OREGON STATE HOSPITAL

POLICY ATTACHMENT

PROCEDURES A:	Medical Equipment Safety Procedures	**POLICY: 3.003**
POINT PERSON:	Director of Facilities	
APPROVED:	Interim Superintendent	**DATE:** July 25, 2024
SELECT ONE:	○ New policy attachment	○ Minor/technical revision of existing policy attachment
	◉ Reaffirmation of existing policy attachment	○ Major revision of existing policy attachment

I. Medical Equipment Inventory and Maintenance

A. The Facilities Department (Facilities) must maintain an inventory database of all medical equipment.

1. Before medical equipment is used, Facilities must perform safety, operational, and functional checks. Facilities must evaluate new types of medical equipment before it is used to determine whether it should be included in the high-risk category in the inventory database.
2. If the medical equipment passes inspection, Facilities must enroll it in the inventory and assign it a property number in accordance with OSH Policy 4.007, “Capital and Non-Capital Assets”.
3. Facilities must enter the manufacturer’s recommended maintenance and inspection requirements in the computerized maintenance management system database as a preventative/ predictable maintenance (PM) work order before placing it into service.

B. Medical equipment inspecting, testing, and maintenance activities must be completed at a frequency in accordance with manufacturer’s recommendations.

1. Preventative maintenance must be completed according to the manufacturer’s recommendations.
2. Medical equipment must be monitored for effectiveness in accordance with manufacturer recommendations.
3. Maintenance and inspection exceptions must be completed in accordance with manufacturer recommendations or department protocol.

C. If medical equipment requires repair, staff must complete a work request and remove the equipment from service.

   1. If Facilities is unable to repair the medical equipment, Facilities will contact the medical vendor as needed.

   2. If a piece of equipment is deemed not repairable, the equipment must be removed from the medical database.

D. Whenever there is reasonable basis to believe that a medical equipment has caused or contributed to a patient or staff serious injury, serious illness, or death, the user of the equipment must notify a supervisor immediately.

   1. All medical equipment related to such an event must be taken out of service, labeled "out of order" or "faulty" and secured until an investigation can be conducted.

   2. The user of the medical equipment must complete an incident report according to OSH Policy and Procedure 1.003, “Incident Reporting”.

   3. A copy of the report must be sent to the Safety Officer.

   4. Facilities must review all incidents.

E. The Chief Medical Officer (CMO) must review reports related to medical equipment failures.

   1. If it is determined that the medical equipment resulted in or contributed to the serious injury or illness or death of a person, the CMO must complete a report and submit it to the Superintendent for review.

   2. The Superintendent or designee must file the report within ten working days with either the manufacturer or the Food and Drug Administration (FDA) in accordance with the following:

      a. In the event of a serious injury or illness, the report must be filed with the manufacturer. If the identity of the manufacturer is not known, the report must be submitted to the FDA.

      b. In the event of a death, the report must be filed with the FDA and the manufacturer, if known.

F. Additionally, the Superintendent or designee must submit semi-annual reports to the FDA for each event that is determined to have resulted in or contributed to serious injury or illness or death. A report must be submitted January 1 for events reported July through December, and July 1 for events reported January through June.