that is not consistent with the routine operation of the hospital or the routine care of a particular individual. It may be an accident or a situation that might result in an accident. It may cause injury or have potential for injury.  Serious injury: an injury 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 such permanent impairment or damage. |

**POLICY:**

1. Any medical personnel who discover, witness, are notified, or otherwise become aware of a suspected medical device malfunction or incident are required to follow the proper notification and reporting procedures.

**PROCEDURE:**

A. Reportable Events

1. A medical device incident reportable under this policy is an incident that occurs as a result of device failure, malfunction, improper or inadequate design, manufacture, labeling, or as a result of user error, and either:
2. The medical device may have caused or may have been a factor in the serious injury or death of a patient or staff member; or
3. Some form of medical or surgical intervention is necessary to preclude serious injury or death of a patient or staff member.

B. Notification

1. Any individual who witnesses, discovers, or otherwise becomes aware of a reportable event as defined above shall immediately report the event:
2. To direct supervisor or the person designated for initiating and completing reporting under this policy.
3. In the cases where the device failure may have caused or may have been a factor in the serious injury or death of a patient or staff member:
   * 1. Notification of Surgical Pathology: regarding any surgical specimens submitted for analysis
        1. To ensure appropriate handling and directed examination of the specimen with photography.
        2. To save specimen for further evaluation as necessary.
     2. Medical Examiner should be contacted for a unanticipated death

C. Information Collection and Reporting

1. The supervisor, or departmental person designated to report under this policy, shall collect relevant documentation, immediately report the incident to Supply Chain at 4-9800, and page the Law Department at RSK4 for serious injury and follow up by filing a safety incident report, at [Safety Incident Report](https://thepoint.healthcare.uiowa.edu/sites/Administration/IncidentReporting/_layouts/15/start.aspx#/SitePages/Home.aspx).
2. The report should include facts of the incident and any other relevant documentation. All reports should include the facts related to the event including:
3. The initial reporter
4. The location of the event
5. The description of the event
6. The patient’s name and MRN
7. The effect to the patient, including condition, outcome, and pre-existing conditions
8. Witnesses to the incident
9. The nature of the device problem
10. Device information including the type, name brand, model number, lot number, serial number, expiration date, manufacturer’s name, and manufacturer’s address
11. The department and name of the person who has possession of the device
12. Reports being filed with the FDA will require more detailed information (see <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>)**.**
13. For patients requesting device:
    1. All medical devices removed from the patient shall be considered the property of the patient and will not be released to anyone without written permission of the patient or legally authorized representative.
    2. All requests for medical devices to be returned to the patient or legal representative are to be handled at the direction of the surgeon.
14. **Device Failure Collection** In order to facilitate the appropriate collection of information and protection of evidence, the individual becoming aware of the device-related incident, the supervisor, or the departmental person designated to report under this policy, should ensure and coordinate the appropriate collection of information and make every effort to secure the device and its packaging, if applicable.
15. Place all components in original container whenever possible, and then place in the Biohazard bag; give to Clinical Director, Nurse Manager, or Supervisor on call.
16. The person discovering the defect, or their direct supervisor, will complete the UI Health Care Device Failure Collection form in Attachment I or at the following link: (enter link).
17. Contact Supply Chain at 4-9800 or email [procurement@uiowa.edu](mailto:procurement@uiowa.edu) to arrange pick up of the device. Devices are not to be submitted to Surgical Pathology.
    1. No product should be given to the manufacturer/vendor representative until a full evaluation of all the details has been completed. Supply Chain will work with Hospital Legal to determine the appropriateness of turning defective item over to the manufacturer.
       * 1. If device is still under warranty and has failed prior to its intended life span, it will be returned to the manufacturer unless otherwise determined prior to the surgery.
18. If the medical device is a mass-produced item maintained in volume within UI Health Care, the following information should be collected and reported along with the incident so that potentially faulty devices are removed immediately.
19. If available:
20. PeopleSoft Number
21. Product Name – including size or style if applicable
22. Manufacturers Name
23. Product Catalog/Serial number
24. Lot number
25. If the Lot number can be identified, all products with that lot number are to be removed immediately.
26. Devices that are maintained within PeopleSoft will be traced by Supply Chain.
27. User areas will be identified and contacted by alert email to look for and remove all affected lot numbers. These items are to be returned to Processed Stores for credit and replacement if appropriate.
28. Processed Stores will identify, evaluate and remove all devices residing within stores as well as all Omni Cells.
29. Supply Chain staff will provide Manufacturer with the following:
    1. Product name, number, lot
    2. Type of incident
    3. Patient’s personal information is to be withheld; only age, sex, and weight can be shared
    4. Request information on similar reports and follow up data once reviewed.
    5. The entire unused product removed from the hospital with the expectation of full replacement or reimbursement of said product.
    6. Failed device will only be returned to the Manufacturer if there has been no injury reported.
       1. After the item has been evaluated by UI Health Care staff (this may include bioengineering, facilities, radiology, Supply Chain and/or legal)
       2. Evaluation may include but is not limited to full testing, visual inspection and photographs taken.
       3. A written report will be returned to Hospital Legal or Supply Chain following Manufacturer’s investigation.
    7. If injury to a patient, staff, or visitor, serious or otherwise has occurred. The device will be kept within the department of Hospital Legal pending potential legal action taken by said injured party or their legal representative.
30. If the device is a piece of equipment serviced by UI Health Care Bioengineering, the device should be tagged and delivered to Bioengineering. A Safety Incident Report and/or Device Failure Collection Form/Kit with a description of the malfunction or failure is to be provided to Bioengineering. Further details can be reviewed in the [Medical Equipment Management Plan](https://uihealthcare.policytech.com/docview/?docid=6361&anonymous=true) (FS.P.82).
31. For staff injured by a device, refer to policy FS.P.66, [Workers’ Compensation –First Report of Injury and Other Reporting Requirements](https://uihealthcare.policytech.com/docview/?docid=5004&anonymous=true).

D. Investigation

1. Investigation of the device failure shall be initiated by Supply Chain Manager in conjunction with the Law Department and with the assistance and cooperation of Bioengineering, Materials Services and other UI Health Care staff with knowledge relating to the incident or the device. Based upon the report and the investigation, the Law Department shall determine if a mandatory device report should be made according to the Safe Medical Device Act (SMDA) and will be responsible for filing the report with the manufacturer or the FDA, as appropriate.
2. The Law Department shall maintain files, for a period of seven (7) years, relating to the investigation and FDA reporting, annual reports to the FDA, as required by the SMDA, and provide an annual report to the Environment of Care Working Group.

**ATTACHMENT:**

1. Device Failure Collection Form

Source: Environment of Care Working Group

Effective Date: 6/94

Version Number: 10

Date Revised: 10/96; 10/98; 10/01; 2/08; 9/09; 2/10; 1/14; 12/14; 06/19

Date Reviewed: 10/04; 12/04; 2/08; 2/10; 9/13; 6/19; 8/19

