



## MONTANA STATE HOSPITAL POLICY AND PROCEDURE

### MEDICAL DEVICE REPORTING

**Effective Date:** June 19, 2020

**Policy:** SF-05

**Page 1 of 3**

- I. PURPOSE:** To comply with the Safe Medical Devices Act (SMDA) of 1990 by providing information to the Food and Drug Administration (FDA) and/or the manufacturer about medical device problems in order that appropriate action can be taken to protect the public from hazardous medical devices.
- II. POLICY:** Montana State Hospital (MSH) will report device-related deaths to the Food and Drug Administration and the manufacturer if known, and will also report device-related serious illnesses and injuries to the manufacturer if known, or if not known, to the Food and Drug Administration.
- III. DEFINITIONS:**
  - A. Medical Device:** An instrument, apparatus, implement, machine, contrivance, implant, invitro reagent, or other similar or related article including any component, part or accessory, which is:
    1. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them.
    2. Intended for use in the diagnoses or other condition, or in the cure, mitigation, treatment or prevention of disease in man or other animals.
    3. Intended to affect the structure or 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 animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
    4. Intended for use in the diagnoses of conditions other than disease, such as pregnancy.
    5. Invitro diagnosis products, including those previously regulated as drugs.
  - B. FDA Reportable Event:** Serious injury, serious illness, or death resulting from user error, failure to service or maintain a medical device, or malfunction of a medical device.

- C. **Serious Illness or Injury:** Those which are (1) life threatening, or (2) result in permanent impairment to body structure or function, or (3) require immediate medical or surgical intervention to prevent permanent illness or injury.

**IV. RESPONSIBILITIES:**

A. Safety Officer will:

1. Be the Hospital's primary contact person between the Medical Device Manufacturer and the Food and Drug Administration;
2. Coordinate compliance with the Safe Medical Devices Act;
3. Submit a Medical and Device Experience Report-FDA Form 3500 A to the FDA and device manufacturer for deaths resulting from a medical device within 10 days of the death;
4. Submit a Medical and Device Experience Report-FDA Form 3500 A to the manufacturer for serious injuries resulting from a medical device within 10 days of the serious injury.
5. Submit a Medical and Device Experience Report-FDA Form 3500 A to the FDA for serious injuries resulting from a medical device within 10 days of the serious injury if the manufacturer is unknown.
6. Submit an annual summary of all reports by January 1 of each preceding year using the Medical Device Reporting Annual User Facility Report – Form FDA 3419 to the Food and Drug Administration.

B. **Staff Development:** Ensure employee training is consistent with this policy.

C. **All employees:** Responsible for reporting incidents of serious illness or injury to their supervisor.

**V. PROCEDURE:**

A. Any incident resulting in injury, illness, or death of a patient or employee caused by, or contributed to, by a medical device will be reported on the Hospital's Incident Report form before the end of the shift. The supervisor must review the report for accuracy and sign by the end of the shift and forward the report to the Safety Officer within 24 hours of the incident.

1. The Safety Officer will determine if the incident reasonably suggests an FDA reportable event and, if so, will complete documentation required by the FDA found in Medical Device Reporting 21 CFR Part 803.
2. Any staff member aware of information which reasonably suggests a reportable event is responsible for reporting the information to the Safety Officer, who is responsible for completing documentation required by the FDA.

## Montana State Hospital Policy and Procedure

### MEDICAL DEVICE REPORTING

Page 3 of 3

3. The Hospital Administrator, Medical Director, Director of Nursing, Occupational Health Safety Specialist and Safety Officer will be notified of any reportable events.
  4. All deaths will be investigated per MSH policy QI-01, Death Reviews. Reportable events will be investigated per MSH policy QI-05, Serious Adverse Events/Significant Event Review.
  5. The Hospital's Safety Officer, in coordination with the Occupational Health Safety Specialist and Staff Development Department, will ensure training is provided to hospital staff regarding their obligations in identifying and reporting events which may be subject to reporting.
  6. All Medical Devices shall be inspected for safe operation by a certified person as needed or at least annually. These devices will be tagged with a certification indicating the device is in good working order with the date of certification, the certifying person's name, and the company who employs the certified person.
- VI. REFERENCES:** H.R.3095 Safe Medical Device Report Act of 1990 (101<sup>st</sup> Congress 1989-1990), 29 CFR 1904.40 (Providing Records to Government Representatives).
- VII. COLLABORATED WITH:** Safety Officer, Medical Director, Director of Nursing, Occupational Health Safety Specialist, Staff Development Coordinator.
- VIII. RESCISSIONS:** SF-05, *Medical Device Reporting* dated December 9, 2015; SF-05, *Medical Device Reporting* dated May 12, 2014; SF-05, *Medical Device Reporting* dated March 15, 2010; SF-05, *Medical Device Reporting* dated March 9, 2007; SF-05, *Medical Device Reporting* dated June 6, 2003; SF-05, *Medical Device Reporting* dated February 14, 2000; and HOPP 6-M.062292, *Medical Device Reporting*, dated April 19, 1996.
- IX. DISTRIBUTION:** All hospital policy manuals.
- X. ANNUAL REVIEW AND AUTHORIZATION:** This policy is subject to annual review and authorization for use by either the Administrator or the Medical Director with written documentation of the review per ARM § 37-106-330.
- XI. FOLLOW-UP RESPONSIBILITY:** Safety Officer.
- XII. ATTACHMENTS:** None.

Signatures:

Kyle Fouts  
Hospital Administrator

Thomas Gray, MD  
Medical Director