POLICY:

The facility will report all incidents that reasonably suggest that a "medical device" caused or contributed to a resident death, serious illness or serious injury.

A "MEDICAL DEVICE" is defined as "any item that is used for diagnosis, treatment, or prevention of a disease, injury, illness or other condition that is not a drug".

PROCEDURE:

1. If there were no reportable incidents in the last six months, no report needs to be filed.

2. The semi-annual reports are due on January 31st and July 31st.

3. A report will be sent to the manufacturer at time of incident.

4. A serious illness or injury includes one that results in permanent impairment of a body function, 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.
If all of the four questions listed below can be answered affirmatively, the incident will be reported to the FDA:

1) Was there injury or illness?

2) Was a device involved?

3) Was the victim a resident or employee working in the facility at the time of the incident?

4) Was the injury or illness serious?

Some sample medical devices are: walkers, canes, Hoyer lift, Century tub chairs and lift, Arjo walker, wheelchair, implantable pacemaker pulse generator, cardiovascular permanent pacemaker electrode, replacement heart valve, automatic implantable cardioverter/defibrillator, tracheal prosthesis, implanted cerebellar stimulator, implantable infusion pump, apnea monitors Bpap and Cpap, continuous ventilator, silicone inflatable breast prosthesis, silicone gel-filled breast prosthesis, testicular prosthesis, chin prosthesis, infusion pumps. There may be other items as defined by a medical device - blood pressure cuffs, or digital thermometers.
Form to be filled out and sent to manufacturer of medical device involved in resident or employee death, serious illness, or serious injury.

Name & address of manufacturer:  ____________________________________________

Name of medical device that caused or contributed to resident/employee death, serious illness, or serious injury:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Was a resident injured? ____________________________________________________

Was an employee injured? __________________________________________________

Describe injuries in detail: _________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Who should the manufacturer contact for more details? _______________________
__________________________________________________________________________

Montana Mental Health Nursing Care Center
800 Casino Creek Drive
Lewistown, MT 59457
Form for reporting to FDA, accidents involving a medical device

Montana Mental Health Nursing Care Center
800 Casino Creek Drive
Lewistown, MT 59457

Name of medical device that caused or contributed to resident/employee death, serious illness or serious injury: ________________________________

Device serial number: ____________________________________________

Device model number: ____________________________________________

Name of manufacturer: ____________________________________________

Address of manufacturer: _________________________________________

Describe the event reported to the manufacturer and/or the FDA.

Person to contact for more information: ______________________________

_________________________________________________________________

Send to:

Food and Drug Administration
Center for Devices and Radiological
Office of Health, Compliance and Surveillance
HF2 351
P.O. Box 3002
Rockville, MD 20847-3002

Reviewed: _______________________

Superintendent: _______________________

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